KCE REPORT 350S

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

# INFANT- AND FAMILY-CENTRED DEVELOPMENTAL CARE FOR PRETERM NEWBORNS IN NEONATAL CARE

## SUPPLEMENT





KCE REPORT 350S
HEALTH SERVICES RESEARCH

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# INFANT- AND FAMILY-CENTRED DEVELOPMENTAL CARE FOR PRETERM NEWBORNS IN NEONATAL CARE

## SUPPLEMENT

JENS DETOLLENAERE, NADIA BENAHMED, ELENA COSTA, WENDY CHRISTIAENS, CARL DEVOS, KOEN VAN DEN HEED

2022 www.kce.fgov.be

# COLOPHON


| | |
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Acknowledgements: We would like to thank Stina Klemming and Siri Lilliesköld (Karolinska University Hospital, Stockholm, Sweden), Sabine Réthoré (Centre Hospitalier de Valenciennes, France), Maria Lopez Maestro (12 de Octubre Hospital, Madrid, Spain) and Monique Oude Reimer-van Kilsdonk (Sophia's Children Hospital, Rotterdam, the Netherlands) for their support in the description of the organisation of the best practices.

In addition, we would like to thank all the parents of preterm newborns, midwives, nurses, neonatologists and paediatricians who participated in the interviews or focus groups. We very much appreciate the time and effort they invested for sharing their stories.

Reported interests: All experts and stakeholders consulted within this report were selected because of their involvement in the topic of infant- and family-centred developmental neonatal care. Therefore, by definition, each of them might have a certain degree of conflict of interest to the main topic of this report.

Layout : Joyce Grijseels

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- **Subsequently, a (final) version was submitted to the validators. The validation of the report results from a consensus or a voting process between the validators. The validators did not co-author the scientific report and did not necessarily all three agree with its content.**
- **Finally, this report has been approved by common assent by the Executive Board.**
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Publication date 22 March 2022

Domain: Health Services Research (HSR)

MeSH : Premature Infant, Preterm Birth, Neonatal Intensive Care, Family Centered Nursing

NLM Classification : WY 157.3

Language : English

Format : Adobe® PDF™ (A4)

Legal depot : D/2022/10.273/10

ISSN: 2466-6459

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How to refer to this document ? Detollenaere J, Benahmed N, Costa E, Christiaens W, Devos C, Van den Heede K. Infant- and family-centred developmental care for preterm newborns in neonatal care – Supplement. Health Services Research (HSR) Brussels: Belgian Health Care Knowledge Centre (KCE). 2022. KCE Reports 350S. D/2022/10.273/10.

This document is available on the website of the Belgian Health Care Knowledge Centre

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# APPENDIX 1. ANNEX TO CHAPTER 1

## Appendix 1.1. Methods concept mapping

Our summary concept map is mainly based on the literature. We started from several key papers which were identified during the scoping of the project and systematic literature review of Chapter 4).[59, 227-229] In addition, a Medline search was conducted via a snowballing approach on the concepts presented in these papers. In addition, we also screened the grey literature via a snowballing approach, based on the concepts encountered. Sources were selected on the basis of the presence of a clear description of concepts. The concept map was presented to a group of external experts, and revised according to their feedback.

# APPENDIX 2. ANNEX TO CHAPTER 4

## Appendix 2.1. Search strategies

**Table 1 – Search strategy Ovid Medline ®**

| Nr | Search term(s) | Hits | Nr | Search term(s) | Hits |
|---|---|---|---|---|---|
| 1 | exp infant, newborn/ | 631 417 | 26 | J Fam Nurs.ja. | 466 |
| 2 | (newborn* or new born or new borns or newly born or baby* or babies or premature or prematurity or preterm or pre term or low birth weight or low birthweight or VLBW or LBW or infant or infants or 'infant s' or infant's or infantile or infancy or neonat*).ti,ab,kf. | 936 599 | 27 | ((parent or mother or father or maternal or paternal) adj3 (child* or infant?) adj3 (relation* or bonding)).ab,ti,kf. | 8 919 |
| 3 | 1 or 2 | 1 213 632 | 28 | ((maternal or paternal or parental) adj2 behavio?r?).ab,ti,kf. | 7 706 |
| 4 | patient-centered care/ | 20 985 | 29 | ((maternal or maternity) adj3 (nursing or care)).ab,ti,kf. | 12 534 |
| 5 | professional-family relations/ | 15 247 | 30 | (maternal-child adj3 (center? or service?)).ab,ti,kf. | 2 042 |
| 6 | family nursing/ | 1 523 | 31 | mother child care.ab,ti,kf. | 11 |
| 7 | exp parent-child relations/ | 58 323 | 32 | (neonatal netw or j perinat neonatal nurs or mcn am j matern child nurs or j obstet gynecol neonatal nurs).ja. | 10 072 |
| 8 | exp maternal child nursing/ | 5 936 | 33 | 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 | 139 690 |
| 9 | Rooming-in care/ | 466 | 34 | 11 or 33 | 212 781 |
| 10 | Kangaroo-Mother Care Method/ | 538 | 35 | 3 and 34 | 40 548 |
| 11 | 4 or 5 or 6 or 7 or 8 or 9 or 10 | 99 892 | 36 | randomized controlled trial.pt. | 539 543 |
| 12 | (family adj2 (cent?red or focused)).ab,ti,kf. | 6 657 | 37 | controlled clinical trial.pt. | 94 320 |
| 13 | (patient adj2 (cent?red or focused)).ab,ti,kf. | 29 312 | 38 | randomized.ti,ab. | 573 329 |
| 14 | (famil* adj5 support*).ab,ti,kf. | 30 387 | 39 | placebo.ti,ab. | 226 193 |
| 15 | (shar* adj3 care).ab,ti,kf. | 4279 | 40 | clinical trials as topic/ | 196 868 |
| 16 | ((care or cared or caring) adj3 (parent* or mother* or father* or famil*)).ab,ti,kf. | 32 468 | 41 | randomly.ti,ab. | 363 887 |
| 17 | Couplet care.ab,ti,kf. | 18 | 42 | trial?.ti. | 325 032 |
| 18 | Developmental care.ab,ti,kf. | 442 | 43 | 36 or 37 or 38 or 39 or 40 or 41 or 42 | 1 421 954 |

| | | | | | |
|---|---|---|---|---|---|
| 19 | Individualized developmental care.ab,ti,kf. | 123 | 44 | exp animal/ not humans/ | 4 870 531 |
| 20 | NIDCAP.ab,ti,kf. | 121 | 45 | 43 not 44 | 1 309 903 |
| 21 | Kangaroo.ab,ti,kf. | 2 272 | 46 | ((systematic review or systematic literature review or systematic scoping review or systematic narrative review or systematic qualitative review or systematic evidence review or systematic quantitative review or systematic meta-review or systematic critical review or systematic mixed studies review or systematic mapping review or systematic cochrane review or "systematic search and review" or systematic integrative review).ti. not comment.pt. not (protocol or protocols).ti. not medline.st.) or (Cochrane Database Syst Rev.ja. and review.pt.) or systematic review.pt. | 198 060 |
| 22 | (Rooming-in adj2 care?).ab,ti,kf. | 56 | 47 | Limit 35 to yr="2000-current" | 27 231 |
| 23 | Skin-to-skin.ab,ti,kf. | 6 491 | 48 | 47 and 45 | 2 298 |
| 24 | ((professional? or caregiver? or clinician? or doctor? or physician? or nurse?) adj2 (family or families) adj3 relation*).ab,ti,kf. | 609 | 49 | 47 and 46 | 778 |
| 25 | family nursing.ab,ti,kf. | 610 | 50 | 48 not 49 | 2 139 |
| Database: Ovid MEDLINE® and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions® <1946 to July 01, 2020> | | | | | |

**Table 2 – Search strategy Embase ®**

| Nr | Search term(s) | Hits | Nr | Search term(s) | Hits |
|---|---|---|---|---|---|
| 1 | 'newborn'/de | 624 715 | 20 | nidcap:ab,ti | 153 |
| 2 | newborn*:ab,ti OR 'new born':ab,ti OR 'new borns':ab,ti OR 'newly born':ab,ti OR baby*:ab,ti OR babies:ab,ti OR premature:ab,ti OR prematurity:ab,ti OR preterm:ab,ti OR 'pre term':ab,ti OR 'low birth weight':ab,ti OR 'low birthweight':ab,ti OR vlbw:ab,ti OR lbw:ab,ti OR infant:ab,ti OR infants:ab,ti OR 'infant s':ab,ti OR infantile:ab,ti OR infancy:ab,ti OR neonat*:ab,ti | 1 114 637 | 21 | kangaroo:ab,ti | 2 506 |
| 3 | #1 OR #2 | 1 395 730 | 22 | ('rooming in' NEAR/2 care$):ab,ti | 62 |
| 4 | 'patient care'/de | 317 082 | 23 | 'skin to skin':ab,ti | 2 207 |

| | | | | | |
|---|---|---|---|---|---|
| 5 | 'professional-patient relationship'/exp | 167 732 | 24 | ((professional$ OR caregiver$ OR clinician$ OR doctor$ OR physician$ OR nurse$) NEAR/2 (family OR families) NEAR/3 relation*):ab,ti | 652 |
| 6 | 'family nursing'/de | 1 469 | 25 | ((parent OR mother OR father OR maternal OR paternal) NEAR/3 (child* OR infant$) NEAR/3 (relation* OR bonding)):ab,ti | 7 688 |
| 7 | 'child parent relation'/exp | 96 239 | 26 | ((maternal OR paternal OR parental) NEAR/2 behavio$r*):ab,ti | 8 945 |
| 8 | 'maternal child health care'/de | 2 489 | 27 | ((maternal OR maternity) NEAR/3 (nursing OR care)):ab,ti | 14 039 |
| 9 | 'rooming in'/de | 295 | 28 | ('maternal child' NEAR/3 (center$ OR service$)):ab,ti | 1 317 |
| 10 | 'kangaroo care'/de | 1 419 | 29 | 'mother child care':ab,ti | 13 |
| 11 | #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 | 565 750 | 30 | #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 | 152 706 |
| 12 | (family NEAR/2 (cent$red OR focused)):ab,ti | 8 022 | 31 | #11 OR #30 | 675 886 |
| 13 | (patient NEAR/2 (cent$red OR focused)):ab,ti | 37 681 | 32 | #3 AND #31 | 53 019 |
| 14 | (famil* NEAR/5 support*):ab,ti | 39 922 | 33 | #32 NOT [medline]/lim | 12 654 |
| 15 | (shar* NEAR/3 care):ab,ti | 6 125 | 34 | #33 AND [2000-2020]/py | 11 552 |
| 16 | ((care OR cared OR caring) NEAR/3 (parent* OR mother$ OR father$ OR famil*)):ab,ti | 40 258 | 35 | #34 NOT ('conference abstract'/it OR 'conference paper'/it OR 'conference review'/it) | 5 017 |
| 17 | 'couplet care':ab,ti | 23 | 36 | #35 AND ('meta-analysis'/exp OR 'meta-analysis' OR 'systematic review'/exp OR 'systematic review') | 186 |
| 18 | 'developmental care':ab,ti | 538 | 37 | #35 AND (random*:ab,ti OR placebo*:de,ab,ti OR ((double NEXT/1 blind*):ab,ti)) | 409 |
| 19 | 'individualized developmental care':ab,ti | 143 | 38 | #37 NOT #36 | 362 |

Database searched on 1 July 2021.

**Table 3 – Search strategy Cochrane Library**

| Nr | Search term(s) | Hits | Nr | Search term(s) | Hits |
|---|---|---|---|---|---|
| 1 | [mh "infant, newborn"] | 16 573 | 19 | "Individualized developmental care":ab,ti | 54 |
| 2 | (newborn* or "new born" or "new borns" or "newly born" or baby* or babies or premature or prematurity or preterm or "pre term" or "low birth weight" or "low birthweight" or VLBW or LBW or infant or infants or "infant s" or infantile or infancy or neonat*):ab,ti | 69 757 | 20 | NIDCAP:ab,ti | 53 |
| 3 | #1 or #2 | 72 823 | 21 | Kangaroo:ab,ti | 479 |
| 4 | [mh ^"patient-centered care"] | 639 | 22 | (Rooming-in NEAR/2 care?):ab,ti | 3 |
| 5 | [mh ^"professional-family relations"] | 220 | 23 | Skin-to-skin:ab,ti | 537 |
| 6 | [mh ^"family nursing"] | 40 | 24 | ((professional? or caregiver? or clinician? or doctor? or physician? or nurse?) NEAR/2 (family or families) NEAR/3 relation*):ab,ti | 29 |
| 7 | [mh "parent-child relations"] | 2 054 | 25 | "family nursing":ab,ti | 30 |
| 8 | [mh "maternal child nursing"] | 186 | 26 | ((parent or mother or father or maternal or paternal) NEAR/3 (child* or infant?) NEAR/3 (relation* or bonding)):ab,ti | 814 |
| 9 | [mh ^"Rooming-in care"] | 13 | 27 | ((maternal or paternal or parental) NEAR/2 behavio?r?):ab,ti | 373 |
| 10 | [mh ^"Kangaroo-Mother Care Method"] | 86 | 28 | ((maternal or maternity) NEAR/3 (nursing or care)):ab,ti | 1 023 |
| 11 | #4 or #5 or #6 or #7 or #8 or #9 or #10 | 3 160 | 29 | (maternal-child NEAR/3 (center? or service?)):ab,ti | 13 |
| 12 | (family NEAR/2 (cent?red or focused)):ab,ti | 1 162 | 30 | "mother child care":ab,ti | 3 |
| 13 | (patient NEAR/2 (cent?red or focused)):ab,ti | 3 873 | 31 | #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 | 13 367 |
| 14 | (famil* NEAR/5 support*):ab,ti | 2 683 | 32 | #11 or #31 | 15 484 |
| 15 | (shar* NEAR/3 care):ab,ti | 464 | 33 | #3 and #32 | 3 640 |
| 16 | ((care or cared or caring) NEAR/3 (parent* or mother* or father* or famil*)):ab,ti | 3 591 | 34 | #33 with Cochrane Library publication date Between Jan 2000 and Jul 2021 | 3 369 |
| 17 | "Couplet care":ab,ti | 0 | 35 | #33 in Cochrane Reviews | 148 |
| **18** | "Developmental care":ab,ti | 129 | 36 | #33 in Cochrane Trials | 3 247 |

Database searched on 1 July 2021.

**Table 4 – Search strategy Cinahl**

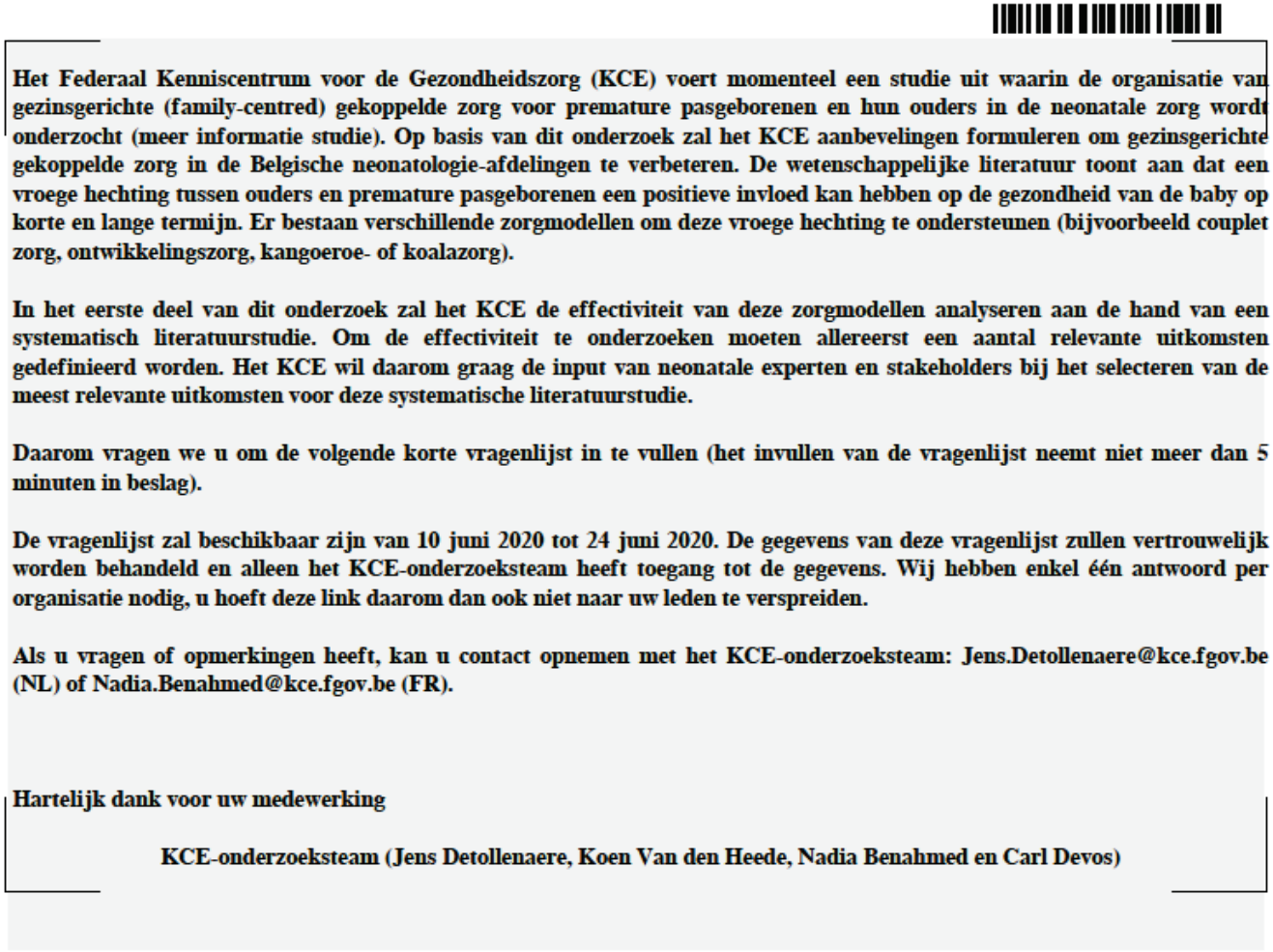
| Nr | Search term(s) | Hits | Nr | Search term(s) | Hits |
|---|---|---|---|---|---|
| 1 | (MH "infant, newborn") | 135 810 | 23 | ((TI Skin-to-skin) OR (AB Skin-to-skin)) | 1 181 |
| 2 | ((TI newborn* or "new born" or "new borns" or "newly born" or baby* or babies or premature or prematurity or preterm or "pre term" or "low birth weight" or "low birthweight" or VLBW or LBW or infant or infants or "infant s" or infantile or infancy or neonat*) OR (AB newborn* or "new born" or "new borns" or "newly born" or baby* or babies or premature or prematurity or preterm or "pre term" or "low birth weight" or "low birthweight" or VLBW or LBW or infant or infants or "infant s" or infantile or infancy or neonat*)) | 524 749 | 24 | ((TI ((professional# or caregiver# or clinician# or doctor# or physician# or nurse#) N2 (family or families) N3 relation*)) OR (AB ((professional# or caregiver# or clinician# or doctor# or physician# or nurse#) N2 (family or families) N3 relation*))) | 639 |
| 3 | S1 OR S2 | 524 749 | 25 | ((TI "family nursing") OR (AB "family nursing")) | 795 |
| 4 | (MH "Patient Centered Care") | 32 347 | 26 | ((TI ((parent or mother or father or maternal or paternal) N3 (child* or infant#) N3 (relation* or bonding))) OR (AB ((parent or mother or father or maternal or paternal) N3 (child* or infant#) N3 (relation* or bonding)))) | 5 599 |
| 5 | (MH "Professional-Family Relations") | 17 142 | 27 | ((TI ((maternal or paternal or parental) N2 behavio#r#)) OR (AB ((maternal or paternal or parental) N2 behavio#r#))) | 3 063 |
| 6 | (MH "Family Nursing") | 2 082 | 28 | ((TI ((maternal or maternity) N3 (nursing or care))) OR (AB ((maternal or maternity) N3 (nursing or care)))) | 8 795 |
| 7 | (MH "Parent-Child Relations+") | 36 396 | 29 | ((TI (maternal-child N3 (center# or service#))) OR (AB (maternal-child N3 (center# or service#)))) | 72 |
| 8 | (MH "Maternal-Child Nursing+") | 27 456 | 30 | ((TI "mother child care") OR (AB "mother child care")) | 5 |
| 9 | (MH "Rooming In") | 336 | 31 | S12 OR S13 OR S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 OR S30 | 95 048 |
| 10 | (MH "Kangaroo Care") | 1 440 | 32 | S11 or S31 | 184 086 |
| 11 | S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 | 112 219 | 33 | S3 and S32 | 50 121 |
| 12 | ((TI (family N2 (cent#red or focused))) OR (AB (family N2 (cent#red or focused)))) | 6472 | 34 | S33<br>- Exclude MEDLINE records | 28 292 |
| 13 | ((TI (patient N2 (cent#red or focused))) OR (AB (patient N2 (cent#red or focused)))) | 20 668 | 35 | S34<br>- Published Date: 20000101-20201231 | 25 818 |

| | | | | | |
|---|---|---|---|---|---|
| 14 | ((TI (famil* N5 support*)) OR (AB (famil* N5 support*))) | 23 772 | 36 | S35<br>- Peer Reviewed | 22 064 |
| 15 | ((TI (shar* N3 care)) OR (AB (shar* N3 care))) | 4 133 | 37 | S36<br>- Randomized Controlled Trials | 458 |
| 16 | ((TI ((care or cared or caring) N3 (parent* or mother* or father* or famil*))) OR (AB ((care or cared or caring) N3 (parent* or mother* or father* or famil*)))) | 32 453 | 38 | (MH "Meta analysis") | 55 947 |
| 17 | ((TI "Couplet care") OR (AB "Couplet care")) | 25 | 39 | ((AB Meta-analys*) OR (TI Meta analys*)) | 82 342 |
| 18 | ((TI "Developmental care") OR (AB "Developmental care")) | 409 | 40 | ((AB Metaanalys*) OR (TI Metaanalys*)) | 1 224 |
| 19 | ((TI "Individualized developmental care") OR (AB "Individualized developmental care")) | 80 | 41 | (MH "Literature review") | 8 404 |
| 20 | ((TI NIDCAP) OR (AB NIDCAP)) | 73 | 42 | ((TI (systematic N2 (review or overview))) OR (TI (systematic N2 (review or overview)))) | 85 695 |
| 21 | ((TI Kangaroo) OR (AB Kangaroo)) | 895 | 43 | (S38 OR S39 OR S40 OR S41 OR S42) | 148 570 |
| 22 | ((TI (Rooming-in N2 care#)) OR (AB (Rooming-in N2 care#))) | 63 | 44 | S37 AND S43 | 475 |

Database searched on 1 July 2021.

## Appendix 2.2. Survey outcome selection

### *Appendix 2.2.1. Dutch survey*



**Het Federaal Kenniscentrum voor de Gezondheidszorg (KCE) voert momenteel een studie uit waarin de organisatie van gezinsgerichte (family-centred) gekoppelde zorg voor premature pasgeborenen en hun ouders in de neonatale zorg wordt onderzocht (meer informatie studie). Op basis van dit onderzoek zal het KCE aanbevelingen formuleren om gezinsgerichte gekoppelde zorg in de Belgische neonatologie-afdelingen te verbeteren. De wetenschappelijke literatuur toont aan dat een vroege hechting tussen ouders en premature pasgeborenen een positieve invloed kan hebben op de gezondheid van de baby op korte en lange termijn. Er bestaan verschillende zorgmodellen om deze vroege hechting te ondersteunen (bijvoorbeeld couplet zorg, ontwikkelingszorg, kangoeroe- of koalazorg).**

**In het eerste deel van dit onderzoek zal het KCE de effectiviteit van deze zorgmodellen analyseren aan de hand van een systematisch literatuurstudie. Om de effectiviteit te onderzoeken moeten allereerst een aantal relevante uitkomsten gedefinieerd worden. Het KCE wil daarom graag de input van neonatale experten en stakeholders bij het selecteren van de meest relevante uitkomsten voor deze systematische literatuurstudie.**

**Daarom vragen we u om de volgende korte vragenlijst in te vullen (het invullen van de vragenlijst neemt niet meer dan 5 minuten in beslag).**

**De vragenlijst zal beschikbaar zijn van 10 juni 2020 tot 24 juni 2020. De gegevens van deze vragenlijst zullen vertrouwelijk worden behandeld en alleen het KCE-onderzoeksteam heeft toegang tot de gegevens. Wij hebben enkel één antwoord per organisatie nodig, u hoeft deze link daarom dan ook niet naar uw leden te verspreiden.**

**Als u vragen of opmerkingen heeft, kan u contact opnemen met het KCE-onderzoeksteam: Jens.Detollenaere@kce.fgov.be (NL) of Nadia.Benahmed@kce.fgov.be (FR).**

**Hartelijk dank voor uw medewerking**

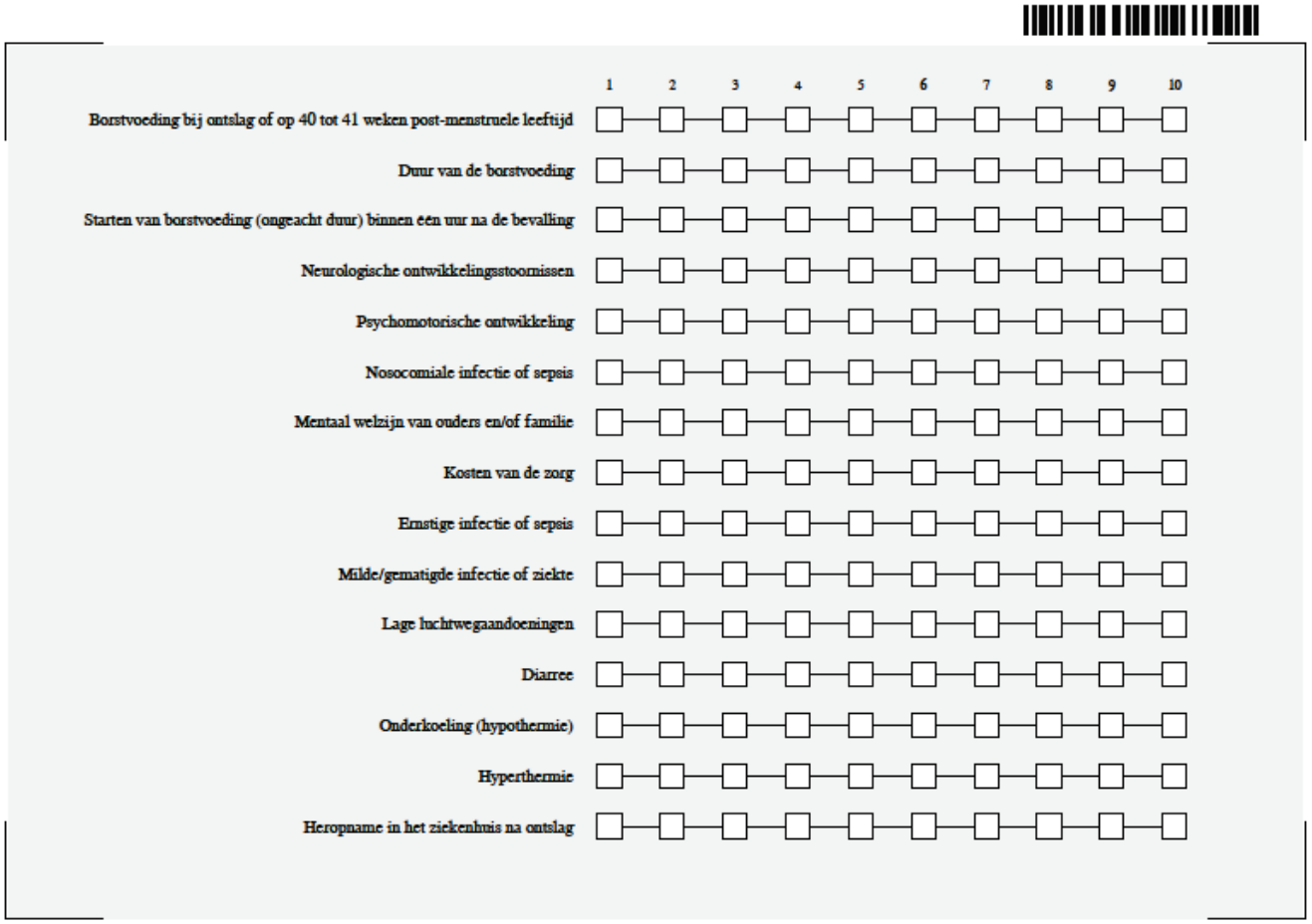
**KCE-onderzoeksteam (Jens Detollenaere, Koen Van den Heede, Nadia Benahmed en Carl Devos)**

## Sectie A: Group 1

**A1.** **Hieronder kan u een lijst vinden met uitkomsten voor het evalueren van zorgmodellen voor premature pasgeborenen op NICU of N*. Kan u elk van deze uitkomsten beoordelen op basis van hun relevantie om opgenomen te worden in de systematisch literatuurstudie.**

**(1 is helemaal niet relevant, 10 is zeer relevant)**

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| Verblijfsduur van de moeder | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Verblijfsduur van de pasgeborene | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Hechting ouder-pasgeborene (gemeten aan de hand van een gevalideerd meetinstrument) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Interactie ouder-pasgeborene (gemeten aan de hand van een gevalideerd meetinstrument) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Gewichtstoename bij ontslag uit het ziekenhuis | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Gewichtstoename op 40 tot 41 weken post-menstruele leeftijd | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Gewichtstoename op laatste opvolgafspraak | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Toename lichaamslengte bij ontslag uit het ziekenhuis | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Toename lichaamslengte op 40 tot 41 weken post-menstruele leeftijd | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Toename lichaamslengte op laatste opvolgafspraak | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Exclusieve borstvoeding bij ontslag of op 40 tot 41 weken post-menstruele leeftijd | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |


1 2 3 4 5 6 7 8 9 10
Borstvoeding bij ontslag of op 40 tot 41 weken post-menstruele leeftijd
Duur van de borstvoeding
Starten van borstvoeding (ongeacht duur) binnen één uur na de bevalling
Neurologische ontwikkelingsstoornissen
Psychomotorische ontwikkeling
Nosocomiale infectie of sepsis
Mentaal welzijn van ouders en/of familie
Kosten van de zorg
Ernstige infectie of sepsis
Milde/gematigde infectie of ziekte
Lage luchtwegaandoeningen
Diarree
Onderkoeling (hypothermie)
Hyperthermie
Heropname in het ziekenhuis na ontslag

Kosten van de zorg

Ernstige infectie of sepsis

Milde/gematigde infectie of ziekte

Lage luchtwegaandoeningen

Diarree

Onderkoeling (hypothermie)

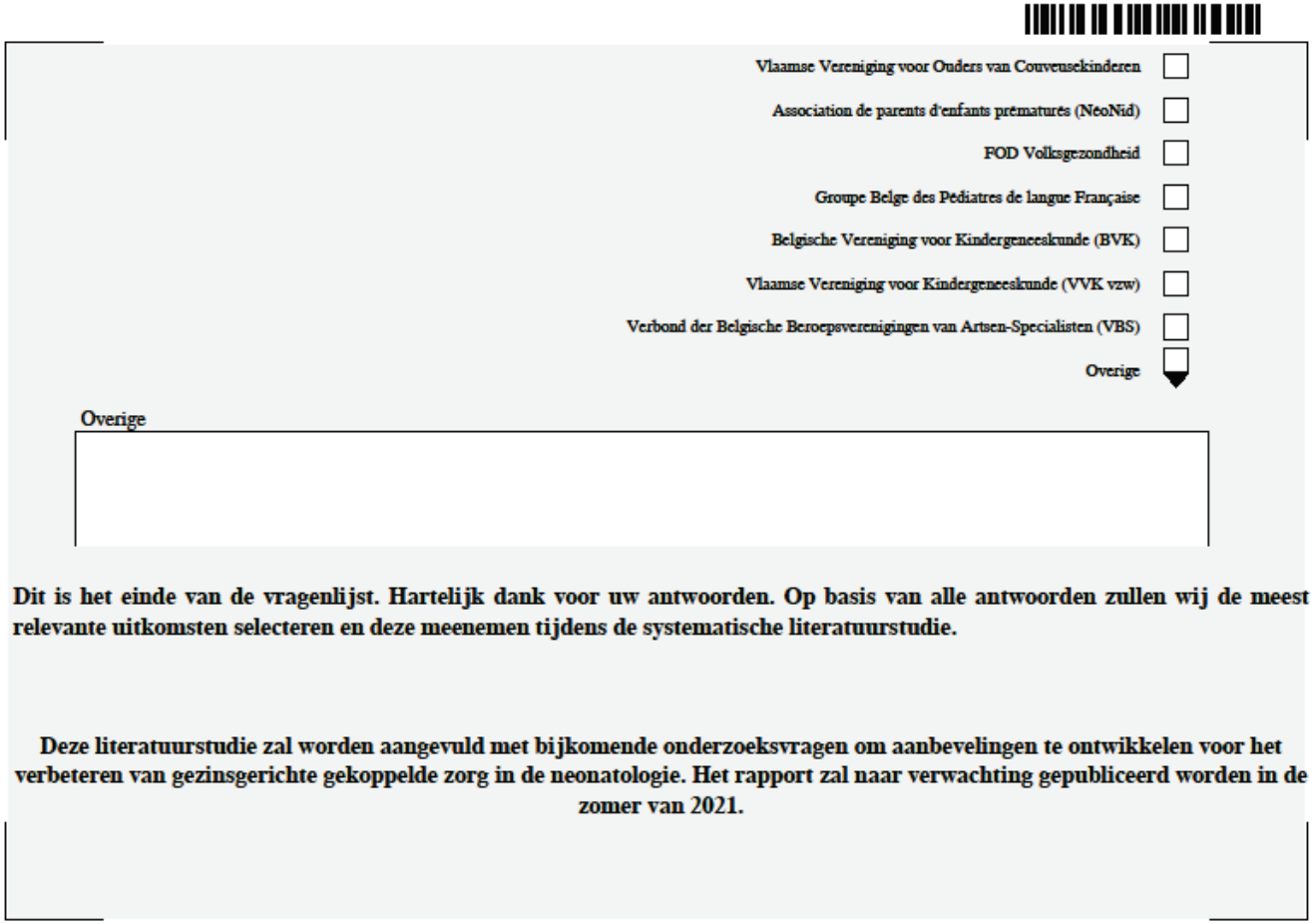
Hyperthermie

Heropname in het ziekenhuis na ontslag

**A3. Denkt u nog aan andere uitkomsten die relevant zouden zijn om te bestuderen tijdens de systematische literatuurstudie?**

**A4. Met welke organisatie bent u geaffilieerd?**

- ☐ Belgische Vereniging voor Neonatologie (BVN)
- ☐ College van geneesheren voor de moeder en de pasgeborene
- ☐ Association des infirmiers spécialisés en pédiatrie et en néonatologie
- ☐ Vlaamse Intensieve Neonatale Zorgen (vzw VINZ)



Vlaamse Vereniging voor Ouders van Couveusekinderen ☐
Association de parents d'enfants prématurés (NéoNid) ☐
FOD Volksgezondheid ☐
Groupe Belge des Pédiatres de langue Française ☐
Belgische Vereniging voor Kindergeneeskunde (BVK) ☐
Vlaamse Vereniging voor Kindergeneeskunde (VVK vzw) ☐
Verbond der Belgische Beroepsverenigingen van Artsen-Specialisten (VBS) ☐
Overige ☐

Overige

**Dit is het einde van de vragenlijst. Hartelijk dank voor uw antwoorden. Op basis van alle antwoorden zullen wij de meest relevante uitkomsten selecteren en deze meenemen tijdens de systematische literatuurstudie.**

**Deze literatuurstudie zal worden aangevuld met bijkomende onderzoeksvragen om aanbevelingen te ontwikkelen voor het verbeteren van gezinsgerichte gekoppelde zorg in de neonatologie. Het rapport zal naar verwachting gepubliceerd worden in de zomer van 2021.**

## *Appendix 2.2.2. French survey*

**Le Centre fédéral d'expertise des soins de santé (KCE) mène actuellement une étude dans laquelle il examine l'organisation des soins couplés centrés sur la famille (family-centred care) pour les nouveau-nés prématurés et leurs parents dans les services néonatals (description de l'étude ici). Sur base de cette étude, le KCE formulera des recommandations pour améliorer les soins couplés centrés sur la famille dans les services de néonatologie. La littérature scientifique démontre que le fait de permettre la création précoce de liens affectifs entre les parents et les nouveau-nés prématurés peut améliorer l'état de santé du bébé à court et à long terme. Différents modèles de soins existent pour favoriser ce lien (par exemple, les soins couplés, les soins de développement, les soins kangourou ou les unités koala).**

**Dans la première partie de cette étude, le KCE analysera l'efficacité de ces modèles de soins au moyen d'une revue systématique de la littérature. Afin d'étudier l'efficacité, il faut tout d'abord définir un certain nombre de résultats de santé (outcomes) pertinents. Le KCE souhaite donc obtenir la contribution d'experts en néonatologie et des stakeholders pour sélectionner les outcomes les plus pertinents pour cette revue systématique de la littérature.**

**C'est pourquoi nous vous demandons de remplir le court questionnaire suivant (il ne faut pas plus de 5 minutes pour le remplir).**

**Le questionnaire sera accessible du 10 au 24 juin 2020. Les données récoltées seront traitées de manière confidentielle, et seule l'équipe de recherche y aura accès. Nous souhaitons limiter les réponses à une seule par organisation, merci de ne pas diffuser ce lien à l'ensemble de vos membres.**

**Pour toute question ou remarque, merci de prendre contact avec l'équipe de recherche : Jens.Detollenaere@kce.fgov.be (NL) ou Nadia.Benahmed@kce.fgov.be (FR).**

**Merci beaucoup pour votre collaboration.**

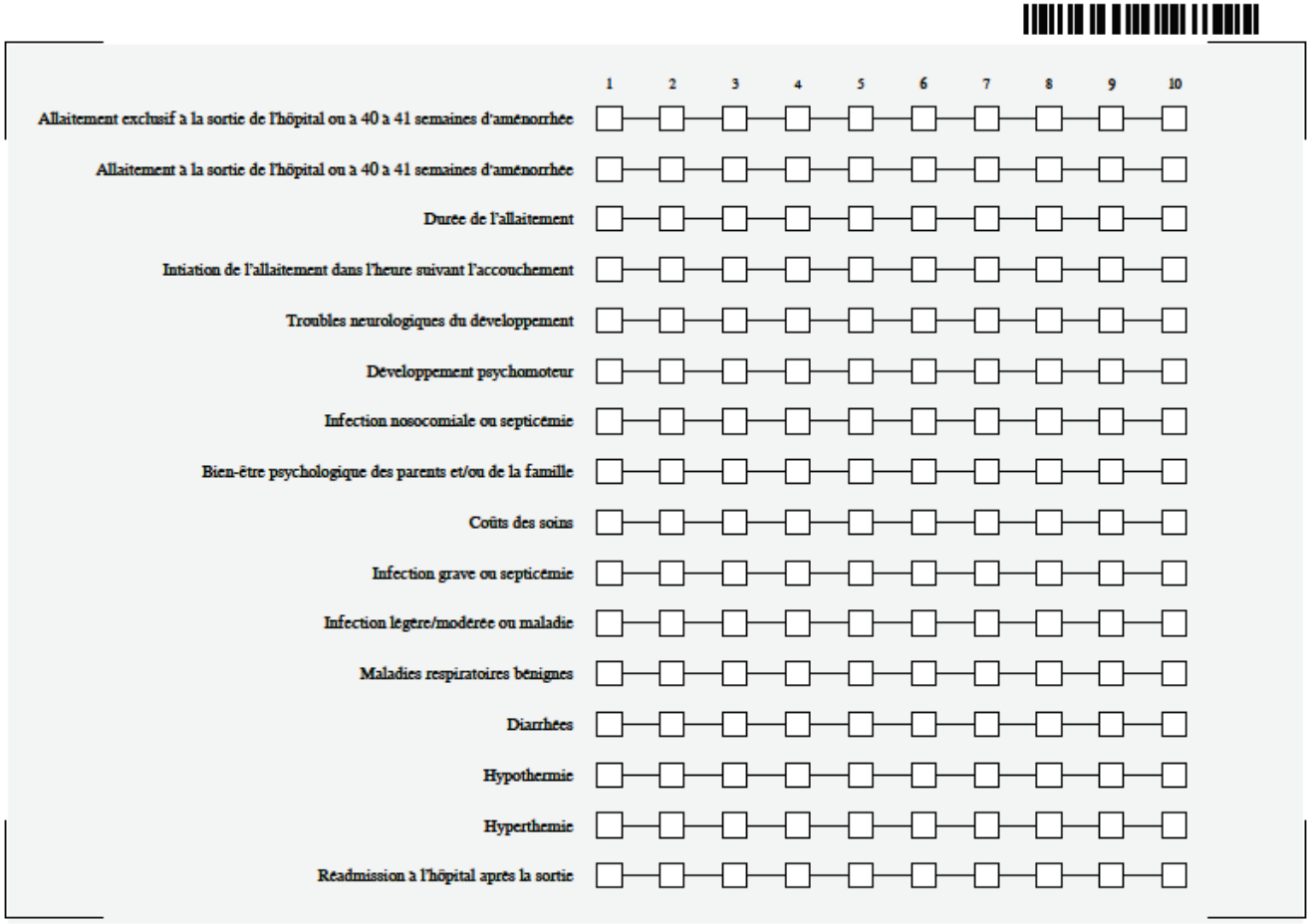
**L'équipe de recherche du KCE (Jens Detollenaere, Koen Van den Heede, Nadia Benahmed et Carl Devos)**

## Partie A: Group 1

**A1.** **Vous trouverez ci-dessous une liste de critères d'évaluation des modèles de soins pour les nouveaux-nés prématurés accueillis dans les services NIC ou N*. Pourriez-vous évaluer chacun des critères en fonction de la pertinence à être pris en compte dans la revue systématique de la littérature ?**

**(1 pas du tout pertinent, 10 très pertinent)**

| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
|---|---|---|---|---|---|---|---|---|---|---|
| Durée de séjour de la mère | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Durée de séjour du nouveau-né | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Lien parent-nouveau-né (mesuré à l'aide d'un instrument de mesure validé) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Interaction parent-nouveau-né (mesuré à l'aide d'un instrument de mesure validé) | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Croissance pondérale à la sortie de l'hôpital | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Croissance pondérale à 40 à 41 semaines d'aménorrhée | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Croissance pondérale lors de la dernière consultation de suivi | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Croissance de la taille à la sortie de l'hôpital | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Croissance de la taille à 40 à 41 semaines d'aménorrhée | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |
| Croissance de la taille lors de la dernière consultation de suivi | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ | ☐ |


1 2 3 4 5 6 7 8 9 10
Allaitement exclusif à la sortie de l'hôpital ou à 40 à 41 semaines d'aménorrhée
Allaitement à la sortie de l'hôpital ou à 40 à 41 semaines d'aménorrhée
Durée de l'allaitement
Initiation de l'allaitement dans l'heure suivant l'accouchement
Troubles neurologiques du développement
Développement psychomoteur
Infection nosocomiale ou septicémie
Bien-être psychologique des parents et/ou de la famille
Coûts des soins
Infection grave ou septicémie
Infection légère/modérée ou maladie
Maladies respiratoires bénignes
Diarrhées
Hypothermie
Hyperthermie
Réadmission à l'hôpital après la sortie

**A2. Quels sont, pour vous, les trois critères d'évaluation les plus importants que le KCE devrait étudier lors de la revue systématique de la littérature ?**

| | | | |
|---|---|---|---|
| | | | |
| Durée de séjour de la mère | | | |
| Durée de séjour du nouveau-né | | | |
| Lien parent-nouveau-né (mesuré à l'aide d'un instrument de mesure validé) | | | |
| Interaction parent-nouveau-né (mesuré à l'aide d'un instrument de mesure validé) | | | |
| Croissance pondérale à la sortie de l'hôpital ou à 40 à 41 semaines d'aménorrhée | | | |
| Croissance pondérale lors de la dernière consultation de suivi | | | |
| Croissance de la taille à la sortie de l'hôpital ou à 40 à 41 semaines d'aménorrhée | | | |
| Croissance de la taille lors de la dernière consultation de suivi | | | |
| Allaitement exclusif à la sortie de l'hôpital ou à 40 à 41 semaines d'aménorrhée | | | |
| Allaitement à la sortie de l'hôpital ou à 40 à 41 semaines d'aménorrhée | | | |
| Durée de l'allaitement | | | |
| Initiation de l'allaitement dans l'heure suivant l'accouchement | | | |
| Troubles neurologiques du développement | | | |
| Développement psychomoteur | | | |

Infection nosocomiale ou septicémie

Bien-être psychologique des parents et/ou de la famille

Coûts des soins

Infection grave ou septicémie

Infection légère/modérée ou maladie

Maladies respiratoires bénignes

Diarrhées

Hypothermie

Hyperthemie

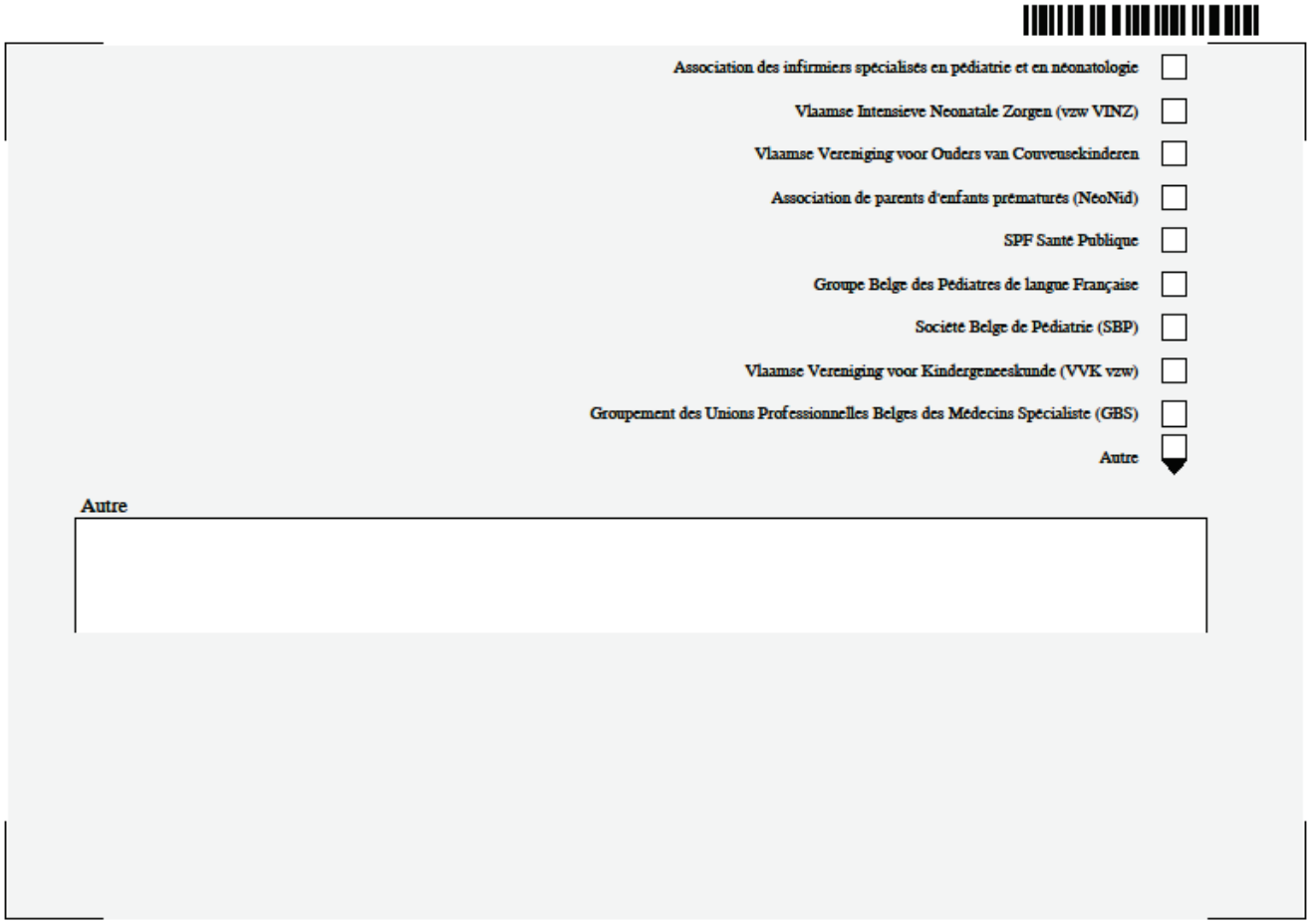
Réadmission à l'hôpital après la sortie

**A3. Pensez-vous à d'autres critères d'évaluation qu'il serait pertinent d'étudier lors de la revue systématique de la littérature ?**

**A4. À quelle organisation êtes-vous affilié ?**

Groupement Belge de Néonatologie (GBN)

Collège de médecins pour la mère et le nouveau-né



Association des infirmiers spécialisés en pédiatrie et en néonatologie ☐
Vlaamse Intensieve Neonatale Zorgen (vzw VINZ) ☐
Vlaamse Vereniging voor Ouders van Couveusekinderen ☐
Association de parents d'enfants prématurés (NéoNid) ☐
SPF Santé Publique ☐
Groupe Belge des Pédiatres de langue Française ☐
Société Belge de Pédiatrie (SBP) ☐
Vlaamse Vereniging voor Kindergeneeskunde (VVK vzw) ☐
Groupement des Unions Professionnelles Belges des Médecins Spécialiste (GBS) ☐
Autre ☐

Autre

**C'est la fin du questionnaire. Merci beaucoup pour vos réponses. Sur la base de l'ensemble des réponses, nous sélectionnerons les critères d'évaluation les plus pertinents et les prendrons en compte lors de l'étude systématique de la littérature.**

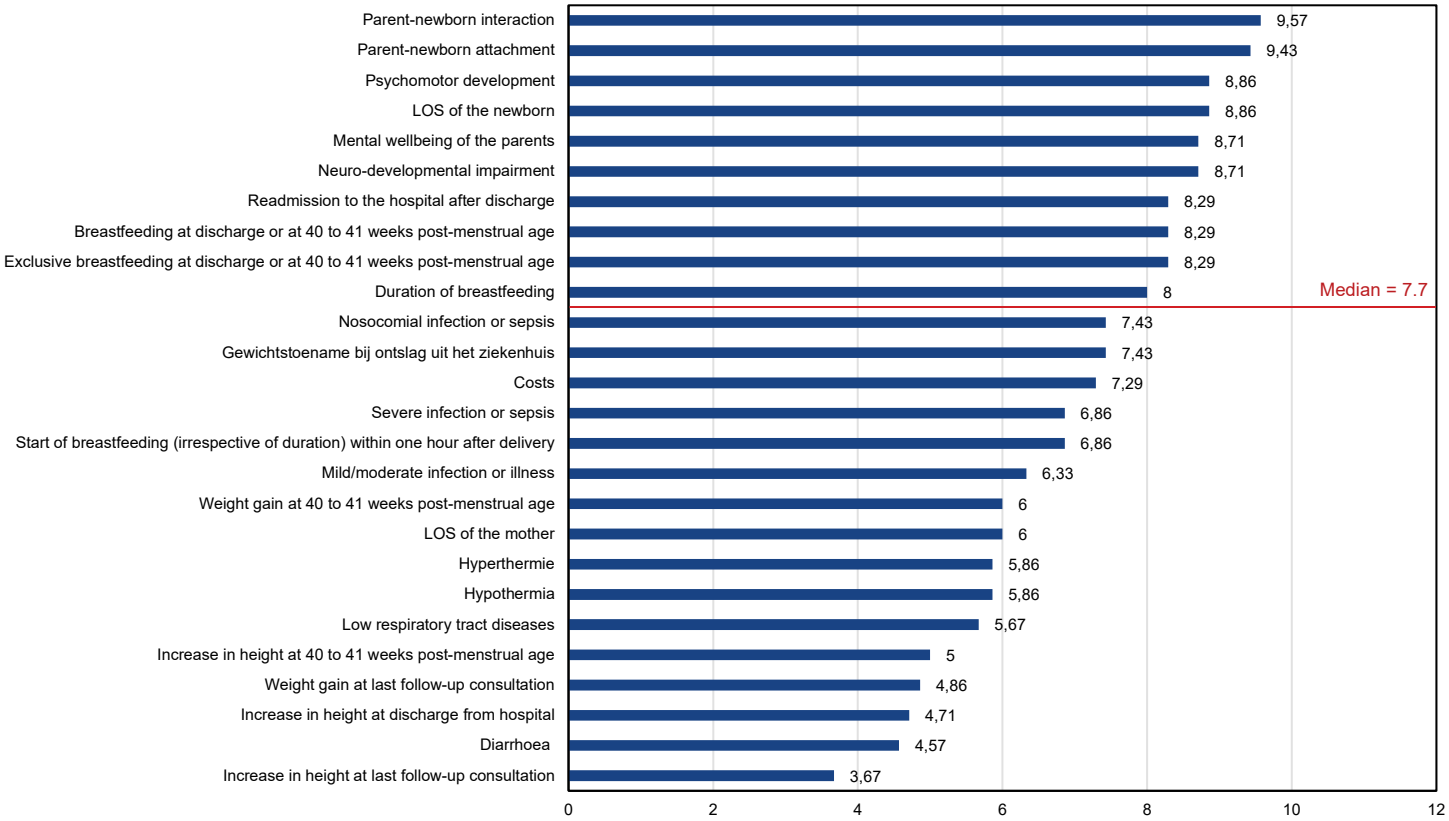
**Cette revue de la littérature sera complétée par d'autres questions de recherche permettant d'élaborer des recommandations pour améliorer les soins couplés centrés sur la famille dans les services de néonatologie. Le rapport sera en principe rendu public à l'été 2021.**

## *Appendix 2.2.3. Results*

Fifteen respondents filled in the survey of which nine were French- and six Dutch-speaking. The mean score per outcome was calculated (Figure 1). The outcomes with the highest scores were parent-newborn interaction (mean 9.57) and parent-newborn attachment (mean 9.43). Outcomes with the lowest mean scores were diarrhoea (mean 4.57) and increase in height (mean 3.67).

The median score across all outcomes was 7.70 and was chosen as the cut-off value for the outcomes to be included in the review.

**Figure 1 – Mean score per outcome (n = 15)**



# Appendix 2.3. Evidence tables

## *Appendix 2.3.1. Interventions focusing on skin-to-skin contact*

**Skin-to-skin contact (SSC)**

| **Miles et al. (2006)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Pragmatic, prospective, controlled, intention-to-treat trial | **Exposure intervention group** | Skin-to-skin contact (20 minutes of SSC once daily for 4 weeks) |
| **Country** | United Kingdom | **Exposure control group** | Standard care |
| **Setting** | Two tertiary referral neonatal intensive care units (Hammersmith Hospital and Queen Charlotte's and Chelsea Hospital) | **Level of prematurity** | < 32 weeks gestational age |
| **Sample size** | We recruited 46 infants into the SSC group and 32 into the control group. The difference in the number of infants recruited to each group arose because of variations in the wash-out phases and the need to complete recruitment within a finite time period. | | |
| **Time frame** | NA | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Newborns*<br>Infants were eligible if born below 32 weeks gestation, less than 7 days of age and without major immediate life-threatening congenital abnormalities.<br>If the infants were not being ventilated and considered by the staff to be medically stable (not having repeated episodes of apnoea or bradycardia, not on inotropic support and with a stable core-peripheral temperature gap of less than 2°C). | | |
| **Exclusion criteria** | - | | |
| **Newborn and parent characteristics** | There were no significant differences between the groups in maternal or infant characteristics at trial entry. | | |
| **Results** | | | |
| **Parent-newborn attachment** | *Instrument: Parent to Infant Attachment questionnaire, measured at 1 year corrected age* | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| | | | relationship | | | |
| | 1 year post-term | Parent to Infant Attachment [45] | Competence Quality of maternal attachment to infant | 21.51 (2.30) | 21.85 (2.60) | ns |

**Stress**

*Instrument: Parental Stressor Scale : Neonatal Intensive Care (PSS : NICU), measured at infant's discharge and 1 year corrected age*

| | | | | | |
|---|---|---|---|---|---|
| *(c) Maternal scores, discharge to 4 months* | | | | | |
| Infant discharge home | Edinburgh Postnatal Depression Scale [39] | Presence of symptoms of postnatal depression | 7.69 (5.31) | 9.26 (5.29) | ns |
| Infant discharge home | State-Trait Anxiety Inventory [40] | State anxiety level | 34.09 (10.78) | 35.26 (12.09) | ns |
| Infant discharge home | Parental Stressor Scale Neonatal Intensive Care [41] | Level of maternal stress related to infant admission to NICU | | | |
| | | Sights and Sounds | 2.85 (1.04) | 2.54 (1.06) | ns |
| | | Infant appearance | 3.35 (0.91) | 3.53 (1.58) | ns |
| | | Parental role alteration | 3.32 (1.07) | 3.40 (1.00) | ns |

*(continued on next page)*

Table 2 (*continued*)

| Time of assessment | Composition of aggregated scores | Description of scale | STS (mean (S.D.)) | Control (mean (S.D.)) | *p* |
|---|---|---|---|---|---|
| *(c) Maternal scores, discharge to 4 months* | | | | | |
| Infant discharge home | Mother and Baby Scale [42] | Maternal perception of confidence in care giving | 14.29 (2.82) | 15.00 (2.14) | ns |
| 4 months post birth | Edinburgh Postnatal Depression Scale [39] | Presence of symptoms of postnatal depression | 6.57 (4.71) | 6.00 (5.09) | ns |
| 4 months post birth | State-Trait Anxiety Inventory [40] | State anxiety level | 31.49 (10.52) | 30.79 (11.94) | ns |
| 4 months post birth | Maternal Soothing Of Infant Distress to Immunisation [43] | Quantity/quality of maternal soothing behaviour | 2.23 (0.46) | 2.21 (0.79) | ns |
| *(d) Maternal scores, 1 year post-term* | | | | | |
| 1 year post-term | General Health Questionnaire [44] | Maternal mental health | | | |
| | | Somatic symptoms | 4.63 (3.26) | 6.65 (4.37) | ns |
| | | Anxiety | 3.50 (2.62) | 4.59 (4.08) | ns |
| | | Social dysfunction | 6.33 (3.35) | 6.29 (1.53) | ns |
| | | Depression | 0.40 (1.30) | 0.82 (1.24) | ns |
| 1 year post-term | Parenting Stress Index [41] | Identification of dysfunctional parental behaviour/stressors in the parenting relationship | 24.48 (5.95) | 25.23 (5.59) | ns |
| 1 year post-term | Parent to Infant Attachment [45] | Competence Quality of maternal attachment to infant | 21.51 (2.30) | 21.85 (2.60) | ns |

| | |
|---|---|
| **Anxiety** | *Instrument: State-Trait Anxiety Inventory for Adults (STAI), measured at infant's discharge and 4 months' post birth*<br>For results see table in row "Stress" |
| **Depression** | *Instrument: Edinburgh Postnatal Depression Scale (EPDS), measured at infant's discharge and 4 months' post birth*<br>For results see table in row "Stress" |
| **Limitations and conclusion** | |
| **Limitations** | A limitation of our study is that there was wide variation in the amount of SSC contact actually administered. It was our impression that many mothers did not appear to enjoy SSC contact. This was unexpected and we regret that our study was not designed to explore such a possibility. A further limitation was the lack of a measure of intention to breast-feed, but we judged it inappropriate to try to establish intentions in mothers who were coming to terms with the birth of a preterm infant. Unit policy was to promote breast-feeding strongly and it is also possible that this may have masked the impact of SSC on lactation. |
| **Authors' conclusion** | Mother-infant skin-to-skin contact after extremely preterm birth results in neither benefit nor adverse consequences. Although there is no reason to dissuade mothers who wish to provide SSC contact, we are unable to recommend resource allocation for the implementation of SSC programmes for extremely preterm infants in a neonatal intensive care unit setting. |

| **Chiu et al. (2009)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | SSC: intervention dyads were encouraged to begin experiencing SSC as early, as often, and for as long each time possible |
| **Country** | USA | **Exposure control group** | Routine care: control dyads were cared for in incubators, warmer beds, or bassinettes and were held wrapped in blankets |
| **Setting** | University Hospitals of Cleveland, Cleveland, Ohio, a large urban teaching and research hospital and Kadlec Medical Center, Richland, Washington, a regional hospital in a somewhat rural setting. | **Level of prematurity** | 32 – < 37 weeks of gestational age |
| **Sample size** | 75 dyads were randomised at the Midwestern hospital and 25 at the North-western hospital<br>Of the 262 women (53%) who consented, 100 (38%) were studied; 52 were randomized to the SSC group and 48 to the control group. During the in-hospital phase, five dyads (two SSC; three controls) withdrew. Five dyads (three SSC; two controls) discontinued their in-hospital participation but | | |

| | |
|---|---|
| | agreed to participate during follow-up. At hospital discharge, 95 dyads were eligible for follow-up. |
| **Time frame** | 1997 - 2000 |
| **Newborn and parent characteristics** | |
| **Eligibility criteria** | NA |
| **Exclusion criteria** | NA |
| **Newborn and parent characteristics** | No demographic between-group differences were found. |
| **Results** | |
| **Parent-newborn interaction** | *Instrument: Nursing Child Assessment Satellite Training Program (NCAST) Feeding and Teaching Scales*<br>*The feeding scale has a possible 76 points and the teaching scale has 73. The feeding scale can be used with infants from birth to one year, the teaching scale with infants from birth to three years. Both scales consist of six subscales to assess mother–infant interaction: sensitivity to cues, response to infant distress, social-emotional growth fostering, cognitive growth fostering, clarity of cues, and responsiveness of the child to the caregiver. Each subscale lists a series of caregiver and infant behaviours that the evaluator observes during a routine feeding session and a teaching session. In the teaching session, the mother teaches her infant a task she thinks the infant will not know how to do. The scales consist of binary (yes/no) items. All items rated yes are summed. A higher score indicates an interaction that is richer in positive affect, sensitivity, synchronicity, vocalization, and reciprocity. The feeding and teaching scales have established validity and reliability*.<br><br>Descriptive statistics (mean and standard deviation) and intention-to-treat analysis were used to describe and analyse data related to mother–infant interaction. Between-group differences in feeding and teaching scores were examined using Student's t-tests. To avoid inflating a Type 1 error, total teaching and feeding scores were first compared at each follow-up, followed by comparisons of the Mother Total and Child Total scores. SSC mothers and infants had higher total feeding scores at 6 and 12 months. When examining mothers and infants separately, SSC mothers had slightly higher Mother Total feeding scores at 6 and 12 months. SSC and control infants had comparable Infant Total feeding scores. Total teaching scores were similar between groups throughout follow-up. SSC mothers had consistently higher Mother Total scores at all three follow-ups. In contrast, SSC infants had lower Infant Total scores at six months (p = .001) but not at 12 and 18 months. Upon further analysis, at six-month follow-up, control infants had higher scores on the Child's Response to Caregiver subscale (p = .001). |
| **Limitations and conclusion** | |
| **Limitations** | Second, heterogeneity of the study infants is another possible reason. During the in-hospital phase of this study, subject recruitment was much slower because, by the time the study was funded, the primary study hospital was competing with secondary level hospitals that had established small NICUs to increase market share. Most of the pregnant women admitted into the primary study hospital were at higher risk than expected, as were their preterm infants after birth. As a result, many preterm infants did not meet the inclusion criteria and expansion of inclusion criteria to permit recruitment of higher-risk dyads was needed. Thus, about 70% of the preterm infants in the study were admitted into the NICU and several of these infants also required ventilator support. Dyads admitted to the NICU and/or needing ventilator support could not begin SSC as early or for as long due to infant care needs. The heterogeneity of this sample may have increased individual differences in terms of the dependent variable, thereby inflating the error variance and decreasing the chance of detecting a significant intervention effect. |

| | |
|---|---|
| | In addition, possible intervention diffusion cannot be ignored. Although our study only studied one dyad at a time, some SSC infants stayed in the NICU after the study ended. Parents of the control infants could have observed other parents experiencing SSC and initiated SSC themselves. This information, however, was not obtained at the time of follow-up visits.<br>Finally, the instruments chosen for this study may not reflect the essence of mother–infant interaction after experiencing SSC. Gross et al. (1993) reported that the NCAST Teaching Scale measures the cognitive experience, rather than affective feeling, of the mother. In addition, each item on the feeding and teaching scales was rated as a dichotomous response (presence or absence). As soon as a behaviour occurred the item was scored ‘‘yes’’ regardless of how often the behaviour occurred thereafter. Then all items scored yes were added to obtain a sum score. Thus, the quantity of each behaviour (e.g., kissing, caressing, and touching) was not measured. For these reasons, these two scales might not be sensitive enough to capture any between-group difference in changes resulting from the intervention. |
| **Authors' conclusion** | Although definitive conclusions regarding the long-term effects of SSC on mother-infant interaction cannot be made at this time, it is important to note that no adverse effects were found. Based on positive findings from current literature about mother-infant interaction during and after SSC, all new mothers, if they are able and whether or not they ask to do SSC, should be encouraged to experience SSC and assured that they will have additional support from hospital staff. The longer term effects of SSC on mother-infant interaction, however, merit further testing. |

| **Mörelius et al. (2015)** | | | |
|---|---|---|---|
| Methods | | | |
| Design | Randomised cross-over controlled trial | Exposure intervention group | Maternal SSC day 1 – paternal SSC day 2: 30 minutes SSC |
| Country | USA | Exposure control group | Paternal SSC – maternal SSC day 2: 30 minutes SSC |
| Setting | Level IV in Connecticut | Level of prematurity | 30 0/7 – 34 6/7 weeks of gestational age |
| Sample size | Intervention group: 26<br>Control group: 19 | | |
| Time frame | NA | | |
| Newborn and parent characteristics | | | |
| Eligibility criteria | Newborns<br>Inclusion criteria were: male and female stable pre-term infants who were 30 0/7–34 6/7 weeks gestational age at birth and 3–10 days old post-natal age; cared for in an incubator; and either NPO or on bolus feeds to control for feeding effects on cortisol levels.<br>Parents<br>Parents had to be 18 years and older without a history of depression so that the influences on OT and cortisol levels were minimized. | | |
| Exclusion criteria | Newborns | | |

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|---|---|
| | Exclusion criteria were: infants who were intubated and receiving mechanical ventilation; had known congenital anomalies; had severe periventricular/intraventricular haemorrhage (≥ Grade III); or had undergone minor or major surgery. |
| Newborn and parent characteristics | Twenty-eight infant–mother–father triads were recruited in the study. Parents of two infants did not provide either M-SSC or P-SSC to their newborn after recruitment, and the reason was unknown. In the final sample of 26 triads, 14 triads were randomized to sequence 1 (M-SSC on day-1 and P-SSC on day-2) and 12 triads were in sequence 2 (P-SSC on day-1 and M-SSC on day-2). Twenty-six mothers and 19 fathers completed the study protocol (Table 2). The majority of parents were white (77% of mothers; 68% of fathers) and with college or higher education (62% of mothers; 79% of fathers). Six-nine present of mothers and 53% of fathers had M-SSC or P-SSC experience since the infant's birth before they participated in the study. |
| Results | |
| Anxiety | Instrument: validated 8-item visual analog scale (VAS)<br>Mothers' anxiety levels were significantly decreased from baseline (24.31 ± 26.25) to during-M-SSC (5.85 ± 11.75), and then returned to the baseline levels of anxiety in post-M-SSC (23.35 ± 26.28), F(2,50) = 11.29, p = 0.01 (Fig. 3). Fathers' anxiety levels were significantly decreased from baseline (19.98 ± 21.22) to during-P-SSC (5.80 ± 6.85), and then increased post-P-SSC (9.81 ± 15.95), F(2, 36) = 9.15, p = 0.01 (Fig. 3). Maternal and paternal anxiety levels (VAS scores) were significantly correlated at pre-SSC (r = 0.61, p b 0.05), during-SSC (r = 0.48, p = 0.05), and post-SSC (r = 0.71, p = 0.01), in mother–father dyads. |
| Limitations and conclusion | |
| Limitations | NA |
| Authors' conclusion | In summary, both M-SSC and P-SSC activated OT release and reduced stress and anxiety responses in mothers and fathers of pre-term infants. However, generalization of these findings may be limited because of small sample size. Nonetheless, parental touch during the early life period is critical for an infant's growth and survival and also for parenting development. The present study lends support to the involvement of an OT-related mechanism in neuroendocrine pathways during parent–infant contact and human parenting. This study lends further physiologic support to the positive role of SSC in the early post-partum period and more studies are especially needed to investigate effects of P-SSC and its underlying mechanisms on infant–father interactions. |

| **Mörelius et al. (2015)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | Continuous SSC: starting in the delivery room and continuing almost 24 hours a day with the parents alternating until hospital discharge |
| **Country** | Sweden | **Exposure control group** | Standard care (SC): separated from each other in the maternity ward and transferred to the NICU, but with the possibility to provide skin-to-skin care during visits |

| | | | |
|---|---|---|---|
| **Setting** | One level-III NICU at Linköping University Hospital and one level-II NICU at Södersjukhuset, Sachs' Children's Hospital in Stockholm | **Level of prematurity** | 32/0 - 35/6 weeks gestational age |
| **Sample size** | Forty-two families agreed to participate; 23 were randomised to almost continuous SSC and 19 to SC. Because the families were randomised prior to the infants' birth, three families were excluded after birth (born full-term n=1, mother unhealthy n=1, and delivered with caesarean section n=1). These families were all randomised to almost continuous SSC. Two families from the SSC group withdrew from the study after two and three days, respectively. In one of the families the mother had diabetes and the father described the situation as very stressful because the mother had to stay at the maternity ward for care. Their infant was born in week 35 and the father found it hard to carry the infant so much, and hard to sleep. The other family withdrew without any further explanation after their infant was born in week 33. | | |
| **Time frame** | April 2008 – April 2012 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Mothers*<br>Healthy women about to give birth vaginally to a single preterm infant (GA $32^0$-$35^6$) without known malformation were eligible for participation. Participating mothers had to be able to read and speak Swedish. | | |
| **Exclusion criteria** | - | | |
| **Newborn and parent characteristics** | There were no significant differences in infants' birth weight, age at birth, or gender or parental demographics between the two groups. | | |

| | Skin-to-skin contact n=18 | Standard care n=19 | |
|---|---|---|---|
| Gender boys/girls | 11/7 | 6/13 | n.s. |
| PMA at birth, mean (SD)/weeks | 243 (6.2)/34 | 243 (4.8)/34 | n.s. |
| PMA at discharge, mean (SD)/weeks | 263 (7.6)/37 | 262 (4.8)/37 | n.s. |
| Birth weight, g, mean (SD) | 2468 (285) | 2512 (274) | n.s. |
| Weight at discharge, g, mean (SD) | 2811 (336) | 2787 (255) | n.s. |
| Weight one month, g, mean (SD) | 4660 (559) | 4649 (662) | n.s. |
| Weight four months, g, mean (SD) | 6930 (655) | 6715 (860) | n.s. |
| Siblings, yes/no/missing data | 5/13/0 | 6/12/1 | n.s. |
| Mothers' age, yrs, mean (SD) | 31 (3.5) | 33 (5.3) | n.s. |
| Fathers' age, yrs, mean (SD) | 33.5 (5.2) | 34 (5.1) | n.s. |
| Cohabitate/single mother/missing data | 18/0/0 | 17/1/1 | n.s. |
| Mothers' education | | | |
| High school/university/other | 3/15/0 | 3/15/1 | n.s. |
| Fathers' education | | | |
| High school/university/other | 5/12/1 | 6/11/2 | n.s. |
| Smoking , yes/no/missing data | | | |
| Mothers | 0/18/0 | 0/18/1 | n.s. |
| Fathers | 1/17/0 | 1/16/2 | n.s. |

Variables are n unless otherwise is stated
PMA=post menstrual age

## Results

**Stress**

*Instrument: Swedish Parenthood Stress Questionnaire (SPSQ)*

There were no significant differences in total SPSQ, or in the sub-scales incompetence, role restriction, social isolation, and health problems, between SSC and SC at one or four months. At four months, fathers in SSC scored significantly lower on the sub-scale spouse relationship problems compared to fathers in SC ($p < 0.05$). Medians (q1 - q3) were 2.0 (1.4 - 2.0) and 2.6 (2.0 - 3.0) for fathers in SSC and SC, respectively. Comparing fathers in the SC group by using paired statistics revealed a significant increase in the sub-scale spouse relationship problems from one to four months ($p < 0.05$), medians (q1 - q3) were 1.8 (1.5 - 2.5) and 2.6 (2.0 - 3.0), respectively.

**Depression**

*Instrument: Edinburgh Postnatal Depression Scale (EPDS)*

At four months corrected age, no significant differences were found between the groups in EPDS, neither between mothers nor between fathers. The proportion of mothers with depressive symptoms (EPDS > 11) was 6.3% in the SSC group and 6.7% in the SC group. Of fathers, 7.1% in SSC and 8.3% in SC had depressive symptoms (EPDS > 9).

| | |
|---|---|
| **Breastfeeding** | All infants (n=18) in the SSC group were breastfeeding partly or exclusively at discharge, compared to 16 out of 19 (84.2%) in the SC group. More infants were breastfeeding partly or exclusively in the SSC group, compared to the SC group at one and four months, but the differences did not reach significance. |
| **Limitations and conclusion** | |
| **Limitations** | It was not possible to include a control group that did not practice skin-to-skin contact because allowing parents to practice as much skin-to-skin contact as they like during their hospital stay is routine. This resulted in an average of 7.0 hours of skin-to-skin contact per day in the SC group, which is a lot compared to other studies, but significantly less than for the families randomised to SSC. One reason for the high use of skin-to-skin contact in the SC group could be the participation in the study itself. The study participants were all informed about the study and skin-to-skin contact before randomisation; a small intervention that possibly made the parents aware of the method and hence increased the use of skin-to-skin contact. |
| **Authors' conclusion** | Early life factors, such as almost continuous SSC, can affect the development of the HPA axis. In the present study, almost continuous SSC decreased the salivary cortisol reactivity during a nappy change and improved the concordance between mothers' and infants' salivary cortisol levels, which could be a sign of a more rapid development of regularity. An intervention, such as almost continuous SSC, that involves and engages both parents immediately after the birth of a preterm infant and continues until discharge from the hospital seems to facilitates the spouse relationship. |

| **Samra et al. (2015)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Longitudinal 2-group randomised controlled trial | **Exposure intervention group** | Were encouraged to provide SSC a minimum of 3 times a week at 50 minutes per session throughout NICU stay |
| **Country** | USA | **Exposure control group** | Held the baby wrapped in a blanket and were also encouraged to hold their infant for a minimum of 3 times a week at 50 minutes per session throughout NICU stay. |
| **Setting** | Open-bay NICU (level III) in a Midwestern US tertiary medical centre | **Level of prematurity** | 34 and 36 6/7 weeks gestational age |
| **Sample size** | Intervention group: n = 19<br>Control group: n = 11<br>Forty-four mother–infant dyads were assessed for eligibility. Four mothers did not meet the study inclusion criteria. Forty dyads were randomized to either intervention or control groups. Ten mother-infant pairs did not complete the study and 30 were included in the analysis. | | |
| **Time frame** | March 2013 – January 2014 | | |

| Newborn and parent characteristics | |
|---|---|
| **Eligibility criteria** | *Mothers*<br>Inclusion criteria were English-speaking mothers. |
| **Exclusion criteria** | *Newborns*<br>Infants with congenital anomalies or positive drug screens were excluded from the study.<br>*Mothers*<br>Mothers 18 or more years of age and mothers who did not write English were also excluded from the study. |
| **Newborn and parent characteristics** | Other than a difference in the SCRIP score (P = 0.05), mothers and infants in the intervention and control groups shared similar characteristics and were considered comparable. SCRIP scores ranged from 3 to 6. |

TABLE 1. Description of Maternal and Infant Clinical and Demographic Characteristics at Baseline

| Variable | Total Mean ± SD/ Proportions (n = 30) | Mean/Proportion for SSC (n = 19) | Mean/Proportion for Holding (n = 11) | *P* Value |
|---|---|---|---|---|
| Maternal variables | | | | |
| Age, y | 25 ± 4.3 | 26 ± 4.8 | 24 ± 2.7 | .17 |
| Education (mothers who earned a college degree) | 60% | 62% | 56% | .78 |
| Marital status (mothers who are single) | 57% | 58% | 56% | .38 |
| Racial and ethnic background (white mothers) | 76% | 62% | 100% | .06 |
| Household income >30,000/y | 50% | 53% | 44% | .68 |
| Gravida | 2.4 ± 1.6 | 2.4 ± 1.5 | 2.5 ± 1.8 | .96 |
| Para | 1.4 ± 1.3 | 1.5 ± 1.4 | 1.3 ± 1.1 | .61 |
| Delivery of multiple gestation | 10% | 16% | 0% | .16 |
| Cesarean section deliveries | 30% | 32% | 36% | .78 |
| Infant variables | | | | |
| Gestational age, wk | 35 ± 1 | 35 ± 1 | 35.5 ± 1 | .17 |
| Birth weight, g | 2566 ± 425 | 2493 ± 483 | 2693 ± 275 | .22 |
| Birth length, cm | 47 ± 2.3 | 46 ± 2.6 | 47.5 ± 1.2 | .15 |
| Head circumference, cm | 32 ± 2.4 | 31.4 ± 2.9 | 32.5 ± 1.0 | .21 |
| Discharge weight, g | 2539 ± 372 | 2491 ± 402 | 2622 ± 314 | .36 |
| Apgar score at 1 min | 7.4 ± 1.6 | 7.4 ± 1.9 | 7.4 ± 1.1 | .97 |
| Apgar score at 5 min | 8.3 ± 1.5 | 8.7 ± 0.5 | 8.6 ± 0.6 | .35 |
| Length of NICU stay, d | 13 ± 6.7 | 13.7 ± 6 | 12.1 ± 8 | .53 |
| Age holding or SSC initiated, h | 31 ± 28 | 31 ± 28 | 31 ± 8 | .97 |
| SCRIP score | 5.7 ± 0.80 | 6.0 ± 0.47 | 5.3 ± 1.1 | .05 |
| Male sex | 73% | 68% | 82% | .41 |

*Abbreviations: NICU, neonatal intensive care unit; SCRIP, Stability of the Cardiorespiratory System in Preterm Infants; SD, standard deviation; SSC, skin-to-skin care.*

| Results | |
|---|---|
| **LOS newborn** | Mean length of NICU stay (SD) intervention group 13.7 days (6) vs. control group 12.1 (8), p = 0.53 |

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| **Stress** | *Instrument: Miles and Carter's Parental Stressor Scale: Neonatal Intensive Care (PSS : NICU), filled in by the mothers within 24 hours of admission (pre-SSC) and 24 hours before NICU discharge (post-SSC)*<br>Comparison of stress scores showed no significant differences between groups except for one difference. The control group had a significantly higher mean stress score for the PRA subscale pre-intervention (P = 0.02), yet this difference disappeared post-SSC. On the basis of results presented in Table 3, SSC did not have a significant effect on maternal stress compared with the control group, and within-group changes from pre- to post intervention were insignificant. |
| **Limitations and conclusion** | |
| **Limitations** | The PSS : NICU does not take into account other sources of stress as they related to parents' daily hassles, other responsibilities, trauma related to pregnancy and delivery, development of the parent role, and sensitivity to the infant.<br>We experienced a high attrition rate in the control group. Our sample was underpowered (30%). The effect sizes were small and (Cohen's d) ranged from 0.21 to 0.42.<br>There were marginal differences in the racial composition of the groups. Although it did not reach a level of significance, it may have had a confounding effect on study findings. |
| **Authors' conclusion** | We did not find a statistical difference in stress perception between mothers who provide intermittent sessions of SSC contact to their LPI throughout the NICU stay and mothers who provide blanket holding, and stress levels did not change from pre- to post-SSC. However, adverse consequences of early maternal separation, we cannot emphasize enough the importance of increasing exposure to SSC and of reducing delays in introduction and obstacles to longer periods of SSC. Although participating in continuous SSC remains the ideal goal, this may not be realistic or possible for some parents. Given the intermittent SSC should be used when continuous or 24/7, SSC is not possible. |

| **Vittner et al. (2018)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Crossover randomised trial | **Exposure intervention group** | 60 minutes SSC with the mother |
| **Country** | USA | **Exposure control group** | 60 minutes SSC with the father |
| **Setting** | Three NICUs: at Connecticut Children's Hartford and Farmington campuses and at Eastern Connecticut Health Network, which are all in central Connecticut | **Level of prematurity** | 30 – 34 weeks of gestational age (and between 3 – 10 days old at the start of the study) |
| **Sample size** | We randomized 15 triads to sequence one (M-SSC on Day 1, P-SSC on Day 2) and 13 to sequence two (P-SSC on Day 1, M-SSC on Day 2). | | |
| **Time frame** | 3 days (year NA) | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Newborns* | | |

| | |
|---|---|
| | Inclusion criteria included infants who were (1) 30 0/7–34 6/7 weeks' gestational age at birth and between 3 and 10 days old at the start of the study and (2) receiving either nothing per oral or on intermittent feeds to control for feeding effects on heart rate variability. |
| **Exclusion criteria** | *Newborns*<br>Exclusion criteria included infants who (1) were intubated and receiving mechanical ventilation, (2) had known congenital anomalies, (3) had severe periventricular/intraventricular hemorrhage (≥ Grade III), (4) had undergone minor or major surgery, (5) were receiving sedation or vasopressors or analgesics to control for the effect of sedative medication on behavioral states, or (6) had positive drug exposure history to control for the effect of drugs on behavioral states and autonomic responses.<br>*Parents*<br>Parental eligibility criteria were (1) age >18 years, (2) English speaking, and (3) without a history of depression. |
| **Newborn and parent characteristics** | The majority of parents were White (68%) and college educated (93% of mothers and 89% of fathers). The mothers' mean age was 32 years, while the fathers' was 33. The infants were relatively healthy, with a mean Score for Neonatal Acute Physiology with Perinatal Extension score of 3.93. This score is a valid indicator of an infant's severity-of-illness predictor of mortality risk. Infants were born at a mean of 33 weeks' postmenstrual age. The majority of infants were White (61%) males (68%). Most mothers (89%) had held their infants SSC prior to the study, while only some of the fathers (27%) had. Only a small percentage of parents (32% of mothers, 21% of fathers) had previous SSC experience with another infant. |
| **Results** | |
| **Parent-newborn interaction** | *Instrument: Dyadic Mutuality Code (DMC), videotaped and independently coded by two researchers*<br>We grouped the parent–infant interactions into three categories based on the video scoring: We considered scores between 6 and 8 to indicate low responsiveness, a score of 9 moderate responsiveness, and a score of 10-12 high responsiveness, or a synchronous interaction. All of the mothers (n = 28) and 26 fathers completed the videotaped interactions. The majority of mothers 67% (n = 19) scored as moderately responsive, with only 7% (n = 2) scoring in the low responsive group and 26% (n = 7) scoring as highly responsive. The fathers also scored as predominately moderately responsive (58%, or n = 15), with 16% (n = 4) scoring in the low responsiveness group and 26% (n = 7) scoring as highly responsive. |
| **Anxiety** | *Instrument: 8-item Visual Anxiety Scale (VAS), filled in by the parents*<br>Maternal anxiety levels dropped from pre-SSC (M = 72.00, SD = 77.84) to during SSC (M = 28.54, SD = 54.72) and post-SCC (M = 32.14, SD = 61.06). Paternal anxiety levels also decreased from pre-SSC (M = 43.59, SD = 58.10) to during SSC (M = 15.57, SD = 19.57) and then increased slightly post-SSC (M = 24.41, SD = 36.08). Using RM-ANOVA, we found that maternal anxiety scores were significantly lower during SSC, $F(1, 26) = 9.69$, $p < .001$, compared to pre- and post-SSC. Paternal anxiety levels were also significantly lower during SCC, $F(1, 26) = 8.86$, $p < .003$, compared to pre- and post-SSC. |
| **Limitations and conclusion** | |
| **Limitations** | Despite the small sample size, the present study had statistically significant results with robust effects showing that SSC activates OT release in mothers, fathers, and premature infants, in addition to decreasing infant SC levels and parental anxiety. Research with a larger sample size is needed, however, to generalize these findings. Our sample was primarily Caucasian with college-educated parents, which may have influenced the findings. Another limitation was the crossover study design, which does not allow for a clear definition of causality. Our convenience sampling techniques may have influenced the findings as well: Although SSC was a standard of practice in all recruiting NICUs, parents may have declined to participate because they did not want to practice SSC with their infants. |

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| **Authors' conclusion** | The present study addresses a gap in the body of knowledge regarding the mechanisms that link parent–infant contact to biobehavioral responses. Skin-to-skin holding activates oxytocin release for mothers, fathers, and infants and decreases infant SC levels and parental anxiety. The nursing intervention of facilitating the implementation of SSC thus may be used to reduce parent and infant stress in the NICU. This study is also an important step in exploring the use of oxytocin as a potential moderator to improve infant developmental outcomes and the responsiveness of the interactions between mothers and infants and fathers and infants. |

| **Mehler et al. (2020)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | Delivery room SSC with mother (60 minutes): DR-SSC |
| **Country** | Germany | **Exposure control group** | Visual contact (5 minutes): VC |
| **Setting** | 1 NICU (level III) | **Level of prematurity** | 25 – 32 weeks of gestational age |
| **Sample size** | Within the study period, 146 infants were eligible for inclusion of these, 88 were included in the study and randomized. One infant in the DR-SSC group was excluded from further analysis because he was diagnosed with Trisomy 21 (a predefined exclusion criterion) on the second day of life. Additionally, two intervention group infants and one control group infant died before the study was completed. Cause of death was severe sepsis on 7th day of life in one DR-SSC infant and severe pulmonary embolism on the 9th day of life in one VC infant. Another DR-SSC infant died from volvulus at the age of 4 months.<br>Intervention group (DR-SSC): 44<br>Control group (VC): 43 | | |
| **Time frame** | October 2013 – July 2015 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | All preterm infants born between 25 + 0 and 32 + 0 weeks of gestation between October 2013 and July 2015 were screened for eligibility. Additional inclusion criteria were as follows: firstborn child, single pregnancy and parental written informed consent. | | |
| **Exclusion criteria** | *Newborns*<br>Infants were excluded if they had a severe underlying disease (severe malformations and syndromic disorder), needed resuscitation after birth (5-minute Apgar score <5) or had cardiopulmonary failure ($FiO_2$ > 0.4 or severe apnoea).<br>*Parents* | | |

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|---|---|
| | Mothers with mental disorders (e.g. depression) or lack of German language skills were excluded. |
| **Newborn and parent characteristics** | *Baseline data newborns*<br>Gestational age (wk, mean (SD)): DR-SSC 29 (2), VC 29 (2), p = 0.662<br>Birthweight (gram, mean (SD)): DR-SSC 1250 (510), VC 1170 (380), p = 0.470<br>Male (n (%)): DR-SSC 21 (48%), VC 27 (63%), p = 0.198<br>Caesarean section (n (%)): DR-SSC 34 (77%), VC 33 (77%), p = 0.998<br>Prenatal steroids (n (%)): DR-SSC 35/41 (85%), VC 39/41 (95%), p = 0.264<br>Apgar 5 min (median (IQR)): DR-SSC 8 (7-8), VC 8 (7-8), p = 0.233<br>$FiO_2$ before VC/SS (mean (SD)): DR-SSC 0.24 (0.05), VC 0.25 (0.06), p = 0.354 |
| **Results** | |
| **Parent-newborn attachment** | *Instrument: German version of the Parental Bonding Questionnaire (PBQ), filled in by the mother at infant's 6 month CA*<br>We observed a poorer quality of bonding (assessed at 6 months of corrected age) in the control group (OR 1.1, 95% CI 1.0 – 1.3, p = 0.031). |
| **Parent-newborn interaction** | *Instrument: Mannheim Rating System, videotaped at 6 months' of corrected age and coded by two trained raters blind to randomisation*<br>The overall rate of intervals positive for maternal and infant responsive behaviour (including all types of responses: vocal, motoric and mimic) was significantly higher in DR-SSC mother-infant dyads compared with VC dyads (86 [±26] vs 71 [±32], P = .041, OR 0.982, CI [0.7-1]). In detail, mothers of DR-SSC infants showed a higher rate of motoric responsive behaviour and DR-SSC infants showed responsive behaviour (motoric and vocal) more frequently after maternal stimulation. |
| **Depression** | *Instrument: German long form of the Center for Epidemiological Studies Depression Scale (CES-D), filled in by the mother at the 3rd day of life, at the infant's discharge from the hospital and at infant's 6 month CA*<br>A significant higher rate of maternal depressive symptoms on the 3rd day of life: DR-SSC 15%, VC 45%, p = 0.003 (OR 0.2, 95% CI 0.1 – 0.6)<br>No significant difference in depressive symptoms at discharge: DR-SSC 30%, VC 31%, p = 1 (OR 1, 95% 0.4 – 2.5)<br>No significant difference in depressive symptoms at six month's corrected age: DR-SSC 6%, VC 12% , p = 0.672 (OR 0.5, 95% CI 0.1 – 2.8) |
| **Stress** | *Instrument: German version of the Parenting Stress Index (PSI), filled in by the mother at infant's 6 month CA*<br>No difference was found between groups regarding stress.<br>Parental Stress Index mean intervention group (SD): 49 (30-70) vs. mean (SD) control group: 51 (30-70), p = 0.559, OR 1.0 (95% CI 1.0 – 1.1) |
| **Breastfeeding** | *Measured by exclusive breast milk at discharge*<br>86% in the intervention group and 69% in the control group (p = 0.072, OR 2.8 (95% CI 0.9 – 8.2)) |
| **Limitations and conclusion** | |
| **Limitations** | Our results barely reached statistical significance. This may be due to higher drop-out rates for MCI assessment than initially expected in an per se small sample size.<br>Our study has several limitations: Although DR-SSC improved quality of MCI, we did not evaluate neurocognitive outcomes or psychological aspects. Both investigations are planned when infants are 6 years old. Our study was limited to primapara because attachment quality is significantly influenced by the factor 'first child' as reported in preceding study of our group. Moreover, we did not assess MCI in full-term controls. Although MCI interaction |

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|---|---|
| | was assessed by a blinded rater, blinding was not possible due to the nature of the intervention and may affect the results of the self-reporting questionnaires. Of note, mothers may have prepared themselves for the videotaping and tried to perform their best – but this would equally affect intervention and control group dyads. |
| **Authors' conclusion** | DR-SSC in preterm infants >25 (to 32 + 0) weeks of GA improves quality of MCI at 6 months of CA and reduces the risk of early postpartum maternal depression and impaired bonding without increasing short-term complications of prematurity. Consequently, DR-SSC may have an impact on maternal sensitivity and maternal mental well-being. These factors are associated with improved development in premature infants. |

| **Sahlen Hemler et al. (2020)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | Continuous SSC: beginning in the delivery room and continuing for almost 24 hours a day until discharge |
| **Country** | Sweden | **Exposure control group** | Intermittent SSC: parents had the opportunity to practice as much SCC as they liked, that is, standard care at the included neonatal intensive care units |
| **Setting** | The hospitals were 1 level III NICU at Linköping University Hospital and 1 level II NICU at Sachs' Children's Hospital in Stockholm. | **Level of prematurity** | 32 0/7 - 35 6/7 weeks gestational age |
| **Sample size** | Families with 42 preterm infants agreed to participate in the study. Of these families, 23 families were randomised to continuous SSC and 19 families were randomised to intermittent SSC. Because of randomisation before birth of the infant, 5 families were excluded after birth. A total of 6 families withdrew from the study, resulting in 17 families receiving continuous SSC and 14 families receiving intermittent SSC. | | |
| **Time frame** | April 2008 - April 2012 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Mothers*<br>Inclusion criteria were Swedish-speaking healthy women about to give birth vaginally to a single preterm infant between gestational age weeks 23 0/7 to 35 6/7. | | |
| **Exclusion criteria** | *See eligibility criteria* | | |

**Newborn and parent characteristics**

There were no significant differences in descriptive data between the two groups.

TABLE 1. Demographic Data of Participating Infants and Mothers

| | Continuous SSC (N = 17) | Intermittent SSC (N = 14) |
|---|---|---|
| Gender, boys/girls | 11/6 | 6/8 |
| PMA at birth, mean (SD)/week | 243 (5.8)/34 | 243 (4.8)/34 |
| PMA at discharge, mean (SD)/week | 263 (7.6)/37 | 261 (4.9)/36 |
| Birth weight, mean, g, (SD) | 2480 (289) | 2519 (246) |
| Weight at discharge, g, mean (SD) | 2809 (345) | 2794 (238) |
| Weight at 4 mo, g, mean (SD) | 6930 (654) | 6760 (874) |
| Siblings, yes/no/missing data | 4/12/1 | 4/9/1 |
| Mother's age, y, mean (SD) | 31 (3.4) | 32 (5.8) |
| Cohabitant/single/missing data | 17/0/0 | 12/1/1 |
| Mother's education, high school/university/ missing data | 2/15/0 | 3/10/1 |
| Breastfeeding, yes/no/missing data | 13/4/0 | 7/6/1 |
| Edinburgh Postnatal Depression Scale score, mean (SD)/missing data | 4.2 (3.3)/1 | 3.9 (3.7)/0 |

*Abbreviations: PMA, postmenstrual age; SSC, skin-to-skin care.*

## Results

**Parent-newborn interaction**

*Instrument:*

1. *Ainsworth's Maternal Sensitivity Scales*

Ainsworth's Maternal Sensitivity Scales, developed from the attachment theory, consist of 4 scales. The first scale measures the mother's sensitivity toward her infant and ranges from 1 (a mother who is highly insensitive to the infant) to 9 (a mother who is highly sensitive). The second scale measures interference versus cooperation toward the infant, with the endpoints 1 (a highly interfering mother) to 9 (a mother that is guiding her infant rather than controlling). The third scale measures availability and ranges from 1 (a highly neglecting mother) to 9 (a highly accessible mother). Finally, the fourth scale measures acceptance versus rejection toward the infant's needs with endpoints 1 (a mother who is clearly rejecting) and 9 (a highly accepting mother). One review of different observational measures of interaction describes the scales as theoretically well-grounded, another how the scales are still well used and continue to influence the development of other tools. The scales have been successfully tested for validity and reliability. Ainsworth's Maternal Sensitivity Scales are commonly used for infants 3 to 24 months of age.

2. *Maternal Sensitivity Scales (MSRS-R)*

The MSRS-R consist of 3 scales. The scales have a 5-point rating, and the interaction is coded during phase 1 and phase 3 of the Still-Face Paradigm. The first scale measures the mother's sensitivity, whether she manages to detect the infant's communication signals, and how she interprets and responds to the infant, from 1 (a mother with an ignoring behaviour) to 5 (a very responsive mother). The second scale measures withdrawal on a reversed scale from 1 (a mother who is engaged in her infant throughout the interaction) to 5 (a consistently under involved mother). The third scale measures intrusiveness on a reversed scale from 1 (mother is aware of the infant's activities but does not intrude) to 5 (a strongly over-controlling

mother). The MSRS-R were used as they were designed to measure interaction during the Still-Face Paradigm, although there is limited information about the validity of these scales.

Interaction scores did not differ significantly between the continuous SSC group and the intermittent SSC group.

TABLE 3. Ainsworth's Maternal Sensitivity Scale and the MSRS-R, for Continuous and Intermittent SSC, Respectively[a]

| | Continuous SSC (N = 17), Median (q1-q3) | Intermittent SSC (N = 14), Median (q1-q3) | *P* |
|---|---|---|---|
| Ainsworth Maternal Sensitivity Scale | | | |
| Sensitivity | 5.0 (3.0-8.0) | 5.5 (3.0-7.0) | .98 |
| Interference | 6.0 (2.5-7.5) | 5.0 (2.75-6.25) | .68 |
| Availability | 6.0 (3.0-8.5) | 6.0 (3.0-9.0) | .83 |
| Acceptance | 6.0 (4.0-8.5) | 7.0 (5.0-7.0) | .68 |
| MSRS-R | | | |
| Sensitivity | 3.0 (2.0-4.0) | 3.5 (3.0-4.0) | .76 |
| Withdrawal[b] | 1.0 (1.0-2.0) | 1.5 (1.0-2.0) | .42 |
| Intrusivity[b] | 3.0 (2.0-4.0) | 3.0 (2.0-4.0) | >.99 |

*Abbreviations: MSRS-R, Maternal Sensitivity and Responsivity Scales; SSC, skin-to-skin care.*
*[a]Ainsworth's Maternal Sensitivity Scale ranging from 1.0 to 9.0. MSRS-R ranging from 1.0 to 5.0.*
*[b]The MSRS-R Withdrawal and Intrusivity scales are reversed.*

| | |
|---|---|
| **Depression** | *Instrument: Edinburgh Postnatal Depression Scale*<br>Mean score (SD) continuous SSC: 4.2 (3.3) vs. intermittent SSC: 3.9 (3.7). No statistical difference, however, p-value not available. |
| **Limitations and conclusion** | |
| **Limitations** | The MSRS-R were used, although the validity of the scales is insufficiently documented. However, since the MSRS-R showed the same results as Ainsworth's Maternal Sensitivity Scales, the criterion validity of the MSRS-R is strengthened by this study. For safety reasons, the families were recommended not to use SSC at home; however, we have no data on the use of SSC after discharge from hospital, which potentially can have affected the results.<br>Another limitation is the sample size, which was based on cortisol reactivity. The sample size is small, but comparable with other studies that measure sensitivity, and the results are supported by the high P values. |
| **Authors' conclusion** | Continuous SSC was not superior to intermittent SSC concerning interaction between moderate to late preterm infants and their mothers, although the intermittent group had SSC comparable with intervention groups in other studies. No dose–response effect was found between time in SSC and interaction. Further studies are needed to find out how interaction between parents and preterm infants can be improved, supported, and facilitated in the NICU and whether there is an optimal dose for SSC. |

**Kangaroo care**

| Roberts et al. (2000) | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | Kangaroo mother care: skin-to-skin contact with the mother (KMC group) |
| **Country** | Australia | **Exposure control group** | Conventional cuddling care, through clothing (CCC group) |
| **Setting** | Neonatal intensive care nursery at the Royal Darwin Hospital and the nursery at the Darwin Private Hospital | **Level of prematurity** | > 30 weeks gestational age |
| **Sample size** | Intervention group (KMC group): 16<br>Control group (CCC group): 14 | | |
| **Time frame** | NA | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Newborns*<br>To be enrolled in the study, infants had to meet criteria similar to those of Ludington-Hoe and colleagues. They had to have been born at 30 or more weeks gestation or corrected age, with a five-minute Apgar of 5. They had to be medically stable, with clearance from the unit specialist, and to have no congenital abnormalities or central nervous system impairment. Infants had to have had a stable temperature for 24 hours, to have been extubated for more than 48 hours, and to have ceased crib or head box oxygen for at least 24 hours. Nasogastric or oral feedings were to be every 1 to 4 hours. Infants could have nasal continuous positive airway pressure in place or a nasal cannula delivering oxygen at less than 2 litters/minute. At the time of entry into the study, infants had to be being cared for in an open crib or an incubator; could have an intravenous infusion in progress; and may have been on a course of antibiotics, theophylline, dexamethasone, or other drugs that did not maintain systemic function (that is, no inotropes). They could not have had phototherapy within the previous 24 hours. Any episodes of apnoea or bradycardia would have had to require mild stimulation only, and infants who had been resuscitated were excluded.<br>*Parents*<br>Parents had to have a good understanding of the English language, be resident in the Darwin area, and be prepared to spend a minimum of two hours a day for five days a week over a maximum of four weeks. Mothers who had a history of drug use were excluded from the study. | | |
| **Exclusion criteria** | *See inclusion criteria* | | |
| **Newborn and parent characteristics** | KMC and CCC groups were not significantly different for mother's age, parity, gravidity, gestational age, type of delivery, Apgar ratings, gender of baby, baby's birth weight, weight at the beginning of the study, or time in KMC/CCC. Thus, the groups were considered to be initially equivalent. | | |
| **Results** | | | |
| **LOS newborn** | Concerning hospital stay, the KMC group spent an average of 48 ± 28 days in the hospital; the CCC group spent an average of 46 ± 19 days. | | |
| **Stress** | *Instrument: Parent Stressor Scale-NICU (PSS-NICU), filled in by the parents* | | |

| | |
|---|---|
| | The Parent Stress Scale-NICU scores were not significantly different in the KMC and CCC groups. The mothers in the sample expressed moderate to very stressful responses in all four subscales: nursery environment, infant appearance, relationship with the infant, and staff behaviour and communication. |
| **Breastfeeding** | For the duration of breastfeeding, 10 KMC and 11 CCC babies were breastfeeding at discharge, with 9 KMC and 6 CCC babies breastfeeding at six weeks, 7 KMC and 5 CCC babies breastfeeding at three months, and 4 from each group breastfeeding at six months. |
| **Limitations and conclusion** | |
| **Limitations** | The results of this study should also be interpreted with caution because of the small sample size. Later in the study, some mothers were requesting to do KMC and refused to enter the study because they did not want to take a chance of being in the CCC group, although one refused because she found the idea of KMC unappealing. In addition, some staff who were aware of the postulated benefits of KMC initiated it with the parents before the researchers were able to discuss the study with them, thus rendering them ineligible to participate. |
| **Authors' conclusion** | Both interventions appear to be equivalent in terms of their effect on infant weight gain and hospital stay, duration of breastfeeding, parental stress, and expectations. |

| **Feldman et al. (2002)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | Kangaroo care |
| **Country** | Israel | **Exposure control group** | Control: no kangaroo care |
| **Setting** | 2 neonatal nurseries (level III) in 2 hospitals<br>Intervention hospital: Schneider Children's Hospital (Tel Aviv)<br>Control hospital: Shaare-Zedek Medical Center (Jerusalem) | **Level of prematurity** | NA (mean gestational age was 30.65 weeks) |
| **Sample size** | Intervention group: 73<br>Control group: 73 | | |
| **Time frame** | NA | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *See exclusion criteria* | | |
| **Exclusion criteria** | *Newborns*<br>Exclusion criteria were intraventricular haemorrhage grade 3 or 4, perinatal asphyxia, or metabolic genetic disease. | | |

**Newborn and parent characteristics**

**TABLE 1.** Family Demographic and Infant Medical Variables

| | KC ($N$ = 73) | | Control ($N$ = 73) | |
|---|---|---|---|---|
| | Mean | SD | Mean | SD |
| Birth weight (g) | 1245.85 | 328.21 | 1289.87 | 358.08 |
| GA (wk) | 30.38 | 2.50 | 30.82 | 2.98 |
| CRIB (medical risk score) | 2.29 | 2.98 | 2.25 | 2.96 |
| Mother age (y) | 29.63 | 4.72 | 29.07 | 6.14 |
| Mother education (y) | 14.70 | 1.94 | 14.11 | 2.32 |
| Father age (y) | 32.29 | 5.89 | 32.46 | 7.75 |
| Father education (y) | 14.47 | 2.27 | 14.55 | 3.78 |
| M/F ratio | 37/36 | | 38/35 | |
| Primiparous/multiparous | 36/37 | | 36/37 | |
| Maternal milk (full, >50%, none) | 27.5%, 27.5%, 45% | | 26%, 31.5%, 42.5% | |
| Cesarean section (yes/no) | 48/25 | | 46/27 | |
| Apgar 1 | 7.21 | 1.90 | 7.56 | 1.30 |
| Apgar 2 | 8.67 | 1.03 | 8.50 | 1.14 |
| Social support network | 30.08 | 9.35 | 29.43 | 11.19 |

## Results

**Parent-newborn interaction**

*Instrument: videotaped before discharge and at 6 months' corrected age, coded by 2 coders (blinded for randomisation) according to the Mother-Newborn Coding System (discharge) and Coding Interactive Behaviour (6 months' corrected age)*

**At discharge**

MANOVA conducted for the mother–infant interaction variables showed an overall effect for KC intervention (Wilks' F [df = 6, 137] = 12.47; P < .001), ie, more positive interactions in the KC group. An overall effect was also found for medical risk (Wilks' F [df = 6, 137] = 2.53; P < .05), ie, less optimal interactions between mothers and high-risk infants. Univariate tests, as tabulated in Table 3, indicated that after KC, mothers looked more at their infants, touched the infant more frequently, showed more positive affect, and were more adaptive to the infant's signals. Infants who received KC had more alert-scanning episodes and showed less gaze aversion during mother–infant interactions. Univariate tests for medical risk showed that infants at lower risk were more alert (F [df = 1, 137] = 2.92; P < .01), and mothers of lower-risk infants displayed more positive affect (F [df = 6, 137] = 4.14; P < .01) and looked more at the child (F [df = 1, 137] = 3.05; P < .01) as compared with premature infants born at high risk.

**Six months' corrected age**

A MANOVA conducted for the 2 mother–infant interaction factors—maternal sensitivity and child social involvement—revealed an overall effect for the KC intervention (Wilks' F [df = 2, 128] = 4.21; P < .05), suggesting that mother–infant interactions were more optimal in the KC group. The medical risk status of the infant did not effect these interaction scores. Univariate tests (Table 4) indicated that maternal sensitivity was higher at 6 months among mothers who provided KC in the neonatal period

## Limitations and conclusion

**Limitations**

The limitations of the study relate primarily to the fact that this was not a prospective randomized study of KC and control infants. As noted, KC is not an experimental technique in Israel but is considered to be a standard care option, and thus randomization was precluded by the institutional research

| | |
|---|---|
| | boards. That different hospitals introduced the KC methods at different points in time provided an opportunity to compare from 2 hospitals matched mother–infant dyads who were being treated by otherwise similar clinical protocols. Thus, the selection bias that would have ensued from comparing infants from mothers who chose KC as opposed to those who refused to provide kangaroo contact was avoided. Future research is clearly needed to examine whether the gains secondary to KC noted in the first half-year persist into later infancy and childhood. We also need to know whether the provision of KC by people other than the mother, such as fathers, grandparents, personnel, or volunteers, has similar effects on the development of premature infants. Finally, comparison of outcomes with other intervention methods, such as massage therapy, minimal handling, or enriched environments, is required to determine which method or combination thereof best fits a specific patient population to provide the most optimal intervention for the high-risk premature infant and his or her parents. |
| **Authors' conclusion** | KC had a significant positive impact on the infant's perceptual-cognitive and motor development and on the parenting process. We speculate that KC has both a direct impact on infant development by contributing to neurophysiological organization and an indirect effect by improving parental mood, perceptions, and interactive behaviour. |

| **Feldman et al. (2003)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | Kangaroo care |
| **Country** | Israel | **Exposure control group** | Control: no kangaroo care |
| **Setting** | 2 neonatal nurseries (level III) in 2 hospitals<br>Intervention hospital: Schneider Children's Hospital (Tel Aviv)<br>Control hospital: Shaare-Zedek Medical Center (Jerusalem) | **Level of prematurity** | NA (mean gestational age was 30.65 weeks) |
| **Sample size** | Intervention group: 73<br>Control group: 73 | | |
| **Time frame** | NA | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | Mother–infant dyads were enrolled in the study if the following three conditions were met: (a) mothers agreed to perform KC for at least 14 consecutive days; (b) on these days, mothers agreed to perform KC for at least 1 hr daily; and (c) infants were not expected to transfer from enclosed incubators to open incubators during that 2-week period. | | |
| **Exclusion criteria** | *Newborns*<br>Infants were excluded from the study if they had intraventricular hemorrhage (IVH) Grades III or IV or suffered from perinatal asphyxia or metabolic or genetic disease. | | |
| **Newborn and parent characteristics** | The sample included 146 premature infants whose mean birth weight was 1,270 g (2.79 lb.), with SD = 343.49 (0.75 lb.) and range = 530–1,720 g (1.16–3.79 lb.), and whose mean gestational age was 30.65 weeks (SD = 2.76, range = 24–34 weeks). In the two groups, each mother was married to the infant's father, mothers were at least 20 years old, parents had completed high school, and families' socioeconomic status was considered middle class by Israeli standards. | | |

| Results | |
|---|---|
| **Parent-newborn interaction** | *Instrument: videotaped before discharge, 3 and 6 months' corrected age and coded by 2 coders (blinded for randomisation) according to the Coding Interactive Behavior Manual (CIB)*<br>A multivariate analysis of variance (MANOVA) with group (KC vs. control) and birth order as the between subjects factors was computed for the six global interaction composites during mother–infant interaction. A significant overall effect was found for group; Wilks's $F(6, 125) = 8.21$, $p < .01$. Univariate tests (Table 2) show that following KC, mothers were more sensitive and less intrusive during interaction, the level of dyadic reciprocity was higher, and infants showed less negative emotionality during social play.<br>A significant overall effect was also found for birth order, Wilks's $F(6, 125) = 2.58$, $p < .05$. Univariate tests revealed differences in infant initiation, $F(1, 125) = 6.13$, $p < .05$, and in infant positive affect, $F(1, 125) = 14.27$, $p < .01$. Firstborn infants showed a lower level of initiation ($M = 1.86$, $SD = 0.64$) as compared with later born infants ($M = 2.13$, $SD = 0.74$), and firstborn infants exhibited less positive affect ($M = 3.55$, $SD = 0.73$) as compared with later-born infants ($M = 3.83$, $SD = 0.66$) during play.<br>Finally, a significant overall interaction effect was found, Wilks's $F(6, 125) = 3.64$, $p < .01$. Univariate analysis revealed a significant interaction effect for infant positive affect, $F(1, 125) = 12.23$, $p < .01$, and for dyadic reciprocity, $F(1, 125) = 16.19$, $p < .01$. Post hoc comparisons showed that for the controls, reciprocity was lower between mothers and firstborn infants (for firstborns, $M = 2.85$, $SD = 1.20$; for later borns, $M = 3.42$, $SD = 1.02$), $F(1, 62) = 3.99$, $p < .05$, but no differences were found for the KC group (for firstborns, $M = 3.89$, $SD = 0.86$; for later borns, $M = 3.54$, $SD = 0.87$). Similarly, later born controls exhibited significantly more positive affect than firstborns (for firstborns, $M = 3.23$, $SD = 0.88$; for later borns, $M = 3.96$, $SD = 0.61$), $F(1, 62) = 14.69$, $p < .01$, but no differences were found in the KC group (for firstborns, $M = 3.77$, $SD = 0.57$; for later borns, $M = 3.64$, $SD = 0.96$). To examine whether the effects of KC on maternal behavior are explained by the reduction in infants' negative emotionality, we computed a multivariate analysis of covariance (MANCOVA) with maternal sensitivity and intrusiveness as the dependent variables, KC as the between subjects variable, and infant negative emotionality as the covariate. An overall effect was found for group, Wilks's $F(2, 129) = 14.07$, $p < .01$, with univariate effects for both sensitivity and intrusiveness. These data indicate that the effect of KC on mothering is independent of its effect on infant state.<br><br>For gaze, during triadic interactions, infants tended to look more at mothers than at fathers, $t(1, 119) = 2.70$, $p < .01$. No difference was found between mothers' and fathers' gaze at the infant or between mothers' and fathers' gaze at the spouse. For affect, during triadic interactions, mothers maintained more neutral affect than fathers, $t(1, 119) = 2.36$, $p < .05$, and fathers showed higher levels of positive affect, $t(1, 119) = 1.96$, $p < .05$. For proximity, no differences were found between mothers' and fathers' spatial position in relation to their infants (infant in arms, within arms' reach, or far). For touch, no differences were found between mothers and fathers in their overall amount of touching of the infant or in any specific type of touch. With regard to spousal touch, mothers exhibited more episodes of functional touch toward fathers than vice versa, $t(1, 119) = 1.99$, $p < .05$, and fathers evidenced more "no touch" of their wives than vice versa, $t(1, 119) = 1.87$, $p < .05$. No differences were found between the infant's touch of mother versus father. |
| **Parenting stress** | *Instrument: Parenting Stress Index (short form, PSI-SF), completed before discharge and at 3 and 6 months' corrected age* |

Table 4
*Predicting Family Cohesiveness*

| Predictors | $\beta$ | Multiple $R$ | $R^2_{change}$ | $F_{change}$ | $df$ |
|---|---|---|---|---|---|
| Step 1 | | | | | |
| Medical risk | −.03 | | | | |
| Birth order | .23* | | | | |
| Kangaroo care | .18* | .38 | .15 | 2.87* | 3, 115 |
| Step 2 | | | | | |
| Mother loving touch | .18* | | | | |
| Father loving touch | .17* | | | | |
| Spousal loving touch | .21* | .53 | .14 | 3.88** | 6, 112 |
| Step 3 | | | | | |
| Infant proximity "free" | .09 | | | | |
| Infant unfocused gaze | −.07 | .59 | .03 | 1.56 | 8, 110 |
| Step 4 | | | | | |
| Mother sensitivity | .24* | | | | |
| Father sensitivity | .16 | .63 | .09 | 4.99** | 10, 108 |
| Step 5 | | | | | |
| Maternal parenting stress | −.08 | | | | |
| Paternal parenting stress | .00 | .64 | .00 | 0.44 | 12, 106 |

Table 5
*Predicting Family Intrusiveness*

| Predictors | $\beta$ | Multiple $R$ | $R^2_{change}$ | $F_{change}$ | $df$ |
|---|---|---|---|---|---|
| Step 1 | | | | | |
| Medical risk | −.08 | | | | |
| Birth order | .07 | | | | |
| Kangaroo care | −.19* | .36 | .13 | 3.60* | 3, 115 |
| Step 2 | | | | | |
| Mother loving touch | −.32* | | | | |
| Father loving touch | −.25* | | | | |
| Spousal loving touch | −.06 | .43 | .05 | 1.95† | 6, 112 |
| Step 3 | | | | | |
| Infant proximity "free" | −.08 | | | | |
| Infant unfocused gaze | .27 | .49 | .06 | 2.76* | 8, 110 |
| Step 4 | | | | | |
| Mother intrusiveness | .03 | | | | |
| Father intrusiveness | .29* | .55 | .09 | 2.87* | 10, 108 |
| Step 5 | | | | | |
| Maternal parenting stress | −.08 | | | | |
| Paternal parenting stress | .00 | .55 | .00 | 0.15 | 12, 106 |

| | |
|---|---|
| **Limitations** | Finally, the limitations of this study primarily relate to the fact that this was not a prospective randomized study of control infants and those who received kangaroo contact. As noted, KC is not an experimental technique but is considered to be a standard care option, and thus randomization was precluded for ethical reasons. The fact that the hospitals introduced the KC methods at different periods provided an opportunity to compare control-matched mother–infant dyads from two hospitals who were being treated concurrently by otherwise similar clinical protocols, thus resolving the issue of bias of historical controls. Similarly, selection bias that would have ensued from comparing infants from mothers who received KC as opposed to those who refused to provide such care was minimized. The final analyses, which showed differences between KC and controls from the same hospital for most findings, further suggest that the effects of KC are probably independent of the hospital site. |
| **Authors' conclusion** | This study's goal was to identify aspects of parent–infant and family relatedness that may be improved following the provision of mother–infant kangaroo contact in premature infants. In addition, the study used the KC intervention to assess how change in one relationship impacts the other components of the family system. Results suggest that following kangaroo contact early in life, later interactions between mothers and infants as well as between fathers and infants were characterized by higher sensitivity, lower intrusiveness, higher parent–infant reciprocity, and lower infant negative emotionality. Similarly, the family's later relational style was more cohesive and less intrusive. The study also showed links between individual, dyadic, and triadic family systems following intervention in infancy. |

| **Coşkun et al. (2020)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Open-label, multicentre, randomised controlled trial | **Exposure intervention group** | Kangaroo mother care: training + Kangaroo care was applied for 15–20 min once a day for five days a week over three weeks |
| **Country** | Turkey | **Exposure control group** | Mothers in the standard care group saw their infants for 15–20 min once a day for five days a week over three weeks. This was the routine practice of the NICU. |
| **Setting** | Fırat University and the Elazığ Education and Research Hospital Neonatal Intensive Care Units (NICU) | **Level of prematurity** | 27–36 weeks of gestational age |
| **Sample size** | Intervention group: 42<br>Control group: 38 | | |
| **Time frame** | December 2017 – October 2018 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Newborns*<br>The inclusion criteria were birth weight ≥ 1000 g, gestational age 27–36 weeks and postnatal age ≤ 28 days, infants who were feeding with a nasogastric tube, orogastric tube or bottle and who were not breastfed by their mothers. The mothers of infants who had these characteristics were included in the study. | | |

| | |
|---|---|
| **Exclusion criteria** | *Newborns*<br>The exclusion criteria for the infants were congenital anomaly, < 27 weeks gestational age, > 36 weeks gestational age, tachycardia (heart beat > 180), bradycardia (heart beat > 80), hyperthermia (body temperature > 38°), apnoea (respiratory rate < 20) and 85% and lower oxygen saturation.<br>*Parents*<br>Mothers who could not visit their infants regularly and mothers with serious health problems were excluded. |
| **Newborn and parent characteristics** | The mothers and the infants in the kangaroo care and the standard care group were found to have similar descriptive characteristics (p > 0.05). |

**Table 1**
Demographic characteristics of the participants.

| Demographic characteristics | Kangaroo care group (n = 42) | | Standard care group (n = 38) | | $X^2$ | p |
|---|---|---|---|---|---|---|
| | Number | % | Number | % | | |
| Mother's age | | | | | | |
| 20–24 years | 5 | 11.9 | 9 | 23.7 | 8.664 | 0.70 |
| 25–29 years | 13 | 31.0 | 8 | 21.1 | | |
| 30–34 years | 7 | 16.7 | 14 | 36.8 | | |
| 35 years and↑ | 17 | 40.4 | 7 | 18.4 | | |
| Mother's level of education | | | | | | |
| Literate | 4 | 9.5 | 2 | 5.3 | 0.797 | 0.850 |
| Primary | 19 | 45.2 | 20 | 52.6 | | |
| High school | 9 | 21.4 | 7 | 18.4 | | |
| University | 10 | 23.9 | 9 | 23.7 | | |
| Number of mother's alive children | | | | | | |
| 1–4 | 36 | 85.7 | 31 | 81.6 | 0.251 | 0.616 |
| 5–8 | 6 | 14.3 | 7 | 18.4 | | |
| Premature infant's gender | | | | | | |
| Male | 27 | 64.3 | 20 | 52.6 | 1.118 | 0.290 |
| Female | 15 | 35.7 | 18 | 47.4 | | |
| Premature infant's gestational age (weeks) | | | | | | |
| 29–31 | 15 | 35.7 | 10 | 26.3 | 1.029 | 0.598 |
| 32–34 | 23 | 54.8 | 25 | 65.8 | | |
| 35–37 | 4 | 9.5 | 3 | 7.9 | | |
| Premature infant's birth weight (g) | | | | | | |
| 1100–1300 | 20 | 47.6 | 17 | 44.7 | 6.018 | 0.111 |
| 1300–1500 | 3 | 7.1 | 9 | 23.7 | | |
| 1500–1700 | 7 | 16.7 | 2 | 5.3 | | |
| 1700–1900 | 12 | 28.6 | 10 | 26.3 | | |
| Premature infant's postnatal age (weeks) | | | | | | |
| 31–34 | 20 | 47.6 | 19 | 50 | 0.045 | 0.832 |
| 35–38 | 22 | 52.4 | 19 | 50 | | |
| Premature infant's actual weight (g) | | | | | | |
| 1700–2100 | 19 | 45.2 | 14 | 36.8 | 5.389 | 0.145 |
| 2101–2501 | 12 | 28.6 | 10 | 26.4 | | |
| 2502–2902 | 8 | 19.1 | 14 | 36.8 | | |
| 2903–3303 | 3 | 7.1 | 0. | 0. | | |

## Results

| | |
|---|---|
| **Stress** | *Instrument: Parental Stressor Scale: Neonatal Intensive Care Unit (PSS: NICU)*<br>The mothers who applied kangaroo care had lower PSS: NICU subdimension and total scale average scores than the mothers in the standard care group. In the pretest comparisons of the two groups, the differences between the means of the images and sounds subdimension scores, the infant's appearance and behaviours subdimension scores and the average total score were not significant. The difference between the means of the parental role subdimension score was significant. In the posttest comparisons of the two groups, the difference between the mean of the PSS: NICU total scale and the subdimension scores was significant (Table 3).<br>The intragroup pretest and posttest PSS: NICU total scale and subdimension scores were compared. The differences in the pretest and posttest PSS: NICU total scale and subdimensions scores in the kangaroo care group were significant. The differences in pretest and posttest infant's appearance and behaviours subdimension scores in the standard care group were significant. The differences in the other subdimension scores were not significant (Table 4). |
| **Limitations and conclusion** | |
| **Limitations** | Our study had some limitations. Blinding was not feasible due to the kangaroo care intervention. However, the data collectors measuring the outcomes were blinded to the group assignments. |
| **Authors' conclusion** | The amount of milk produced by the mothers in the kangaroo care group gradually increased from the first to the last measurement, and there were significant differences in all intragroup measurements. It was found that the stress levels of the mothers who applied kangaroo care decreased significantly when compared with the stress levels the mothers of in the standard care group. These results show that kangaroo care is a very important intervention for promoting bonding between mothers and premature infants and increasing production of maternal breast milk for infants. |

## *Appendix 2.3.2. Massage and auditory, tactile, visual, and vestibular (ATVV) intervention*

### Massage

| **Feijó et al. (2006)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | Performing the infant massage |
| **Country** | USA | **Exposure control group** | Observing the infant massage |
| **Setting** | NICU at University Hospital | **Level of prematurity** | < 37 weeks of gestational age |
| **Sample size** | Intervention group: 20<br>Control group: 20 | | |
| **Time frame** | NA | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | born <37 weeks gestation, medically stable, scheduled to be discharged within 24 h | | |

| | |
|---|---|
| **Exclusion criteria** | - |
| **Newborn and parent characteristics** | The participants were 40 mothers and their preterm infants (23 boys and 17 girls) who were scheduled for discharge from a Neonatal Intermediate Care Nursery (NICU) at a University Hospital.<br>On average, the preterm infants had been hospitalised for 54 days (S.D. = 39 days). The two groups did not differ on number of days in the NICU ($p > .10$). The mothers assigned to "performing" infant massage versus "observing" infant massage did not differ on maternal age (29 years versus 29 years old, respectively), ethnicity (Caucasian: 10% versus 15%; Black: 30% versus 25%; Hispanic: 45% versus 50%; Other: 15% versus 10%, respectively), education (13.5 years versus 13.3 years, respectively) or socioeconomic status (3.3 versus 3.4, respectively, on the Hollingshead). The preterm infants assigned to the performing massage versus the observing massage group were comparable on gender (males: 60% versus 55%, respectively) and gestational age at birth (28 weeks versus 30 weeks gestation, respectively).<br>The mothers' and infants' background data were analysed via chi-square and t-tests between groups. No group differences were observed on these variables |
| **Results** | |
| **Anxiety** | *Instrument: State-Anxiety Inventory, completed before and after the massage session*<br>A significant Time by Group interaction effect was noted for the anxiety measure (STAI), $F(1, 38) = 10.36$ $p < .01$, indicating that only the mothers who conducted the preterm infant massage reported decreased anxiety. |
| **Depression** | *Instrument: Profile of Mood States (POMS), completed before and after the massage session*<br>A significant main effect of Time was noted for the depressed mood scale (POMS), $F(1, 38) = 13.51$, $p < .001$, indicating that both groups experienced a decrease in depressed mood. |

Table 1
Means (and standard deviations in parentheses) for the Conducting Massage versus Observing Massage groups on Maternal Mood scales

| Variables | Massage groups | | | |
|---|---|---|---|---|
| | Conducting | | Observing | |
| | Pre | Post | Pre | Post |
| Maternal distress | | | | |
| STAI (anxiety) | $32.9\,(7.3)_a$ | $27.9\,(7.1)_b$ | $34.9\,(7.4)_a$ | $33.7\,(7.2)_a$ |
| POMS (depressed mood) | $2.4\,(3.0)_a$ | $1.0\,(2.1)_b$ | $2.5\,(2.9)_a$ | $.9\,(1.8)_b$ |

*Note:* Different letter subscripts indicate means that differ at $p < .05$.

| | |
|---|---|
| **Limitations and conclusion** | |
| **Limitations** | NA |
| **Authors' conclusion** | In sum, the findings from this study support the use of preterm infant massage as an intervention for reducing depressed mood and anxiety in mothers of preterm infants prior to the infants' hospital discharge. Infant massage has been reported to facilitate growth and development in preterm infants (Field, Hernandez-Reif, & Freedman, 2004). The bidirectional effects of "giving" and "receiving" massage support its use as a safe and cost-effective intervention for mothers and their infants. Future studies may focus on bidirectional massage effects for fathers of preterm infants. |

| Matricardi et al. (2012) | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | In addition to standard support (see below), each couple in the intervention group met the unit's physical therapist 8 times in session (1h) from 31 to 36 weeks post-menstrual age of their infant.<br>Joint observation method and infant massage provided by both parents |
| **Country** | Italy | **Exposure control group** | Standard support: daily information about the health and care of the infant by a paediatrician, daily support to assist care by a nurse, daily kangaroo-care for one and a half hours, weekly parents' group interview with a psychologist and a weekly interview with a physical therapist about developmental care practices |
| **Setting** | NICU at Fatebenefratelli – San Giovanni Calibita Hospital (Rome) | **Level of prematurity** | < 32 weeks of gestational age |
| **Sample size** | Intervention group: 21<br>Control group: 21 | | |
| **Time frame** | February 2010 – September 2011 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Newborns*<br>Infants were recruited according to the following inclusion criteria: gestational age (GA) <32 weeks (range: 25+1/7 to 31+6/7 weeks), no twins, no congenital malformation, inborn, hospital stay expected for more than 3 weeks and parents whose mother-tongue was Italian. | | |
| **Exclusion criteria** | *Parents*<br>Exclusion criteria were as follows: parents under 18 years of age, manifest psychiatric and/or mental disorders, drug addiction and single-parent families. | | |

**Newborn and parent characteristics**

**Table 1** Maternal obstetric history, perinatal infants characteristics, parental behaviours and socio-demographic variables of parents for standard support and intervention group.

| | Standard group (no. of dyads = 21) | | Intervention group (no. of dyads = 21) | |
|---|---|---|---|---|
| **Maternal obstetric history** | **N** | **%** | **N** | **%** |
| Primipara | 12 | 57.1 | 11 | 52.4 |
| No abortions | 13 | 61.9 | 17 | 81.0 |
| *In vitro* fertilization | 4 | 19.0 | 3 | 14.3 |
| **Infants characteristics** | **Mean** | **SD** | **Mean** | **SD** |
| Gestational age (weeks) | 29.10 | 1.87 | 29.35 | 1.99 |
| Birth weight (g) | 1141.24 | 272.41 | 1214.19 | 342.80 |
| Duration of hospitalization (days) | 56.53 | 25.79 | 50.72 | 17.40 |
| SNAPPE II (score) | 17.11 | 14.28 | 23.65 | 12.01 |
| **Parental behaviours** | **N** | **%** | **N** | **%** |
| Breastfeeding rate | 10 | 47.6 | 10 | 47.6 |
| | **Mean** | **SD** | **Mean** | **SD** |
| Weekly mothers visits (days) | 6.90 | 0.65 | 6.50 | 1.12 |
| Weekly fathers visits (days) | 4.60 | 1.67 | 4.30 | 1.70 |
| Number days of kangaroo-care | 22.20 | 4.62 | 19.70 | 6.65 |
| **Parental socio-demographic variables** | **Mean** | **SD** | **Mean** | **SD** |
| Mother's age (years) | 35.14 | 4.16 | 34.95 | 4.57 |
| Mother's years of study (years) | 14.19 | 3.12 | 15.38 | 3.75 |
| Father's age (years) | 38.35 | 5.62 | 37.95 | 6.40 |
| 'Father's years of study (years) | 13.25 | 3.43 | 13.00 | 3.87 |
| Family SES (score) | 61.00 | 12.10 | 62.38 | 19.98 |

SNAPPE II = score for Neonatal Acute Physiology Perinatal Extension II; SES = socio-economic status.

## Results

**Stress**

*Instrument: Parental Stressor Scale: Neonatal Intensive Care Unit (PSI:NICU), completed a week after the infant's admission and at infant's discharge*

Table 2 shows the mean scores, standard deviations and the results of three separate ANOVAs that analysed the three scales of PSS:NICU for mothers and fathers at Time 1 and Time 2, stratified for the standard support and intervention groups. A significant Parent effect was observable for the SS, IBA and PRA scales. Mothers reported higher scores than fathers in their perception of stress associated with SS of the unit (mothers: mean = 2.47, SD = 0.71; fathers: mean = 2.19, SD = 0.70), appearance of the infant (mothers: mean = 2.65, SD = 0.84; fathers: mean = 2.20, SD = 0.72) and PRA (mothers: mean = 3.32, SD = 1.02; fathers: mean = 2.67, SD = 0.95). A significant main effect was seen for the Time of assessment factor for stress related to PRA. Regardless of the group, both mothers and fathers experienced higher role-related stress at the time of their infant's admission (Time 1: mean = 3.19, SD = 1.12) than at the infant's discharge (Time 2: mean = 2.81, SD = 0.92). Significant two-way interactions between

| | |
|---|---|
| | Group and Time of assessment were present for all scales. Paired t-tests, separately for standard support group and intervention group were performed for the three scales. In the standard support group, stress associated with SS increased from the infant's admission to infant's discharge, t (41) = -2.48, p = 0.017. The IBA scores decreased from the infant's admission to infant's discharge in the intervention group t (41) = 2.56, p = 0.014, while the IBA scores increased in the standard support group, t (41) = -2.71, p = 0.010; finally, intervention group parents reported lower role-stress at Time 2 than at Time 1, t (41) = 4.31, p = 0.000 (see Fig. 1). A significant interaction between Parent and Time of assessment emerged for the PRA scale. Paired t-tests, performed separately for mothers and fathers, indicated that the PRA scale scores decreased significantly from Time 1 to Time 2 for mothers, t (41) = 3.57, p = 0.001 (Time 1: mean = 3.67, SD = 0.97; Time 2: mean = 2.98, SD = 0.97), but not for fathers. |
| **Limitations and conclusion** | |
| **Limitations** | One was the relatively small sample size, which might affect the reliability of the results and which could reduce the generalizability of the findings. In addition, the results are based on mean scores of groups, and there was no attempt to control the variation of individual scores of parents between Time 1 and Time 2. Therefore, replication with a larger sample size is recommended and inter-individuals profile of parents should be considered when designing future studies on this topic.<br>Second, the intervention used in the study was based on an approach including joint observation, to increase parental ability to recognize infant behaviours, and infant massage to improve the physical contact between parents and their infant. Consequently, it was not possible to establish which of these two components was more effective in reducing the parental stress levels. This is an important area for further research and has significance for the parental support strategies that are used. Third, other possible sources of stress experienced by the fathers (e.g. the amount of information perceived) have not been inquired about in the study. This did not permit us to examine what other stressors in the NICU could affect paternal stress levels. |
| **Authors' conclusion** | The intervention was effective in reducing the stress-role alteration in mothers ($p < 0.05$), but not in fathers. |

### ATVV intervention

| **White-Traut et al. (2002)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | Received the ATVV intervention (twice daily, 5 days per week until hospital discharge) |
| **Country** | USA | **Exposure control group** | Standard nursing of care (which included a stress reduction program) |
| **Setting** | Rush-Presbyterian-St. Luke's Medical Center in Chicago, Illinois, USA, a large, metropolitan university tertiary care neonatal intensive care unit (NICU) | **Level of prematurity** | 23 – 26 weeks of gestational age |
| **Sample size** | Intervention group: 14<br>Control group: 11 | | |
| **Time frame** | NA | | |

| | |
|---|---|
| **Newborn and parent characteristics** | |
| **Eligibility criteria** | *Newborns*<br>Eligibility criteria were limited to medically stable, very-low birthweight infants born between 23 and 26 weeks' gestation without intracranial pathology and low-birthweight infants born between 23 and 31 weeks' gestation with severe intracranial brain injury (grade III or IV intraventricular hemorrhage [IVH] or periventricular leukomalacia [PVL]). Cranial ultrasounds were reviewed for evidence of acute or cystic PVL or grade III or IV IVH. Infants were eligible if they were receiving oxygen via nasal cannula. |
| **Exclusion criteria** | *Newborns*<br>Infants were excluded from the study if they were medically unstable (i.e. diagnosed with sepsis or necrotizing enterocolitis), had only flare PVL, required ventilatory support, had chronic lung disease, congenital anomalies, or did not tolerate enteric feedings. |
| **Newborn and parent characteristics** | Over the course of the study, 37 medically stable infants were enrolled. Twelve infants born at 23 to 26 weeks' gestation with normal head ultrasounds and 25 infants born at 23 to 31 weeks' gestation with documented CNS injury were included. Groups were equivalent for birthweight, weight at entry, gestational age at birth, age at entry, Apgar scores, and PCS scores. Fourteen infants were diagnosed with PVL, seven were diagnosed with IVH (grades III or IV) and four were diagnosed with both IVH and PVL. Groups were not equivalent for sex. There were no other significant differences between the groups. Table II presents the sample demographics for the infants included in the feeding progression analysis. |
| **Results** | |
| **LOS newborn** | Study group infants were discharged at a mean of 36.54 weeks, or 1.6 weeks earlier than control group infants (38.19 weeks; p=0.0432). Nine of the study group infants were discharged during the third week of the study, while none of the control group infants were discharged until the fourth week. Because so many study group infants were discharged during the third week, subsequent analyses of behavioural state focused on changes in state during the first 2 weeks of the study, before discharge of any of the infants. |
| **Breastfeeding** | *Total 24-hour volume of formula and the amount that was gavaged and/or nippled at each feeding was recorded. The proportion of nipple feeding to total intake was calculated daily for each infant.*<br>Control group infants averaged 16 days to progress from gavage-only to complete nipple feeding while study group infants averaged 12 days. A repeated-measures ANOVA revealed significant differences between groups for the proportion of nippled intake over the first 10 days of ATVV intervention, with the study group infants progressing faster to complete nipple feeding than control group (Fig. 2). Mean proportional increase per day was 0.065 and 0.042 for study group and control group, respectively. The proportion of nippled intake increased significantly faster for the study group ($F(1,24)=17.45$, $p=0.0001$). |
| **Limitations and conclusion** | |
| **Limitations** | Given that the feeding progression/length of stay analysis was a secondary analysis of a study that investigated ATVV intervention on a very select sample of very-low-birthweight and preterm infants with severe CNS injuries, the number of infants in this study was small. The proportions of unaffected infants differed by group (study, eight children; control, four children). However, the number of infants with severe CNS injury was equivalent within both groups. In addition, severe CNS injury was based upon ultrasound diagnosis of detectable lesions and both acute and cystic PVL lesions were grouped together, which may have confounded the results. It is also possible that parenchymal injury existed in ATVV intervention 'non-responders' or in the late maturing control infants, which was beyond the detectable limits of the technology. The high rate of attrition, due to hospital discharge, made statistical differences more difficult to detect. Finally, a significantly greater proportion of females were randomized to the study group. It is not known whether a sex difference in response to touch exists for infants. |
| **Authors' conclusion** | ATVV intervention facilitated increased alertness, faster transition to complete nipple feeding, and decreased length of hospitalization. |

| Holditch-Davis et al. (2013) | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Three-group longitudinal randomised controlled trial | **Exposure intervention group** | Intervention group 1: administered White-Traut's ATVV intervention<br>Intervention group 2: administered kangaroo care |
| **Country** | USA | **Exposure control group** | Attention control group |
| **Setting** | Four hospitals: two in North Carolino (NC-A and NC-B) and two in Illinois (IL-A and IL-B) | **Level of prematurity** | Birth weight less than 1750 g |
| **Sample size** | Intervention group 1: 66<br>Intervention group 2: 68<br>Control group: 73 | | |
| **Time frame** | NA | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Newborns*<br>Mothers of all other infants, including those with postnatal neurological insults or substance exposure without symptoms, were eligible so that the sample included mothers of infants with varied health status and outcomes.<br>Mothers of multiple birth infants were included, and one infant from each set was selected randomly to be the focus of the study | | |
| **Exclusion criteria** | *Newborns*<br>We excluded infants with congenital neurological problems or symptoms of substance exposure.<br>*Parents*<br>We excluded mothers of infants with congenital neurological problems (e.g., congenital hydrocephalus, Down syndrome) or symptoms of substance exposure.<br>Mothers were excluded if they did not have custody of the infant, if their situations would affect mothers' ability to administer or respond to the intervention (age younger than 15; history of HIV, psychosis, or bipolar disease; current diagnosis of major depression; ongoing critical illness; or non-English speaking), or if follow-up for several months was unlikely (out of-state visitors as mothers). | | |
| **Newborn and parent characteristics** | The only difference among the intervention groups was that there were more first-time mothers in the ATVV group. | | |

**Table 1: Comparison of Control, Auditory-Tactile-Visual-Vestibular (ATVV) Intervention, and Kangaroo Care Mothers on Maternal Demographic Characteristics and Infant Illness Variables at Enrollment**

| | Total Sample | | Control | | ATVV | | Kangaroo Care |
|---|---|---|---|---|---|---|---|
| | Mean (*SD*) | *n* | Mean (*SD*) | *n* | Mean (*SD*) | N | Mean (*SD*) |
| Gestational Age (Weeks) | 27.2 (3.0) | 73 | 27.6 (3.2) | 66 | 27.0 (2.7) | 68 | 27.4 (3.0) |
| Birth weight (Grams) | 1025 (373) | 73 | 1031(353) | 66 | 1004 (312) | 68 | 1038 (317) |
| Sex: % Male | 45.7% | 73 | 43.8% | 67 | 46.3% | 68 | 47.1% |
| Size: % SGA | 17.7% | 73 | 18.5% | 65 | 15.4% | 68 | 19.2% |
| Apgar Score: 1 Min. | 5.2 (2.5) | 73 | 5.3 (2.4) | 65 | 5.2 (2.6) | 68 | 5.2 (2.4) |
| 5 Min. | 7.3 (1.6) | 72 | 7.4 (1.4) | 65 | 7.2 (1.7) | 68 | 7.3 (1.6) |
| Neurological Insults[a] | 3.8 (3.7) | 73 | 3.6 (3.6) | 66 | 4.2 (3.8) | 68 | 4.5 (4.2) |
| Mech. Vent. (Days) | 14.2 (17.8) | 73 | 14.3 (18.9) | 67 | 14.6 (18.3) | 68 | 13.7 (16.3) |
| IVH: % None | 65.7% | 73 | 65.7% | 66 | 69.7% | 68 | 61.8% |
| % Grade I | 18.8% | | 17.8% | | 16.7% | | 22.1% |
| % Grade II | 6.8% | | 12.3% | | 3.0% | | 4.4% |
| % Grade III | 1.0% | | 0.0% | | 1.5% | | 1.5% |
| % Grade IV | 7.7% | | 4.1% | | 9.0% | | 10.3% |
| % Having Surgery | 36.4% | 73 | 40.0% | 66 | 30.8% | 68 | 38.5% |
| % Multiple births | 18.8% | 73 | 16.4% | 66 | 21.2% | 68 | 19.1% |
| % PDA | 41.3% | 73 | 42.5% | 67 | 43.3% | 68 | 38.2% |
| % NEC | 15.1% | 72 | 16.7% | 66 | 10.6% | 68 | 17.7% |
| % Cesarean | 57.9% | 73 | 58.0% | 67 | 61.7% | 68 | 53.9% |
| Maternal Age | 27.0 (6.2) | 73 | 26.7 (6.6) | 67 | 26.4 (5.4) | 67 | 28.0 (6.3) |
| Race/Ethnicity: White | 18.3% | 73 | 16.4% | 67 | 19.4% | 68 | 19.1% |
| Black | 72.1% | | 78.1% | | 70.2% | | 67.6% |
| Hispanic | 7.7% | | 5.5% | | 7.5% | | 10.3% |
| Other | 1.9% | | 0.0% | | 3.0% | | 2.9% |
| % Mothers Married | 32.2% | 73 | 27.4% | 67 | 36.0% | 65 | 33.8% |
| % First-Time Mothers* | 54.0% | 69 | 43.5% | 65 | 66.2% | 64 | 53.1% |
| Maternal Ed. (Years) | 13.4 (2.3) | 71 | 13.1 (2.2) | 66 | 13.6 (2.1) | 66 | 13.5 (2.5) |
| % Public Assistance | 20.3% | 73 | 21.9% | 67 | 19.4% | 67 | 19.4% |

*Note.* Gestat. = gestational; SGA = small for gestational age; Min. = minute; Mech. Vent. = mechanical ventilation; IVH = intraventricular hemorrhage; PDA = patent ductus arteriosis; NEC = necrotizing enterocolitis; Ed. = education; Ethn. = Ethnicity.
[a]Scored on Neurobehavioral Risk Scale.
*Groups were compared using chi-squared test for categorical variables and general linear models for continuous variables, $P < .05$.

| Results | |
|---|---|
| **Satisfaction** | *Instrument: questionnaire designed by study team, completed by the mothers at infant's discharge and at 2 and 6 months' corrected age*<br>Mothers completed a 26- item questionnaire designed by the study team to assess how satisfied they were with the intervention and with the helpfulness of the nurses who taught them the intervention. It also asked about the impact of the intervention and study on them.<br>*Items were rated on a 5-point scale with 5 as the highest and assessed three dimensions of satisfaction: efficacy, caring, and technical quality. Two items dealing with activities at home were only included on the 2-month version. The scale has two subscales: satisfaction with the intervention (12 items) and satisfaction with the helpfulness of the study nurse (11 items). Subscale scores and a total score are calculated by the mean of the items.*<br>*Three other global items asked whether them other would recommend the study to others and the degree of change in the mother as a person and as a mother as a result of being in the study. Cronbach's alphas for the intervention satisfaction subscale were .85 at discharge and .89 at 2 months corrected age. Alphas for the nurse helpfulness subscale were .91 at discharge and .92 at 2 months. Convergent validity between the subscale score and the three global items was shown by all bivariate correlations at each age being significant: at discharge correlations varied from .16 (satisfaction with nurse helpfulness with the degree to which the mother changed as a person as a result of being in the study) to .50 (satisfaction with nurse helpfulness with whether the mother would recommend the study to others) and at 2 months, from .19 (satisfaction with nurses helpfulness subscale with the degree to which the mother changed as a person as a result of being in the study) to .52 (satisfaction with nurses helpfulness with whether them other would recommend the study to others).*<br>The mothers in all three groups were satisfied with the intervention (mean scores of 3.3 or higher on a 5-point scale) and the helpfulness of the nurse (mean scores of 4.6 or higher on a 5-point scale). No significant differences occurred between the groups in the subscale or on the three global items: whether the mother would recommend the study to others, the degree to which she changed as a person, and the degree to which she changed as a mother.<br>There were very few differences among the groups and no differences in the nurse helpfulness items. On the intervention satisfaction subscale at discharge, ATVV mothers had significantly higher scores on Item #8 (learn new ways to stimulate and teach my infant) than did the other two groups. Kangaroo care mothers had higher scores on Item #11 (feel I was helping my baby while in the hospital) than did the other two groups. At 2 months, the ATVV and kangaroo care mothers scored significantly higher than the control mothers on Item #3 (feel like a mother in the hospital), and the ATVV mothers still had higher scores on Item #8 (learn new ways to stimulate and teach my infant) than the other two groups. |
| **Limitations and conclusion** | |
| **Limitations** | This study had a few limitations including the use of the same nurses to perform all three interventions, conducting the study in NICUs rather than a more controlled environment, and the large number of analyses conducted on an investigator developed instrument. The same study nurses instructed the mothers in all groups, raising the possibility that the nurses' preference for one intervention might have affected the mothers' responses to the interventions. However, the protocols for each intervention were straight forward and specific. Weekly teleconferences between study nurses and investigators insured that the nurses at all sites followed intervention protocols. The similarity of the three groups of mothers' satisfaction with the interventions and the study nurses strongly suggests that the mothers did not detect any differences in the study nurses' behaviours. Also, by using the same nurses for all intervention groups, we insured that the interventions were not confounded with any differences among the nurses.<br>Another potential limitation was that the interventions were performed in an NICU environment, where other distractions or health care provider perceptions of the interventions might have affected the mother or the mothers' feelings about their intervention. Conducting the study in a controlled environment such as a laboratory was not feasible since the infants were by definition patients in an NICU. Also, by conducting our study in an NICU, the ecological validity of the study was insured since the NICU is the environment in which these interventions are used clinically. Thus, the study findings could be more easily translated into practice. |

| | |
|---|---|
| | The final limitation of this study was the large number of statistical tests conducted on an investigator-developed instrument. No standardized instruments to measure maternal satisfaction with administering interventions for their infants exist. The instrument was derived from theory and tapped three dimensions of satisfaction: efficacy, caring, and technical quality. Evidence of the appropriateness of the instrument is found in the excellent internal consistency of the two subscales at both study time points. However, because little was known about maternal satisfaction with administering interventions and nothing was known about the satisfaction instrument's functioning, a number of exploratory analyses were performed including examining individual items on the questionnaire and correlations with a large number of maternal and infant characteristics. Because no correction for multiple statistical tests was made, the possibility of finding a significant difference by chance was increased. Thus, findings of this study need to be replicated. |
| **Authors' conclusion** | Mothers were satisfied with interventions for their infants regardless of the intervention performed. Maternal satisfaction with the intervention was related to recruitment site, maternal demographic characteristics, and maternal psychological distress, especially at 2 months. Thus, nursing interventions that provide mothers with a role to play in the infant's care during hospitalization are particularly likely to be appreciated by mothers. |

| **Holditch-Davis et al. (2014)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Three-group longitudinal randomised controlled trial | **Exposure intervention group** | Intervention group 1: administered White-Traut's ATVV intervention<br>Intervention group 2: administered kangaroo care |
| **Country** | USA | **Exposure control group** | Attention control group |
| **Setting** | Four hospitals: two in North Carolino (NC-A and NC-B) and two in Illinois (IL-A and IL-B) | **Level of prematurity** | Birth weight less than 1750 g |
| **Sample size** | Intervention group 1: 78<br>Intervention group 2: 78<br>Control group: 81 | | |
| **Time frame** | NA | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Newborns*<br>All other infants, including those with postnatal neurological insults or substance exposure without symptoms, 1were eligible. Multiple birth infants were included, and one infant from each set was randomly selected for the study. | | |
| **Exclusion criteria** | *Newborns*<br>We excluded infants with congenital neurological problems or symptoms of substance exposure. | | |
| **Newborn and parent characteristics** | The sites differed on infant characteristics: gestational age at birth, birthweight, 1 and 5 min Apgar scores, number of neurological insults, length of mechanical ventilation, intraventricular haemorrhage, percent having surgery, percent with necrotizing enterocolitis, number of infections, and per-cent delivered by caesarean section. NC-A was a children's hospital that was a referral centre for surgery; the infants at NC-A were smaller and sicker and | | |

| | |
|---|---|
| | had more medical complications and more surgeries than infants from the other hospitals. Some maternal variables also differed among the sites: mothers from the Illinois sites were more likely to be younger, unmarried, Black or Hispanic, not a first-time mother, less educated, and on public assistance than the North Carolina mothers. |
| **Results** | |
| **Parent-newborn interaction** | *Instrument: videotaped and coded at 2 and 6 months' corrected age*<br>Next, we examined the longitudinal effects of intervention on maternal infant-interactions at 2 and 6 months (see Table 6). Maternal positive involvement, developmental stimulation, and the HOME total score did not differ between the groups. Positive involvement decreased and the HOME total score increased with age. Mothers from the Illinois hospitals exhibited lower scores on positive involvement, developmental stimulation, and the HOME than the North Carolina mothers. First time mothers had more positive involvement, more developmental stimulation, and higher HOME scores. Child irritability did not differ between the groups. Social behaviours and developmental maturity increased with age, and child irritability decreased. For social behaviours, although the overall intervention effect was significant, neither ATVV nor KC differed from the control group. ATVV infants had the lowest amount of social behaviours, KC the highest, and control infants intermediate amounts. The time × intervention interaction for social behaviours was due to KC infants having a slower increase over age than infants in the other groups. Intervention and time × intervention effects for developmental maturity was due to KC infants showing more mature behaviors but a slower increase over age than the infants in the other two groups. Infants of first-time mothers exhibited significantly more developmental maturity than later born infants. Analyses were repeated for the interventions that mothers reported using, and similar findings were obtained except for the HOME. Mothers who performed either a form of massage (including ATVV) or both interventions had higher HOME scores than mothers who engaged in neither (massage only—$t(92) = 2.51$, $p < 0.05$; both—$t(92) = 2.62$, $p < 0.05$). HOME scores were also higher for mothers who only performed KC, but this was not significant ($t(92) = 1.86$, $p = 0.07$). |
| **Stress** | *Instrument: Parental Stress Scale: Prematurely Born Child (PSS:PBC), completed at infant's discharge and at 2 and 6 months' corrected age*<br>General linear models indicated that no maternal psychological distress variable differed among the groups at enrollment. Table 5 shows the longitudinal effects of the interventions on these variables. KC, ATVV, and control mothers did not differ on depressive symptoms, state anxiety, post-traumatic stress symptoms, or parenting stress. Time and time squared effects indicated that depressive symptoms, state anxiety, and post-traumatic stress symptoms decreased over time and the rate of decrease slowed over time. Parenting stress was measured at only three time points so only the linear effect of time was examined and showed a decrease over time. The study sites differed only on post-traumatic stress (mothers from Illinois reported less than North Carolina mothers), and parity did not have any significant effects. These analyses were repeated for mother reported intervention usage, and significant effects of the interventions on maternal distress were found. Mothers who only did a form of massage (that included ATVV) had a more rapid decline in depressive symptoms that leveled out earlier than mothers not in engaging in any intervention (usage × time—$t(453) = 2.49$, $p < 0.05$; usage × time squared—$t(453) = 2.43$, $p < 0.05$); mothers doing KC only or both interventions did not differ from mothers not engaging in any intervention. Parenting stress was lower for mothers who engaged in any intervention than those who did not (a form of massage only—$t(195) = -3.33$, $p < 0.001$; KC only—$t(195) = -2.90$, $p < 0.01$; both—$t(195) = -2.66$, $p < 0.01$). |
| **Anxiety** | *Instrument: State-Trait Anxiety Inventory (STAI), completed at infant's discharge and at 2 and 6 months' corrected age*<br>*See results "Stress"* |
| **Depression** | *Instrument: Center for Epidemiologic Studies Depression Scale (CESD), completed at infant's discharge and at 2 and 6 months' corrected age*<br>*See results "Stress"* |
| **Limitations and conclusion** | |

| | |
|---|---|
| **Limitations** | The sample size may also limit the generalizability of this study. About 21% of the sample left the study before its end. Comparison of dyads withdrawing from the study with those completing it found that younger, single mothers and those with boys were more likely to withdraw. However, psychosocial risk cannot be the major cause of withdrawals because other variables related to psychosocial risk (e.g., race and public assistance) did not differ between withdrawals and completers. Interestingly, no infant health variable differed based on attrition despite the fact that about 20% of attrition was due to infant death. Overall, the mothers leaving the study appeared to do so from reasons that were as heterogeneous as the sample. The variables that most clearly differed between mothers completing and leaving the study were the maternal enrolment distress measures of anxiety and depressive symptoms. Mothers who withdrew from the study averaged higher scores. Thus, maternal distress appeared to be both an outcome of the intervention and for some mothers a factor affecting their ability to engage with the intervention. However, this effect was relatively small, and a number of mothers with high distress did complete the study. Thus, instead of high distress being a risk factor, lower distress scores may have been protective against withdrawal by allowing mothers to be more fully engaged with the project.<br>In addition, some measures had large amount of missing values. For example, only about 60% of mothers completed the visit diary. Infants often experienced medical crises or rapid transfers to other hospitals. As a result, mothers may have been too preoccupied to complete forms, and completed forms were sometimes lost in the chaotic NICU environment. The enrolment characteristics of mothers completing visit diaries and those not completing them had only minimal differences suggesting that the data on intervention usage should generalize to the entire sample. Despite a small sample, the maternal reported usage analyses found several significant differences between the groups that were not found in the primary analyses.<br>In the infant responsiveness in the hospital analyses, the sample of about 65 subjects per group may have lacked power for detecting statistically significant differences. However, this sample size was similar to other studies finding short-term effects of these interventions (Rojas et al., 2003; Vickers, Ohlsson, Lacy, & Horsley, 2004; White-Traut et al., 1999, 2002a,b,c). It is more likely that interventions were less powerful when provided by mothers, rather than professional interveners, because the mothers provided the intervention less frequently than expected, as has been found with mothers of healthy infants during the postpartum hospitalization (Anderson et al., 2003). The interventions are currently being used clinically primarily by family members.<br>Because of a limited sample size, we could not examine all of the factors potentially affecting maternal distress and parenting. For example, several studies have suggested mothers of multiple birth infants have more distress and less positive interactions than mothers of singletons (Holditch-Davis et al., 2007; Spinelli, Poehlmann, & Bolt, 2013). Thus, determining if the interventions had differential effects on mothers of multiples and mothers of singletons would be interesting. Future research needs to be designed so that sub-groups benefitting most from the intervention can be identified.<br>Finally, the results of this study are limited by the evidence of diffusion of the intervention: 20–30% of KC and ATVV mothers and 58% of control mothers engaged in a non-assigned intervention. This diffusion is inevitable in translational research on interventions already in use in practice. The visit diary results showed that very few mothers engaged in a non-assigned intervention frequently, and doing a non-assigned intervention was a greater problem in the attention control group than in the intervention groups. Because intervention diffusion would have made the control group more like one of the intervention groups, our analyses were conservative tests of the effects of the interventions. |
| **Authors' conclusion** | In conclusion, the findings of this study have implications for the care of preterm infants. We found that two frequently used NICU interventions – ATVV and KC – had positive effects on maternal psychological distress and interactions. Although the long-term effects are not as great as previously reported, the positive short-term outcomes support the continued use of these two interventions. Most likely, the small preterm infants in this study need other interventions to continue over the first year of life after ATVV or KC was discontinued. We also found some infant interactive variables (social behaviours, moderate activity, express positive affect, gesture) differed significantly among the groups, but neither the KC or ATVV group differed from the control group because the interventions had opposite effects with one intervention group higher and other lower than the control group. Thus, whether these interventions can be effectively combined is unclear and requires further study. Finally, we found more differences when mothers reported on their activities than in the primary intent-to-treat |

## *Appendix 2.3.3. Newborn Individualized Developmental Care and Assessment Program (NIDCAP)*

| **Westrup et al. (2000)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | NIDCAP |
| **Country** | Sweden | **Exposure control group** | Standard neonatal care |
| **Setting** | Tertiary neonatal intensive care unit of the Karolinska Hospital in Stockholm | **Level of prematurity** | < 32 weeks of gestational age |
| **Sample size** | Intervention group: 12<br>Control group: 13 | | |
| **Time frame** | September 1994 – April 1997 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | Inclusion criteria consisted of: 1) inborn, 2) singleton, 3) post-conceptual age (PCA) of ,32 weeks, 4) absence of severe malformation, 5) need of ventilatory support 24 hours after birth, at least in the form of continuous positive airway pressure (CPAP), 6) family residence in the geographical district of the hospital to ensure full hospital stays at the study hospital, and 7) Swedish language facility attributable to the design of the follow-up. | | |
| **Exclusion criteria** | - | | |
| **Newborn and parent characteristics** | | | |
| **Results** | | | |
| **LOS newborn** | The age of the infant at discharge was 38.3 (36.1–57.7) vs 41.0 (36.9–48.4) weeks of PCA (not significant). | | |
| **Limitations and conclusion** | | | |
| **Limitations** | There were 2 major reasons for terminating the trial before the desired number of subjects were obtained. Because the recruitment took a much longer time than anticipated, we noticed that the risk for a spill-over effect to the control group increased. Nurses involved in NIDCAP care soon became convinced of its beneficial effects and, from time to time, exchanges of personnel between the 2 groups were necessitated by acute staffing problems. Furthermore, the staff of the controls was increasingly expressing feelings of discomfort and disloyalty, not being able to offer developmentally supportive care to their patients. | | |
| **Authors' conclusion** | NIDCAP does not seem to have detrimental effects on Swedish very low birth weight infants in comparison with conventional care. Indeed, NIDCAP might even be advantageous. | | |

| Als et al. (2003) | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Three-centre, randomised controlled trial | **Exposure intervention group** | Received developmental care as defined in NIDCAP |
| **Country** | USA | **Exposure control group** | Routine care: In all three nurseries this included some degree of shielding of incubators, sound containment, use of breast milk, and referral to occupational and physical therapy and to community early intervention. Kangaroo care (skin-to-skin holding) was used at the BWH |
| **Setting** | Newborn intensive care unit (NICU) at Brigham and Women's Hospital (BWH) in Boston, Massachusetts, a 46-bed, level III nursery with an exclusively inborn population and primary care nursing; the NICU at Children's Hospital Oakland (CHO) in California, a 54-bed, level III nursery with a 100% transported population and conventionally scheduled nursing; and the NICU at Children's Hospital Boston (CHB) in Massachusetts, a 16-bed, level III nursery, with a 100% transported population and primary care nursing | **Level of prematurity** | ≤ 28 weeks of gestational age |
| **Sample size** | Intervention group: 45<br>Control group: 47 | | |
| **Time frame** | April 1990 – June 1992 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | The infants met the following criteria: (1) Birth weight less than 1250 g; (2) gestational age at birth less than 28 weeks; (3) mechanical ventilation starting within the first 3 hours after birth and (4) lasting longer than 24 hours in the first 48 hours; (5) alive at 48 hours; (6) absence of chromosomal or other major genetic anomalies and congenital infections; (7) singleton; and (8) at least one family member with some English language facility. | | |
| **Exclusion criteria** | - | | |
| **Newborn and parent characteristics** | There were no significant differences between the control and experimental groups in the infant or parent medical or demographic background measures, nor were significant interaction effects found.<br>In terms of the infants' medical and demographic backgrounds, the Children's Hospital Oakland (CHO) infants differed from both the Children's Hospital Boston (CHB) and Brigham and Women's Hospital (BWH) infants; the latter were similar. The CHO infants received on average higher levels of oxygen in the first 10 days, had lower acuity scores, and had more surfactant therapy. In addition, CHO infants were more likely to be African-American, and their mothers had more children and were younger, more often single, and of lower socioeconomic class. The CHO mothers differed medically from the BWH mothers, but not from the CHB mothers, perhaps because both sites serve transported infants. Compared with the BWH mothers, the CHO mothers had fewer abortions, consumed alcohol and used cocaine more during pregnancy, received fewer antenatal corticosteroids, and had fewer deliveries by Caesarean section; nevertheless they had overall better Obstetric Complication Scale scores. | | |

## Results

**LOS newborn**

*Measured by age at discharge, number of days in the NICU*

Experimental group infants were younger age at discharge home, fewer days in intensive care and in the hospital.

**Table 4. Medical Outcome Variables[a]**

| | BWH | | | | CHO | | | | CHB | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | C (n = 19) | | E (n = 18) | | C (n = 20) | | E (n = 16) | | C (n = 8) | | E (n = 11) | | G | S |
| Variable | Mean | SD | Mean | SD | Mean | SD | Mean | SD | Mean | SD | Mean | SD | (*r*) | (*r*) |
| No. of days on respirator | 34.5 | 21.9 | 28.7 | 16.3 | 43.4 | 17.6 | 46.6 | 17.1 | 50.4 | 27.2 | 40.6 | 26.5 | .14 | −.23* |
| No. of days of oxygen | 74.0 | 61.3 | 80.9 | 67.7 | 113.3 | 110.1 | 74.2 | 32.0 | 107.0 | 99.5 | 102.4 | 98.9 | .16 | −.07 |
| No. of days of parenteral feeding | 20.6 | 14.0 | 16.4 | 6.0 | 41.8 | 14.8 | 33.3 | 14.5 | 27.8 | 22.8 | 19.9 | 13.3 | .46 | −.59** |
| No. of days of parenteral and enteral | 10.0 | 26.1 | 9.7 | 4.4 | 25.8 | 11.4 | 15.9 | 8.8 | 25.1 | 27.2 | 10.7 | 9.8 | .56 | −.40** |
| Average daily weight gain (g) to 42 wk | 19 | 5 | 22 | 5 | 17 | 5 | 21 | 6 | 19 | 5 | 19 | 5 | −.48 | .17 |
| PCA at discharge, wk | 40.5 | 3.1 | 38.3 | 2.4 | 47.6 | 14.0 | 41.6 | 4.4 | 40.3 | 2.4 | 40.1 | 2.5 | .47 | −.37** |
| No. of days in ICU to discharge | 48.7 | 20.1 | 43.1 | 16.0 | 127.5 | 103.9 | 86.6 | 28.5 | 65.3 | 27.2 | 60.0 | 27.9 | .37 | −.53** |
| No. of days in hospital to discharge | 101.3 | 20.5 | 85.9 | 18.7 | 148.3 | 99.5 | 105.4 | 29.6 | 101.3 | 15.7 | 99.7 | 21.0 | .47 | −.34** |
| Weight at 42 wk PCA, g | 3074 | 588 | 3294 | 544 | 2718 | 465 | 3093 | 576 | 3047 | 569 | 2916 | 604 | −.37 | .22* |
| Height at 42 wk PCA, cm | 47.4 | 2.3 | 47.9 | 3.2 | 45.7 | 2.7 | 48.2 | 2.8 | 46.4 | 3.2 | 47.1 | 1.9 | −.48 | .12 |
| Head circumference at 42 wk PCA | 35.8 | 1.3 | 36.1 | 2.0 | 34.2 | 1.8 | 35.4 | 1.9 | 35.3 | 1.8 | 35.3 | 2.2 | −.33 | .29*** |
| Hospital charges ($K) | 181 | 49 | 157 | 59 | 395 | 205 | 314 | 100 | 187 | 70 | 203 | 81 | .34 | −.68** |
| Bronchopulmonary dysplasia, No. none-mild-moderate-severe | 3–3–7–6 | | 3–2–13–0 | | 2–6–7–5 | | 1–4–6–5 | | 1–1–3–3 | | 1–2–3–5 | | .08 | −.009 |
| Intraventricular hemorrhage, No. grade 0-1-2-3-4 | 12–3–3–1–0 | | 15–0–1–2–0 | | 11–7–0–1–1 | | 8–3–1–2–2 | | 3–0–0–3–2 | | 5–1–2–3–0 | | .003 | −.008 |
| Necrotizing enterocolitis, No. absent-present | 17–2 | | 17–1 | | 18–2 | | 16–0 | | 5–3 | | 10–1 | | .20* | −.05 |
| Retinopathy of prematurity, No. stage 0-1-2-3-4-5 | 13–3–1–1–0–1 | | 10–4–4–0–0–0 | | 1–5–10–4–0–0 | | 4–4–5–3–0–0 | | 4–2–0–1–0–1 | | 4–2–2–1–0–2 | | .06 | −.30*** |

Summary analysis: MANOVA: Group: F = 2.02; *df* = 16,71; *p* = .02
Site: F = 7.16; *df* = 32,142; *p* = .00005
Group × site: F = 1.22; *df* = 32,142; *p* = .21
Mahalanobi's $D^2$, F-matrix: BWH vs CHB F = 1.16; *df* = 16,74; *p* = .30
BWH vs CHO F = 15.35; *df* = 16,74; *p* = .001
CHB vs CHO F = 10.43; *df* = 16,74; *p* = .001

ICU, intensive care unit; BWH, Brigham and Women's Hospital; CHO, Children's Hospital Oakland; CHB, Children's Hospital Boston; PCA postconceptional age; C, control; E, experimental; S, site; G, group.
[a]As in Table 1.
*$p \leq .05$; **$p \leq .001$; ***$p \leq .01$.

**Stress**

*Instrument: Parenting Stress Index (PSI)*

The four summary scores from the Parenting Stress Index and the summary score from the Mother's View of the Child (MVC) (K.J. O'Donnell, unpublished data, 1986) were available for 76 families. The results, as hypothesized, showed significantly more favourable scores for the experimental group mothers (Table 6). The experimental group mothers perceived their children as better regulated and more gratifying (Child Domain score) than did the control group mothers. They also perceived their own competence as parents (Parent Domain score) as greater and other life situations as less stressful (Life Stress score). Moreover, the experimental group mothers perceived their children as more autonomous (MVC overall score). There were no significant site differences in any of these measures

**Costs**

Measured by hospital charges from admission to discharge

Experimental group infants had lower total hospital charges *(see table "LOS newborn")*

## Limitations and conclusion

**Limitations**

NA

| | |
|---|---|
| **Authors' conclusion** | The results consistently favoured the experimental groups. The following contributed to the group effects: shorter duration of parenteral feeding, transition to full oral feeding, intensive care, and hospitalization; lower incidence The results consistently favoured the experimental groups. The following contributed to the group effects: shorter duration of parenteral feeding, transition to full oral feeding, intensive care, and hospitalization; lower incidence |

| **Kleberg et al. (2007)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | Received care based on NIDCAP |
| **Country** | Sweden | **Exposure control group** | Conventional neonatal care: care-giving was based on the current routines and was centred on the activity being performed. The children were fed and cared for according to a set schedule. The parents participated in this care-giving. Skin-to-skin contact at a set schedule of twice a day was practiced. The environment in the room was not modified, but a certain "spill-over" of the principles of the NIDCAP programme occurred, e.g., in the form of routine bed support, placing a towel over the incubator or supporting the child during handling. Such activities were neither encouraged nor prevented. |
| **Setting** | Level III Neonatal Intensive Care Unit (NICU) Karolinska Hospital (Stockholm) | **Level of prematurity** | < 32 weeks of gestational age |
| **Sample size** | Intervention group: 10<br>Control group: 10 | | |
| **Time frame** | NA | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Newborns*<br>The infants were inborn, singleton infants with gestational age below 32 weeks, who needed ventilatory support with continuous positive airway pressure (CPAP) or mechanical ventilation during the first 24 h of life.<br>*Parents*<br>The parents also needed to be able to speak Swedish. | | |
| **Exclusion criteria** | *Newborns*<br>Infants with major malformations were not included. | | |

**Newborn and parent characteristics**

**Table 1** Characteristics of the 20 mothers in the two study groups

| | Infant assigned to NIDCAP care ($n$=10) | Infant assigned to conventional care ($n$=10) |
|---|---|---|
| Age (y)[a] | 31.0 (27.4–36.4) | 33.2 (20.5–39.5) |
| Level of education[b] <12/12/13–14/ ≥15 years | 0/5/1/4 | 2/5/1/2 |
| Pregnancy order/parity[a] | 3.5 (2–6)/1 (0–2) | 3 (1–7)/0 (0–3) |
| Hospitalized on one or more occasions prior to delivery? Yes/no | 6/4 | 7/3 |
| Vaginal delivery/ caesarean section | 4/6 | 6/4 |
| Received opioids analgesics prior to delivery? Yes/no | 5/5 | 4/6 |
| Preeclampsia? Yes/no | 2/8 | 2/8 |
| High blood pressure before and after delivery? Yes/no | 2/8 | 2/8 |
| Infection? Yes/no | 4/6 | 6/4 |
| Extent of bleeding: <1000 ml/>1000 ml/ information lacking | 2/8 | 2/7/1 |

[a] Median (range). None of the differences were statistically significant.
[b] 12 years indicates a high school degree; 15 years indicates a college degree.

**Table 2** Clinical characteristics of the 20 infants whose mothers were enrolled in the present study

| | NIDCAP care ($n$=10) | Conventional care ($n$=10) |
|---|---|---|
| Gender (female/male) | 3/7 | 5/5 |
| Gestational age at birth (wks)‡ | 27.7 (24–28.7) | 26.1 (23.9–30.3) |
| Birth weight (g)‡ | 1083 (630–1411) | 818.5 (636–1939) |
| Small for gestational age/ appropriate for gestational age | 1/9 | 2/8 |
| Head circumference (cm) at birth‡ | 24 (22.5–26.5) | 23.5 (21.1–30.0) |
| Severity of illness (CRIB)‡† | 4.5 (0–11) | 5 (2–15) |

‡ Median (range). None of the differences were statistically significant.
† According to the International Neonatal Network [39].

## Results

**Parent-newborn interaction**

*Instrument: self-constructed attitude scale, completed by the mothers at 36 weeks' corrected age*

The mothers in the NIDCAP group gave "the feeling of closeness between her and her infant" a significantly higher score than mothers of infants treated with conventional care, median (range) 4 (3–4) versus 3.5 (2–4), p=0.022.Of the 5 statements included in this subscale, there was a significant difference in the mothers' attitudes towards the importance of eye contact, 4 (3–4) for the NIDCAP group versus 3 (2–4) for the conventional care group, p=0.05 (see Table 6). In order to investigate whether the mother's feeling of closeness was related to the infant's gestational age, birthweight or severity of illness, possible correlations between these variables were examined independently for the NIDCAP and control groups. For the mothers of infants receiving care based on NIDCAP there was no significant association between the mothers' feeling of "closeness to her infant" and the infant's gestational age ($r_s$=0.15; p=0.68), birth weight ($r_s$=0.23; p=0.52) or severity of illness ($r_s$=−0.15; p=0.68). In contrast, for the group receiving

| | |
|---|---|
| | conventional care, the feeling of "closeness" was significantly, and negatively, correlated to the infant's birth weight ($r_s$=−0.67; p=0.036), and positively correlated with the infant's severity of illness ($r_s$=0.71; p=0.02), but there was no significant correlation with gestational age detected ($r_s$=−0.49; p=0.15).<br>There was no significant difference between the two groups regarding the mothers' perception of their ability to interpret the infant's signals and needs, and of their role as a mother. In addition, no difference was found regarding the mothers' perception of her reaction to the infant. The question asking whether the mother had a "feeling of being rejected by the infant", was scored "do not agree at all" by 15 of the 20 mothers, while 2 mothers replied that they "disagreed somewhat", 2 mothers "agreed somewhat" and one mother "agreed completely". There was no significant difference between the two groups of mothers. |
| **Anxiety** | *Instrument: self-constructed attitude scale, completed by the mothers at 36 weeks' corrected age*<br>The mothers in the NIDCAP group experienced a significant higher level of "anxiety" when the three statements concerning the survival of her baby, or risk of the baby being injured, and the technical environment were calculated together, than did the mothers in the conventional care group, 3.2 (2.0–3.7) versus 2.5 (1.3–3.3), respectively, p=0.033. |
| **Limitations and conclusion** | |
| **Limitations** | A limitation of the current study is the relatively small number of participants, which was a result of political health care decisions (including downsizing the NICU) and drop in birth rate. The findings should be interpreted with caution until they have been confirmed in larger studies. Inclusion of a larger number of subjects might perhaps have revealed significant differences with respect to additional variables in the present investigation. Moreover during certain periods it was difficult to keep the different care teams separate, so a "spill-over" effect from the NIDCAP care to conventional care happened, which might thus have obscured certain differences between the two groups. In spite of this, there were significant differences between the two groups of mothers. |
| **Authors' conclusion** | The mothers of premature infants receiving care according to NIDCAP felt closer to their infants, perceived more eye contact, experienced more anxiety, who might be interpreted as a sign of early bonding, and tended to experience more support from the staff in taking over the care of their infants than did the mothers given conventional care. This finding indicates that early NIDCAP intervention may facilitate participation of the mother in care-giving on a neonatal intensive unit, as well as facilitating emotional bonding to their premature child. |

| Van der Pal et al. (2007) | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Two randomised controlled trials | **Exposure intervention group** | Trial 1: developmental care<br>Trial 2: NIDCAP |
| **Country** | Netherlands | **Exposure control group** | Trial 1: standard NICU care<br>Trial 2: basic developmental care |
| **Setting** | Two NICUs (level III): Leiden University Medical Center and Juliana Children's Hospital | **Level of prematurity** | < 32 weeks of gestational age |
| **Sample size** | Trial 1: intervention group = 66, control group = 67<br>Trial 2: intervention group = 75, control group = 75 | | |
| **Time frame** | Trial 1: April 2000 – May 2002<br>Trial 2: July 2002 – August 2004 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | - | | |
| **Exclusion criteria** | *Newborns*<br>Exclusion criteria were: infants of drug-addicted mothers and infants with congenital heart disease or other major birth anomalies. | | |
| **Newborn and parent characteristics** | The two groups in the first RCT were comparable regarding the infant and parent characteristics (Table S1). The two groups in the second RCT were comparable regarding the infant characteristics and most parent characteristics, but mothers in the NIDCAP group tended to be younger (p = .02). | | |
| **Results** | | | |
| **Stress** | *Instrument: Parental Stressor Scale-NICU (PSS-NICU), completed at home 1 week after their infant's birth*<br>No significant differences were found on mother's confidence, perceived nurse support and parental stress scores in both trials (Table S2). The expected decrease in maternal stress in both trials and the expected increase in maternal confidence and perceived nurse support in the NIDCAP group in the second trial, were not found. Mothers in the basic DC intervention group during the first trial tended to show more stress on the subscale staff behaviour and communication (p = .05), compared to the standard care controls.<br>The scores of fathers in both RCT's also did not show significant differences and the expected effects were not observed (Table S2). Fathers in the NIDCAP intervention group (mean = 1.55) in the second trial reported more stress on the subscale staff behaviour and communication, compared to fathers in the basic DC control group (mean = 1.34), but this difference was not significant (p = 0.046, corrected difference between means (99% CI) = −0.25(−0.56; 0.07)).<br>No significant effects of the two interventions were found on the difference of mothers and fathers regarding parental confidence, perceived nurse support and parental stress in both trials (Table S3). The difference in total stress levels of mothers (higher) compared to fathers tended to be lower in the NIDCAP intervention group in the second RCT (p = 0.034). The largest differences in stress level between mother and father were on the PSS-NICU subscales parent role alterations and infant's appearance. | | |

| Limitations and conclusion | |
|---|---|
| **Limitations** | NA |
| **Authors' conclusion** | In conclusion, both basic developmental care and the complete NIDCAP intervention, with individual observations and guidance, had no significant effect on confidence, perceived nurse support and parental stress. The expected positive effect of the NIDCAP intervention on parental confidence and perceived nurse support and the expected decrease in parental stress after both interventions, were not observed. As a result of increased paternal stress, the NIDCAP intervention tended to decrease the difference in stress levels of fathers and mothers. The NIDCAP program might lead to increased involvement of fathers, compared to a basic form of developmental care, leading to more comparable stress levels of fathers and mothers. |

| Peters et al. (2009) | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Cluster randomised controlled trial | **Exposure intervention group** | NIDCAP-based care |
| **Country** | Canada | **Exposure control group** | Standard NICU care |
| **Setting** | NICU at the Royal Alexandra Hospital (Edmonton) | **Level of prematurity** | ≤ 32 weeks of gestational age (500 - 1250 gr) |
| **Sample size** | Intervention group: 56<br>Control group: 55 | | |
| **Time frame** | September 1999 – September 2004 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Newborns*<br>Inclusion criteria were birth weight of 500 to 1250 g, gestational age of ≤32 weeks, birth weight between the 3rd and 97th percentiles for gestational age, and age of 2 to 7 days at the time of study entry. | | |
| **Exclusion criteria** | *Newborns*<br>Exclusion criteria were chromosomal or major congenital anomalies, known maternal alcohol or drug abuse, known congenital infection, and/or decision to withdraw life support before 48 hours of life. | | |
| **Newborn and parent characteristics** | During part II, 328 infants with birth weights of <1250 g were admitted to the study site, 201 infants were eligible, and 120 infants enrolled, with 60 infants (50 singletons and 5 sets of twins) in each group (Fig 1). While at the study site, NIDCAP group infants received a median of 83% (range: 49%–95%) of total nursing care hours from NIDCAP-educated nurses, whereas all except 1 control infant received 0% (range: 0%–27%) NIDCAP-educated nursing care hours.<br>No evidence of a statistically significant difference between groups was found for any maternal or infant demographic characteristic. | | |
| **Results** | | | |
| **LOS newborn** | *Defined as the number of calendar days spent in the hospital.* | | |

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| | The median LOS was significantly reduced for NIDCAP group infants (NIDCAP: 74.0 days; control: 84.0 days; P = .003) (Table 4 and Fig 2). The estimated HR was 1.83 (95% CI: 1.24 –2.72). When other important factors such as gestational age and days of ventilation before randomization were considered (Table 5), LOS was still significantly reduced for NIDCAP group infants (HR: 1.65 [95% CI: 1.05–2.59]). |
| **Neuro-developmental impairment** | *Instrument: Bayley Scales of Infant Development II, during follow-up visit at adjusted age of 18 months, included a neurodevelopmental assessment by a certified developmental psychologist*<br>No evidence of a statistically significant difference in Psychomotor Developmental Index scores was found (mean±SD: NIDCAP: 85.1± 15.4; control: 81.1 ± 15.3; difference: 3.95 [95% CI:-2.78 to 10.69]; P=.246). |
| **Limitations and conclusion** | |
| **Limitations** | Although a prospective RCT design was used, the limitations of this study are the unblinded intervention and possible volunteer bias. Interventions such as high-frequency oscillatory ventilation50–52 and caesarean section because of breech presentation53 are other examples of treatments that cannot be blinded but have been well studied in RCTs. A meta-epidemiological study showed that there is little evidence of exaggerated treatment effect for unblinded intervention studies with adequate allocation concealment and objectively determined outcomes. Concealed, random allocation was used, and objective outcomes were determined by clinicians blinded to the study group (i.e., LOS by paediatricians not involved in the RCT and 18-month outcomes by the follow-up team). |
| **Authors' conclusion** | In this RCT, NIDCAP-based care for VLBW infants improved LOS, CLD incidence, and neurodevelopmental outcomes at 18 months of adjusted age significantly. This study provides additional evidence to support NIDCAP based care |

## *Appendix 2.3.4. Mother-infant transaction program (MITP)*

| Kaaresen et al. (2006) | | | |
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| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | Received a modified version of the Mother-Infant Transaction Program (MITP). The modifications included an initial session in which the parents could vent experiences from the hospital stay and possibly their feelings of grief. Such feelings include feelings of grief for not having "a normal infant," guilt and blame about possible reasons for the preterm birth, anxiety about their infant's survival, and concerns for the future normality of their infant.<br>Second, we tried to adopt a more active participation from both the mother and the father in evaluating and handling the infants and their cues. |
| **Country** | Norway | **Exposure control group** | Followed the unit's standard protocol for discharge of preterm infants, which includes an examination and offer of training in infant massage from the unit's physical therapist, a clinical examination including visual and hearing screening, and a discharge consultation with one of the doctors. |
| **Setting** | 1 NICU (level III) in University Hospital North Norway Trust (UNN) | **Level of prematurity** | < 2000 gr of birthweight |
| **Sample size** | One hundred forty-six infants were randomly assigned to a preterm intervention or preterm control group. Seventy-five infants were recruited to the term control group during the same period. The infants whose parents declined to participate were slightly more mature than the preterm infants who were included (GA: 32.5 vs 30.1 weeks, respectively; P = 0.001), but there was no significant difference in BW (1419 vs 1398 g, respectively; P = 0.1). Almost all mothers completed the PSI at both 6 and 12 months' corrected age, whereas the overall response rate for the fathers was 79%: 86% in the preterm intervention group and 74% and 78% in | | |

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| | the preterm and term control groups, respectively. The nonresponding fathers were not different from the responders regarding number of years of education or their infant's BW or GA. The 4 families that did not attend the 12-month examination still want to participate in the study. |
| **Time frame** | March 1999 – August 2002 |
| **Newborn and parent characteristics** | |
| **Eligibility criteria** | *Newborns*<br>All infants born at UNN with a birth weight (BW) below 2000 g and without congenital anomalies and whose mothers' native language was Norwegian were eligible for this study. Outborn infants were included if they were transferred to the NICU in Tromsø within 1 week after birth. |
| **Exclusion criteria** | *Newborns*<br>Triplets were excluded because of the character of the intervention. Infants who were unable to go through the planned test program because of neurologic sequelae were withdrawn from the study. |
| **Newborn and parent characteristics** | The preterm groups were well balanced except for a small but significant difference in the preterm mothers' number of years of education (mean difference: 1.1 year; 95% CI: 0.03 to 2.2; P = 0.04). Three infants were diagnosed with cerebral palsy at the clinical examination at 12 months' corrected age (1 in the preterm control group and 2 in the intervention group). Four infants (2 in each preterm group) had visual defects and required glasses, and 1 infant in the intervention group had reduced hearing on one side. Seven infants (3 in the preterm control and 4 in the intervention group) were considered developmentally delayed by > 2 months. |
| **Results** | |
| **Stress** | *Instrument: Parenting Stress Index (PSI), filled in by the mothers at 6 months' corrected age and by both parents at 12 months' corrected age*<br>*The PSI has been standardized with parents and children ranging in age from 1 month to 12 years in different cultures and is considered to be a reliable instrument across cultures. The self-reported questionnaire consists of 101 items that are scored on a 5-point Likert scale. The Norwegian version used was translated and back-translated by Abidin and J.A.R. The PSI consists of a child domain and a parent domain. The child domain score reflects parental stress associated with the child's individual characteristics as measured on 6 subscales: distractibility/hyperactivity, adaptability, reinforces parent, demandingness, mood, and acceptability. The parent domain reflects parental stress associated with the parental role and is measured on 7 subscales: competence, isolation, attachment, health, role restriction, depression, and spouse. Overall scores for the child and parent domains are obtained by summing the scores of their respective subscales, and a combination of the domain scores gives the total stress score. Higher scores indicate more stress. The life stress dimension of the PSI was also calculated. This dimension is a measure of negative life experience during the last 12 months. Missing values on different items were handled according to the PSI manual, so the numbers with valid summary scores, therefore, will vary slightly.*<br><br>The preterm intervention group had significantly lower scores in all scores at both 6 and 12 months compared with the preterm control group except child domain reported by the mothers at 12 months, where the difference was only borderline significant (P = 0.08). The effect sizes of the interventions were small to moderate, with Cohen's d ranging from 0.30 to 0.50 (Table 2). There were no significant differences between the 2 preterm groups in the life stress dimension reported by the mothers at 6 and 12 months and fathers at 12 months. |

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| | To test whether there were any differences in the reported stress between mothers and fathers at 12 months, we compared their reported mean stress scores by paired t tests and calculated the ICCs within each group. There were no significant differences in mean scores between the genders in child or parent domain or total stress, although the differences in means tended to be somewhat lower in the preterm intervention group. In child domain, the ICC was substantially higher in the preterm intervention group than in the preterm control group and lowest in the term control group. There was a significant negative correlation between the number of intervention sessions in which the fathers participated and the father-reported total stress score at 12 months (Spearman's p = -0.33; P = 0.01). |
| **Limitations and conclusion** | |
| **Limitations** | A possible weakness is that BW rather than GA was used as the inclusion criterion. As a result, some more mature growth-restricted infants were included in the study, which makes the conclusion more difficult to generalize. However, the growth-restricted infants were evenly distributed between the 2 preterm groups and should not influence the group differences found. The number of extremely preterm infants is rather limited in this study. This is a consequence of the sparsely populated area we serve, with a limited number of extremely preterm infants. An alternative could have been to prolong the inclusion period. However, the inclusion period was, even with this design, rather long. No important changes in the treatment of preterm infants except for the intervention program were introduced in our NICU during the inclusion period. The potential spill-over effect from the intervention group to the control group was minimized by late randomization, and only selected, trained nurses performed the intervention. If a spill-over effect still occurred, it would have tended to reduce the observed effects of the intervention program. |
| **Authors' conclusion** | We have shown a persistent increased parenting stress in both mothers and fathers of preterm infants compared with their term peers. A limited, structured, clearly defined early-intervention program can prevent the parenting stress in both mothers and fathers to the same level as found in term parents. We are now studying the long-term effect of this on later cognitive and behavioural outcome in these infants. |

| Newnham et al. (2009) | | | |
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| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | Mother-infant transaction program |
| **Country** | Australia | **Exposure control group** | Standard hospital care |
| **Setting** | Mercy Hospital for Women in Melbourne | **Level of prematurity** | < 37 weeks of gestational age |
| **Sample size** | Intervention group: 35<br>Control group: 33 | | |
| **Time frame** | 2001 – 2002 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Newborns*<br>As in the original MITP study, the major inclusion criterion was having an infant with a gestational age (GA) of <37 weeks.<br>The original MITP excluded twins and single mothers, but were included here since they each form a significant proportion of the preterm population and we aimed for results to be generalised to them as well. | | |
| **Exclusion criteria** | *Parents*<br>Mothers were excluded if their infants had congenital abnormalities, gross neurological damage, were triplets or higher multiples, or if parents were non-English speaking or drug dependent. | | |
| **Newborn and parent characteristics** | | | |
| **Results** | | | |
| **Parent-newborn interaction** | *Instrument: Synchrony Scale, videotaped at 3 and 6 months corrected age, rated by research assistant who was blind for randomisation*<br>At 3months Intervention mothers were more responsive than control mothers (M= 1.97, S.D. = 0.08 v sM= 1.64, S.D. = 0.45, CI = 0.17–0.50, p < .05) and intervention infants were significantly more attentive than control infants (M= 1.03, S.D. = 0.10 vs M=0.59, S.D. = 0.54, CI = -0.13-0.70, p < .012). Intervention infants were more alert at both 3 (M= 1.57, S.D. = 0. 24 vs M= 1.44, S.D. = 0.61, CI =−0.13 to 0.68, p < .012) and 6 (M= 1.94, S.D. = 0.25 vs M= 1.82, S.D. = 0.72, CI = 0.09–0.41. p < .012) months. There was more mother–infant reciprocity/synchrony at 3 months (M= 0.29, S.D. = 0.09 vs M= 0.23, S.D. = 0.11, CI =−0.11 to 0.22, p < .012) and more mutual attention at 6 months (M= 0.45, S.D. = 0.08 vs M= 0.24, S.D. = 0.13, CI = 0.11–0.67, p < .012) in the intervention compared with control dyads. | | |
| **Stress** | *Instrument: Parenting Stress Index, used at 3 and 6 months corrected age*<br>At 3 months CA, there was a significant difference in total Child Domain scores of the PSI between the intervention (M= 91.34, S.D. = 104.68) and control groups (M= 94.60, S.D. = 12.24), F1,62 = 3.83, p < .012, mean difference = 3.25, CI =−10.15 to 3.63). Thus, control mothers were more stressed by infant characteristics than intervention mothers. | | |
| **Depression** | *Instrument: Edinburgh Postnatal Depression Scale, completed at study entry and at 3 and 6 months corrected age* | | |

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| | Mean maternal depression scores at entry (7.29, S.D. = 4.69) were well below the cut off score of ≥12 on the EPDS which is commonly used to designate a high probability of depression (three mothers had scores above 12). Mean scores at 3 (8.46, S.D. = 4.30) and 6 months (8.90, S.D. = 5.23) were higher but not significantly different to entry scores (p1,62 = >.012) (at each age four mothers had scores above 12). There were no group differences in mean depression scores at 3 (M= 7.93, S.D. = 4.56 vs M= 8.99, S.D. = 4.99) or 6months (M=8.10, S.D. = 5.40 vs M= 9.70, S.D. = 4.99). There were no significant associations between maternal EPDS scores and infant outcome measures (all p's > .05). |
| **Limitations and conclusion** | |
| **Limitations** | The problems with the study concern mainly the limitations of the sample size (and the expensive, time-consuming nature of this kind of intervention with this population). The nature and number of statistical tests were constrained by the small sample. In addition, the use of a developmental screen at 2 years was not optimal. |
| **Authors' conclusion** | In terms of maternal adjustment, intervention mothers were found to be less stressed by their infants at 3 months but not at 6 months. The nature of preterm birth and of the appearance and medical instability of the infant themselves can sometimes result in mothers having long-term anxieties and preoccupations with their infant and child. These results suggest that the intervention was able to help mothers adjust quickly to their experience of parenting an at-risk child. We did not find any group differences in maternal depression as was hypothesized possibly due to low scores at baseline. |

| **Ravn et al. (2011)** | | | |
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| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | Received the MITP intervention |
| **Country** | Norway | **Exposure control group** | Standard neonatal care |
| **Setting** | NICU in urban level III hospital | **Level of prematurity** | ≥ 30.0 and < 36 weeks gestational age |
| **Sample size** | Mothers of a total of 190 preterm infants were invited to participate in the study, and 118 (62.1%) accepted. Table 2 provides baseline clinical and demographic characteristics at 12 months. Among the participating families, 15 (24.6%) were excluded/lost to follow-up in the preterm intervention group and 10 (17.5%) in the preterm control group. One twin in the intervention group was excluded from the analysis because of sequela. No significant differences were found between non-consenting and consenting preterm groups in terms of birth weight (1941 g vs. 1930 g), GA (33.3 vs. 33.0 weeks) and gender (50% vs. 54.7% males), all with p > .05. Each mother-infant dyad allocated to the intervention group participated in all 11 sessions.<br>Intervention group: 46 mothers/infants<br>Control group: 47 mothers/infants | | |

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| **Time frame** | January 2005 – December 2006 |
| **Newborn and parent characteristics** | |
| **Eligibility criteria** | *Parents*<br>They were eligible if they could speak, read and write Norwegian, had no history of drug or alcohol abuse or severe psychiatric disorders, and if a hospital stay of minimum eight days was anticipated. |
| ***Exclusion criteria*** | *Newborns*<br>*Infants with congenital anomalies, neurological sequelae, hearing loss or chromosomal disorders were excluded.* |
| **Newborn and parent characteristics** | Mothers of a total of 190 preterm infants were invited to participate in the study, and 118 (62.1%) accepted. Table 2 provides baseline clinical and demographic characteristics at 12 months. Among the participating families, 15 (24.6%) were excluded/lost to follow-up in the preterm intervention group and 10 (17.5%) in the preterm control group. One twin in the intervention group was excluded from the analysis because of sequela. No significant differences were found between non-consenting and consenting preterm groups in terms of birth weight (1941 g vs. 1930 g), GA (33.3 vs. 33.0 weeks) and gender (50% vs. 54.7% males), all with p > .05. Each mother-infant dyad allocated to the intervention group participated in all 11 sessions. |
| **Results** | |
| **LOS newborn** | *Instrument: Qualitative Ratings for Parent-Child Interaction at 3-15 months of age, videotaped at corrected age of 12 months (approximately 9 months after the intervention had been completed) and coded by raters blind to group affiliation*<br>*Global ratings of seven subscales of maternal behaviour and five subscales of infant behaviour were coded according to a predetermined scale from 1 to 5, indicating the degree to which behaviours specified in the manual characterized the interaction, based on both quality and quantity of the observed behaviours. Higher scores indicate more evidence of the dimension being coded regardless of whether this dimension is considered good or bad for the interaction.*<br>When comparing the preterm groups the intervention mothers scored significantly higher on sensitivity/responsiveness (p = 0.048). Group differences of borderline statistical significance were found on maternal intrusiveness (p = 0.06), child positive mood (p = 0.07) and dyadic mutuality (p = 0.06), all in favour of the intervention group. No significant group differences were found on the variables of maternal stimulation and child negative mood. |
| **Limitations and conclusion** | |
| **Limitations** | Only 61% of the families eligible for inclusion consented to participate in the study. However no significant differences were found between non-consenting and consenting preterm groups on birth weight, gestational age and gender, and the preterm groups were still relatively balanced after 12 months. However attrition might have affected the groups in different ways. Further most of the mothers were first-time mothers of preterm infants with GA 30–36 weeks, and infants were selected for the study for whom a hospital stay of at least 8 days was expected, which resulted in a selection of preterm infants with lower gestational age. Thus the data have to be interpreted with caution, and one should be careful about generalizing the conclusions. |
| **Authors' conclusion** | Effective interventions may increase maternal sensitivity and contribute to a more optimal caretaking environment for fragile preterm infants. The present results showed a positive effect of MITP on important qualities of social interaction between mothers of moderately and late preterm infants at 12 months. Being a first-time mother seems to be a moderator that enhances the effects of the intervention. The intervention method has been assessed on differential populations in differential contexts, and there is growing evidence for the beneficial effects of MITP on diverse aspects of social interaction during the preterm infant's first year of life (Newnham et al., 2009; Olafsen et al., 2006). Additional studies are required to find out if |

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| | MITP has long-term developmental effects, to identify families in greatest need of the intervention, and to ensure that the implementation of MITP can produce the intended effects. |

| **Ravn et al. (2012)** | | | |
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| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | Received the MITP intervention |
| **Country** | Norway | **Exposure control group** | Standard neonatal care |
| **Setting** | NICU in urban level III hospital | **Level of prematurity** | ≥ 30.0 and < 36 weeks gestational age |
| **Sample size** | A total of 158 fathers of preterm infants were invited to participate (provided the mother had consented to participate), and 82 (51.9%) accepted.<br>Twins had been recruited to the preterm groups only, and one twin in the intervention group was already excluded from the analysis due to sequela. At 12 months, 10 (28.3%) fathers were lost to follow-up in the intervention group, 7 (17.9%) in the preterm control group and 5 (11.1%) in the term reference group (Figure 1). The response rate at 12 months was 74.4% in the intervention group, 82.1% in the preterm control group and 88.6% in the term reference group. Many of the families were lost to follow-up or excluded at baseline because of withdrawal or due to early discharge with insufficient time to accomplish the intervention programme. | | |
| **Time frame** | January 2005 – December 2006 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Parents*<br>Parents were eligible if they could speak, read and write Norwegian and had no history of drug/alcohol abuse or severe psychiatric disorders, and if a hospital stay of minimum eight days was anticipated. | | |
| **Exclusion criteria** | *Newborns*<br>Infants with congenital anomalies, neurological sequelae, hearing loss or chromosomal disorders were excluded. | | |
| **Newborn and parent characteristics** | No differences were found between non-consenting and consenting preterm groups in mean birthweight (1941 g vs. 1930 g), gestational age (33.3 weeks vs. 33.0 weeks) and gender (50% males versus 54.7% males), all with $p > .05$. | | |
| **Results** | | | |
| **Stress** | *Instrument: Norwegian translation of the Parenting Stress Index (PSI)* | | |

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| | *The PSI short version (PSI/SF), administered at six months, is a self-report questionnaire with 36 items, each rated on a five-point Likert scale with three subscales of 12 items each. The parental distress subscale indicates stress related to parenting. The parent–child dysfunctional Interaction subscale focuses on the parent–child interaction. The difficult child subscale focuses on the child's self-regulatory processes. Higher scores indicate poorer function. A total stress score is computed by summing the subscales. Cronbach's alpha level was > 0.80 on all subscales, and 0.92 for total stress. A defensive responding score of 10 or less indicates response bias. The PSI long version (PSI), administered at 12 months, comprises 123 questions and separates three sources of stressors: child characteristics (six subscales), parental characteristics (seven subscales), and 22 life stress items that indicate stress outside the parent-infant relationship. Three more life stress items were added in the Norwegian version of the PSI. A total stress score is computed by summing the scores in the child and parent domains. The child domain reflects stress associated with the perception of infant characteristics: distractibility/hyperactivity, adaptability, reinforces parents, demandingness, mood and acceptability. The parent domain reflects stress associated with parental functioning: competence, isolation, attachment, health, role restriction, depression and spouse. The long version had satisfactory Cronbach's alpha level in all domains (> 0.75) and for total stress (0.93). A defensive responding score of 24 or less indicates response bias*<br><br>**Stress scores of fathers in the preterm control group and the term reference group**<br>At six months, fathers in the preterm control group (n = 37) scored significantly higher on total stress and on the subscales of parental distress, parent–child dysfunctional interaction, difficult child and defensive responding as compared with fathers in the term reference group (n = 39) (Table 2). At 12 months, fathers in the preterm control group (n = 32) evidenced significantly more stress than fathers in the term reference group (n = 39) on the subscale of acceptability and demandingness in the child domain, and on the subscales of competence and isolation in the parent domain. Still, fathers of preterm infants scored significantly higher on total stress. With the exception of reinforces parents, mood and life stress, fathers in the preterm control group had non-significantly higher stress scores on the other subscales (Table 3).<br>**Stress scores of fathers in the preterm intervention group and the preterm control group**<br>When comparing the preterm groups at six months, there were no significant differences in stress scores between fathers in the intervention group (n = 32) and fathers in the preterm control group on any of the subscales (Table 2). No significant differences in stress scores were found between fathers in the intervention group (n = 29) and those in the preterm control group (Table 3) at 12 months.<br>**Stress scores of fathers with low and high 'intervention dose'**<br>Table 4 presents stress scores of fathers at six months after dichotomising intervention sessions in low- and high-exposure groups. As shown, no significant differences in stress scores between the two groups were found. At 12 months, however, the fathers who had participated in 0 to 5 sessions reported significant lower stress scores than fathers who had participated in 6 to 11 sessions on total stress, the parent domain and the subscales of mood and competence. |
| **Limitations and conclusion** | |
| **Limitations** | We used different PSI forms at six and 12 months which made it impossible to compare the subscales. Fathers' participation in the study and in the intervention sessions was relatively low, and no baseline stress data were available for the fathers. Furthermore, the study may be underpowered to detect clinically significant differences in stress scores, with a substantial attrition in both preterm groups. The small sample size may limit the generalisation of the results, and the findings must be interpreted with caution due to multiple statistical testing and increased risk of Type 1 error. |
| **Authors' conclusion** | No significant differences were found in stress between preterm intervention and preterm control group. The intervention failed to reduce paternal stress, and the results may indicate that fathers require different intervention strategies. |

| Ravn et al. (2012) | | | |
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| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | Received the MITP intervention |
| **Country** | Norway | **Exposure control group** | Standard neonatal care |
| **Setting** | NICU in urban level III hospital | **Level of prematurity** | ≥ 30.0 and < 36 weeks gestational age |
| **Sample size** | Among the participating families, 10 (19.2%) were lost to follow-up in the intervention group and 9 (18.0%) in the control group. One twin in the intervention group was excluded from the analysis due to sequelae. Four twins in the intervention group and seven twins in the control group were randomly excluded from the analysis. | | |
| **Time frame** | January 2005 – December 2006 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Parents*<br>Parents were eligible if they could speak, read and write Norwegian and had no history of drug/alcohol abuse or severe psychiatric disorders, and if a hospital stay of minimum eight days was anticipated. | | |
| **Exclusion criteria** | *Newborns*<br>Infants with congenital anomalies, neurological sequelae, hearing loss or chromosomal disorders were excluded. | | |
| **Newborn and parent characteristics** | No significant differences were found between non-consenting and consenting preterm participants in terms of birth weight (1941 g versus 1930 g), GA (33.3 versus 33.0 weeks) and gender (50% versus 54.7% males), all with p > 0.05. More than 60% of the mothers in the preterm groups were first-time mothers. N = 12 (21.4%) in the intervention and n = 12 (24%) in the control group were very preterm infants with GA between 30.0 and 31.6 weeks. The intervention group had significantly more mothers with earlier preterm birth and non-Norwegian origin. When mothers filled out self-reported depression one month after discharge, the mean postnatal age was 3 (intervention group) and 6 days (control group) after expected day of delivery. All mothers allocated to the intervention group participated in all the intervention sessions. | | |
| **Results** | | | |
| **Stress** | *Instrument: Parenting Stress Index (PSI)*<br>*The PSI short version, administered at 6 months, has 36 items; each rated on a 5-point Likert scale with three subscales of 12 items each: The Parental Distress subscale, The Parent-child Dysfunctional Interaction subscale and The Difficult Child subscale. Total stress scores in PSI/SF range from 36 to 180, high scores indicate poor function. The Cronbach's alpha levels were > 0.77 on the subscales, and 0.82 for Total stress. The PSI long version, administered at 12 months, comprises 123 questions and distinguishes three major sources of stressors: child characteristics (6 subscales), parental characteristics (7 subscales), and 22 Life stress items (LS) that indicates stress outside the parent-infant relationship. Three Life stress items are added in the Norwegian version of the PSI. A defensive Responding score of 24 or less indicates defensive responding or cheating. Total stress scores may range from 101 to 505; computed by summing the scores on the Child and the Parent domains. The Child domain reflects stress associated with* | | |

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| | *parental perception of infant characteristics. The Parent domain reflects stress associated with parental functioning. The Cronbach's alpha levels were 0.83 and 0.85 for the Child and Parents domain, respectively, and 0.94 for Total stress.*<br><br>At 6 months, no significant differences were obtained in PSI scores between the mothers in the intervention (n = 40) and control group (n = 38) on the subscales or Total stress (M = 59.8, SD = 11.5 versus M = 55.0, SD = 12.1, p = 0.08). Again, at 12 months no significant differences in stress scores were reported in Child Domain, Parent Domain, Life stress, Defensive scoring or Total stress [M = 197.2, SD = 32.5 (n = 41) versus M = 192.3, SD = 28.2 (n = 39), p = 0.46]. |
| **Depression** | *Instrument: Center for Epidemiological Studies Depression Scale (CES-D)*<br>*CES-D was used to measure mothers' self-reported current levels of depressive symptoms one month after discharge, and again at 6 and 12 months. CES-D has 20 items and 4 subscales: depressive affect, somatic symptoms, positive affect and inter-personal relations. Total possible scores range from 0 to 60; higher scores indicate more depression symptoms. The cut off-point for depressive symptoms was 16. In this study Cronbach's alphas ranged from 0.71 to 0.82 on the subscales; total alpha was 0.85.*<br><br>One month after infant discharge mothers in the intervention group (n = 43) reported fewer somatic symptoms on the CES-D than control mothers (n = 44) (M = 3.8, SD = 2.8 versus M = 5.2, SD = 3.5, p = 0.05), as well as lower total depression scores (M = 8.3, SD = 5.1 versus M = 10.9, SD = 6.7, p = 0.04) (Fig. 2). Otherwise no significant differences in depression scores were found between the groups at 1, 6 and 12 months on any of the scales. A paired t-test showed a decrease in total depression scores in both groups from 1 to 12 months (p < 0.001). Between 6 and 12 months the mean total CES-D scores of the preterm groups stabilized at the level of 7.5–8.0. The differences in number of mothers reporting clinical depression symptoms above the cut off-point of 16 (at-risk scores) during the first year were not significant (Table 2), but one month after discharge, n = 6 (14%) mothers in the intervention group and n = 12 (27.3%) in the control group reported depression scores at clinical at-risk levels |
| **Breastfeeding** | *Measured by reporting of the mother at 6, 9 and 12 months, based on the WHO breastfeeding categories: exclusive breastfeeding (breast milk only, but allows vitamins and medicines), predominant breastfeeding (breast milk a source of nourishment, but allows water, juice, vitamins and medicines) and partial breastfeeding (breast milk combined solid or semi-solid foods, formula or non-human milk). Mothers also reported on not breastfeeding.*<br><br>At 9 months n = 14 (34.1%) mothers in the intervention group were not breastfeeding their infants compared with n = 24 (60%) in the control group (p = 0.02). This tendency was also found at 12 months when n = 26 (61.9%) versus n = 32 (80%) in the control group were not breastfeeding their infants (p = 0.07) |
| **Limitations and conclusion** | |
| **Limitations** | The findings must however be interpreted with caution due to multiple statistical testing and relatively small sample size. For some of the IBQ subscales the reliability was low. We did not use the same PSI form at 6 and 12 months, we cannot rule out a possible baseline imbalance in stress and depression scores between the groups, and we did not discuss possible consequence of significantly more mothers with earlier preterm births and non-Norwegian origin in the intervention group. Other researchers have modified the number of sessions and content of the original MITP protocol, making it difficult to directly compare the results. |
| **Authors' conclusion** | Despite increased risk for health problems, moderately and late preterm infants have received little attention in follow-up studies. The present study suggests that one reason for implementing MITP in a NICU setting is that this intervention method may reduce postpartum depression and extend the period of breastfeeding, which may benefit mothers as well as infants. We consider it important to report all results obtained by using MITP in order |

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| | for health professionals better consider its usefulness. Preterm infants constitute a heterogeneous group with respect to development and communication, and one should ask if infants with different GA will benefit from the same interventions. Clearly, prospective clinical studies are needed to ensure a good follow-up of these families, as the results of this intervention are not conclusive. |

## *Appendix 2.3.5. Family nurture intervention*

| **Welch et al. (2013)** | | | |
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| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | Family nurture intervention (FNI) |
| **Country** | USA | **Exposure control group** | Standard care (SC): were able to engage in nurturing activities of their choosing, which in this NICU included SSC or non-SSC holding. These activities were optional and not documented by the study staff. However, control mothers recorded these activities on a self-report visit log. |
| **Setting** | NICU (level IV) at Morgan Stanley Children's Hospital at Columbia University Medical Center | **Level of prematurity** | 26 – 34 weeks gestational age |
| **Sample size** | Intervention group: 67<br>Control group: 67 | | |
| **Time frame** | June 2012 – September 2012 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Newborns*<br>Infants were eligible for the study if they were 1) born between 26 and 35 weeks postmenstrual age, 2) free of major congenital defects, 3) singleton or twin gestation and, 4) above the third percentile of weight for gestational age at birth. | | |
| **Exclusion criteria** | *Parents*<br>Infants were excluded if their mother 1) had a history of drug dependence, psychosis or other severe mental health problems, 2) could not speak adequate English for obtaining consent, 3) was younger than 18 years of age, 4) did not have support from at least one additional adult in the home, 5) was too ill to participate. Additional factors that prevented participation were: 1) anticipated infant discharge within less than 10 days, 2) inability of the mother to meet the visitation goal of 4 times/week, 3) inability of the family to participate in post-discharge follow-up, 4) prior enrolment of the mother and/or infant in a competing study, 5) withholding of approval by attending physician, 6) infant death. | | |
| **Newborn and parent characteristics** | There were no significant differences between groups. Consistent with risk of pre-term delivery, antenatal treatment with steroids was high (93%), as was use of labour suppressants (82%). Consistent with the study design, the mean gestational age of enrolled infants was between 30 and 31 weeks for both groups. Overall, the rate of C-section for singleton gestations was not different for SC and FNI mothers (55% vs. 59%). However, C-sections | | |

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| | for twin gestations were less frequent in the SC group (81% vs. 100%). The rate of C-section in singletons is slightly higher than the national average in preterms as of 2006 [20], which at the time was trending upward. |
| **Results** | |
| **LOS newborn** | Measured as the duration of the hospitalisation from date of birth to date of discharge home<br>All 150 infants were included in an initial intent-to-treat analysis; 16 infants who were not discharged to their home (transferred to other NICUs) were considered as LTFU and their data were right-censored at the date of last contact, or death [21]. All other infants (N = 134) were followed until discharge home from our NICU. LOS ranged from 5 to 212 days, with a median of 35.5 (IQR 20 – 60) days. Kaplan-Meier survival analysis (time to event, discharge home) produced an estimated mean (±SD) LOS of 47.4 ± 27.4 days for the FNI group and 50.8 ± 45.8 days for the SC group. Although mean LOS was 3.4 days shorter in the FNI group, median LOS was 4 days longer in the FNI group (SC median = 36, 95% CI = 29 – 43; FNI median = 40, 95% CI = 30 – 50) with no significant difference between the groups (Mantel-Cox log-rank $\chi 2 = 0.163$, df = 1, p = .687). Controlling for gestational age at birth, a proportional hazards model revealed no significant association between LOS and amount of FNI (expressed as a weekly rate of facilitated visits) in intervention group infants ($\beta = .959$, Wald $\chi 2 = .340$, df = 1, p = .560). |
| **Limitations and conclusion** | |
| **Limitations** | A significant limitation of this trial was that a large number of families declined to participate. This was largely due to the considerable study burden imposed by the trial: for both groups, the protocol included multiple time consuming physiological and neurobehavioral assessments during the NICU stay and during multiple follow-up visits over a two-year period; for the intervention group, mothers were additionally asked to meet regularly with the Nurture Specialists throughout the NICU stay and the families were asked to meet once prior to discharge. In future studies of FNI, we plan to reduce study burden by separating the intervention portion of the study from the follow-up. We believe this will significantly help to reduce the refusal rate. There was no indication that anyone refused because they did not want to do nurture. Therefore, we do not see the low percentage of study enrolment itself as an impediment to intervention acceptance in the NICU. Another limitation to consider is that the sample might be biased towards those who had better support systems, more time and fewer competing responsibilities. We believe this to be a limitation that worked against us. These mothers would be more similar to each other than to the rest of the population and more likely to give lots of attention to the baby, whichever group they were assigned to. So, the self-selected sample would make it harder to show an effect, not easier.<br>Contamination is a potential limitation in this study. It was impossible to prevent some communication between subjects in the FNI and SC groups. However, the great majority of the mothers on our 80 bed capacity unit were not in the study. Usually, there were fewer than 3 study mothers in the NICU, thus limiting the chances of contamination; the maximum number of enrolled subjects at one time was 4 FNI mothers and 2 SC mothers. Occasionally, SC mothers expressed regret at their group designation. One SC mother tried scent cloth exchange with her infant.<br>A limitation of this report is that longer-term follow-up assessments of neurophysiologic and cognitive and behavioural development were not available. However, they are on-going and will continue until at least two years of age. These longer-term assessments will be used to test the hypothesis that FNI leads to improved neurobehavioral outcomes of prematurely born infants. Nevertheless, we have documented improved EEG activity in FNI infants compared with SC infants at near to term [25], which supports that FNI may indeed be associated with improved neurodevelopmental outcomes. |
| **Authors' conclusion** | FNI did not significantly affect the primary outcome of this study, LOS in the NICU. Nonetheless, this trial did demonstrate that FNI is safe in a high acuity NICU. In addition, we found that mothers were willing to engage in the study intervention activities, and that FNI was compatible with routine NICU activities. |

| Welch et al. (2016) | | | |
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| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | Family nurture intervention (FNI) |
| **Country** | USA | **Exposure control group** | Standard care (SC): were able to engage in nurturing activities of their choosing, which in this NICU included SSC or non-SSC holding. These activities were optional and not documented by the study staff. However, control mothers recorded these activities on a self-report visit log. |
| **Setting** | NICU (level IV) at Morgan Stanley Children's Hospital at Columbia University Medical Center | **Level of prematurity** | 26 – 34 weeks gestational age |
| **Sample size** | Intervention group: 59<br>Control group: 56 | | |
| **Time frame** | January 2009 – June 2012 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Parents*<br>Mothers eligible for the RCT had recently delivered a singleton or a set of twins between 26 and 34 weeks gestational age (GA) who were free of congenital defects. Mothers were ≥18 years old; fluent in English; free of current or prior mental illness, addiction, or substance use; and had access to social support from at least one adult in the home. | | |
| **Exclusion criteria** | *See eligibility criteria* | | |
| **Newborn and parent characteristics** | Randomization produced no significant differences between SC (N=56) and FNI (N=59) families with regard to mothers' and fathers' age, race/ethnicity, education, or household income at study entry. | | |
| **Results** | | | |
| **Depression** | *Instrument: the Center of Epidemiologic Studies Depression Scale (CES-D), completed at enrolment in the study, near to term age, and at the infants' 4 months' corrected age follow-up visit*<br>*Mothers selected responses from a Likert scale ranging from 0 (never) to 3 (almost always) for each of the 20 items representing various manifestations of depression, for a total scale score ranging from 0 to 60. A score equal to or greater than 16 is typically considered a criterion for referral (Radloff 1977). The CES-D has been widely used in epidemiological and social science research and demonstrates reliability and construct validity in evaluating depressive symptoms in adult populations, including among mothers during and after parturition (Ballantyne et al. 2013; Melchior et al. 2012; Miles et al. 2007; Phillips et al. 2010).*<br><br>At enrollment, there were no significant differences in mean self-reported depressive symptoms between groups. However, at 4 months CA, average CES-D scores were significantly lower in FNI mothers (t=2.12, p=0.038). Of the N=108 mothers who completed the CES-D at baseline, 38.3%(SC: N=20, 36 %; FNI: N=24, 45 %) rated themselves at or above a 16-point cutoff to indicate possible clinical depression (Radloff 1977). CES-D scores | | |

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| | declined in both groups over time (see Fig. 1a), but group comparisons at each visit showed a progressive divergence in mean depression scores over the follow-up periods. By 4 months, eight mothers had scores that exceeded the 16-point depression cutoff; seven of these were in the SC group (17.5 %) whereas only one (2.5 %) was FNI (Fisher's exact test p=0.028). |
| **Anxiety** | Instrument: State-Trait Anxiety Inventory (STAI), *completed at enrolment in the study, near to term age, and at the infants' 4 months' corrected age follow-up visit*<br>This instrument comprises two 20-item subscales, one for "State", a transitory response to a temporary stressor, and one for "Trait", a stable response style for approaching life stress. Item responses range from 1 to 4 representing low (1=not at all) to high (4=very much) state stress and rare (1=almost never) to frequent (4=almost always) trait stress, giving possible subscale scores between 20 and 80, following reverse coding. Construct validity has been demonstrated for the state anxiety subscale through concordance with the Anxiety Sensitivity Index (Peterson and Reiss 1987), while strong correlation with both the Anxiety Scale Questionnaire and Manifest Anxiety Scales (Tilton 2008) has provided evidence of concurrent validity for the trait anxiety subscale. This instrument has been successfully used among new mothers of both term and preterm infants (Brandon et al. 2011; Dayan et al. 2006; Kikkert et al. 2010; Neu et al. 2014). There is no standard cut-off for referral; however, we used a score of 30 as a threshold to signify elevated levels of anxiety.<br><br>As was the case for CES-D depressive symptom scores, mean state anxiety scores were significantly lower in FNI mothers at 4 months CA (t=2.79, p=0.004); whereas at baseline, neither the current state nor the more stable trait anxiety scores differed by group (see Fig. 1b). At baseline, 57 % of SC mothers and 53 % of FNI mothers reported trait anxiety scores greater than 30 (ns). Also at baseline, 70 % of SC mothers and 71 % of FNI mothers reported state anxiety scores greater than 30 (ns). At baseline, 36 % of SC mothers and 43 % of FNI mothers had CES-D scores greater than 15 (ns). At the near to term age evaluations, the percentage of women with state anxiety scores above 30 had declined from 70 to 59 % of SC and from 71 to 41 % of FNI mothers; this group difference approached significance ($\chi2=2.64$, p=0.10). Similarly, the percentage of women with CES-D scores greater than 15 had declined from enrolment to term age from 36 to 17 % for SC and from 43 to 9 % for FNI; but the group difference at term age was not statistically significant. However, by the time of the 4-month CA follow-up visit, the percentage of SC mothers reporting state anxiety greater than 30 (53 %) was significantly higher than that for FNI mothers (26 %; $\chi2=5.96$; p=0.015). At 4 months, 18 % of SC mothers reported CES-D depressive symptoms greater than 15 while only 3 % of FNI mothers exceeded this threshold ($\chi2=5.00$; p=0.025). |
| **Breastfeeding** | In the SC group, 28.6 % of the mothers were recorded as attempting to breastfeed at least one time as compared to 37.5 % of the FNI mothers ($\chi2=1.02$, p=0.32). Moreover, there was no significant main effect of breastfeeding (Y/N) nor a significant interaction between breastfeeding and the intervention group with regard to 4-month CES-D (p=0.13, p=0.24) or STAI (p=0.24, p=0.94) levels. Similarly, CES-D and STAI scores were decreased by FNI at 4 months, controlling for twin status (p<0.04 and p<0.02, respectively). |
| **Limitations and conclusion** | |
| **Limitations** | First, there were no control conditions employed for specific aspects of the intervention. For example, the SC mothers and infants did not exchange sham odor cloths, i.e., cloths not exposed to the infants and mothers. FNI was designed to improve emotional connectivity by normalizing, to the extent possible in the NICU, the mother/infant experiences of each other. Accordingly, there were multiple opportunities and modes of facilitated interactions: odor exchange, soothing touch, vocal and eye contact, as well as skin-to-skin holding. In this first trial of FNI, it was not possible to include control manipulations for all activities comprising the intervention. Thus, for the present, the effectiveness of FNI can only be evaluated as an integrated and comprehensive intervention strategy.<br>It is also possible that the effectiveness of the intervention, even on long-term outcomes, was not related to specific aspects of the intervention but rather a more general effect related to the special attention that the FNI mothers received. It is important to note that the SC control group, while |

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| | receiving clinical care as usual, also received increased attention from the study staff throughout their infants' NICU stay. SC control mothers were aware that they were in a study and, prior to their acceptance in study, agreed that they could be available to meet on a regular basis with study staff, regardless of which group they were assigned. Study research assistants met with the SC control mothers each week to administer and collect questionnaire information. These questions included tracking when and for how long they visited as well as questions about their activities during visits, for example, "How long did you hold your baby?" Thus, while increased attention from study staff could in part be responsible for effectiveness of the trial, increased attention given to the control group may have actually contributed to smaller differences between the groups. Even if the positive effects of FNI on reducing maternal depressive and anxiety symptoms at 4 months were merely due to participation in the protocol, this would indicate that relatively simple changes in non-clinical activities in the NICU can benefit these mothers and infants. |
| **Authors' conclusion** | The present study demonstrates that FNI is also effective in alleviating self-reported depressive symptoms and anxiety in mothers of preterm infants at 4 months CA, well beyond the time when FNI mothers were engaged in the facilitated intervention. These results indicate that this early hospital-based intervention, which is aimed at facilitating mother-infant emotional connection, may be an effective way to reduce maternal depressive and anxiety symptoms during a crucial period of development of mother/infant coregulation. Reductions in maternal symptoms mediated by FNI are of potential clinical significance to infant development, as well as to maternal health. |

| **Beebe et al. (2018)** | | | |
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| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | Family Nurture Intervention |
| **Country** | USA | **Exposure control group** | Standard care |
| **Setting** | 1 NICU | **Level of prematurity** | 26 – 34 weeks of gestational age |
| **Sample size** | Intervention group: 39<br>Control group: 32 | | |
| **Time frame** | NA | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *See exclusion criteria* | | |
| **Exclusion criteria** | *Parents*<br>We excluded mothers who did not speak English or had a history of drug addiction or mental illness, as well as infants with birth weight below the third percentile for gestational age or significant congenital defect. | | |
| **Newborn and parent characteristics** | A total of 115 mothers and 150 infants (35 sets of twins, 80 singletons, delivered 26–34 weeks gestation) were enrolled. | | |
| **Results** | | | |
| **Parent-newborn interaction** | *Instrument: videotaped at 4 months' corrected age and coded for mother gaze and infant gaze, mother touch, infant vocal affect, and maternal touch* | | |

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| | The first goal was a descriptive evaluation of differences between Family Nurture Intervention (FNI) and standard care (SC) groups. Comparing FNI and SC dyads in mean levels of behaviours using independent t tests, we found no differences. |
| **Limitations and conclusion** | |
| **Limitations** | Lacking sufficient prior literature, we made no specific hypotheses regarding self-contingency. We did not code maternal vocalization, because it will be coded by an automated method, reserved for a future report. A comparison of these preterm infants with a term sample is under way. |
| **Authors' conclusion** | Our randomized control trial of the Family Nurture Intervention in the NICU generated more positive forms of mother and infant engagement at 4 months CA. Our microlevel behavioural coding and time-series approach revealed dimensions of maternal touch, infant vocal affect, and mother and infant gaze hitherto undetected by global coding methods. These results, suggesting greater positive emotional connection, add to the published findings showing immediate and long-term improvements for the FNI group. Because mother–infant coordination during face-to-face communication in the early months of life is a critical foundation for development, this documentation of positive effects of the FNI for 4-month mother–infant face-to-face communication has important implications for an improved developmental trajectory of these infants. |

## *Appendix 2.3.6. CUES program*

| **Zelkowitz et al. (2011)** | | | |
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| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | CUES program: The 6-session Cues program was designed to teach mothers to (1) recognize signs of their anxiety/distress, (2) use various strategies to alleviate their distress, (3) read their infant's communication cues, and (4) respond sensitively to their infant's cues and distress. |
| **Country** | Canada | **Exposure control group** | CARE program: were given general information about infant care, such as sleep position and crib safety |
| **Setting** | 2 tertiary care hospitals in Montreal | **Level of prematurity** | Birth weight < 1500 gr |
| **Sample size** | Intervention group: 48<br>Control group: 50 | | |
| **Time frame** | August 2006 – May 2009 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | Inclusion criteria included singleton births, birth weight <1500 g, mothers able to speak and read either English or French, and living within a 90-minute radius of the hospital. | | |
| **Exclusion criteria** | Exclusion criteria included multiple births, highly unstable infant medical condition such as a Grade IV cerebral haemorrhage, major congenital anomaly, infant likely to be transferred or discharged in <4 weeks, infant hospitalized in a room with the infant of a mother previously recruited into the study (to avoid exchange of information about the experimental program), and infant not in mother's care after discharge. | | |

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| **Newborn and parent characteristics** | **Table 2.** Comparison of the Cues and Care Group Infant Characteristics |

| Variable | Cues | Care |
|---|---|---|
| Infant characteristics | | |
| Infant birth weight (g) | 992.8 (280.7) | 973.4 (219.8) |
| Infant gestational age (wk) | 28.0 (2.3) | 27.9 (2.2) |
| NBRS total score | 3.6 (2.9) | 3.4 (3.0) |
| Infant gender (male) | 26 (43.3%) | 35 (57.4%) |
| IVH Grade 4 (yes) | 0 (0%)[a] | 0 (0%)[b] |
| PVL (yes) | 3 (5.0%)[a] | 3 (4.9%)[b] |
| BPD (yes) | 23 (38.3%) | 26 (42.6%)[c] |

NBRS, Nursery Neurobiological Risk Score; IVH, intraventricular hemorrhage; PVL, periventricular leukomalacia; BPD, bronchopulmonary dysplasia. [a]n = 2 are missing. [b]n = 3 are missing. [c]n = 9 are missing. Continuous variables are presented as mean (SD) unless otherwise noted. Categorical variables are presented as n (%).

| Results | |
|---|---|
| **Parent-newborn interaction** | *Instrument: Global Rating Scales of Mother-Infant Interaction, videotaped and coded for sensitivity, intrusiveness, remoteness, and depression*<br>Infants in the Cues group did not differ from those in the Care group in their interaction with their mothers. They exhibited similar levels of activity, responsiveness and distress. |
| **LOS newborn** | In an exploratory analysis, the 2 groups were virtually identical in terms of the length of the infant's stay in the NICU. |
| **Stress** | *Instrument: Parental Stress Scale : Neonatal Intensive Care Unit, completed at discharge*<br>We found no differences between mothers in the Cues and Care groups in their levels of stress related to their restricted parental role or the infant's appearance and behavior. |
| **Anxiety** | *Instrument: State-Trait Anxiety Inventory (STAI)*<br>There was no difference between Cues group mothers and Care group mothers in mean anxiety scores immediately following the intervention in the univariate analysis, or after conditioning on the baseline score and other a priori determined variables. Following the intervention, both groups of mothers reported fewer symptoms of anxiety than they had at baseline (mean [SD] change score for the Cues group: -20.0 [13.5], p <.0001; Care group: -19.1 [13.8], p < .0001). At baseline, the mean level of anxiety in both groups of mothers was high, with more than half the mothers in both groups scoring in the clinical range. However, at the postintervention assessment the mean anxiety scores were well within the normal range, with only 2 mothers (both in the Care group) having scores in the clinical range. |
| **Depression** | *Instrument: Edinburgh Postnatal Depression Scale*<br>We did not have adequate power to test differences between the experimental and control groups on rates of maternal depression. However, exploratory analysis of this variable indicated that the 2 groups were similar in the prevalence of scores above the cut-point on the Edinburgh Postnatal Depression Scale. |

| | |
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| **Satisfaction** | *Instrument: Visual Analogue Scale*<br>Both groups were very satisfied with the intervention that they received and reported a strong therapeutic alliance with their interveners, indicating that they felt understood and respected and were working on issues of importance to them. |
| **Limitations and conclusion** | |
| **Limitations** | One limitation of the present study is that 23 (19%) of the participants who were randomized were lost to follow-up. It should be noted that in 5 of these 23 cases (22%), this was due to infant death. The majority of those lost to follow-up (15 of 23, 65%) did not complete the intervention, and 6 of them dropped out prior to receiving even a single session of the intervention. Many factors may have contributed to the decision not to start the intervention, including the baby's medical condition. Only 3 participants who completed the intervention were lost to follow-up, suggesting that compliance with the intervention may have affected retention for the purposes of follow-up.<br>The timing of the immediate postintervention assessment (at 6 to 8 wk of corrected age) may have been too early to observe the intervention effects,which may only emerge over time. |
| **Authors' conclusion** | The results of this trial did not show differences between an experimental intervention to reduce anxiety among mothers of very low birth weight (VLBW) infants and an attention control condition, in the immediate postintervention period. It is possible that nonspecific attention may be just as beneficial as specific skills training for mothers during the stressful neonatal intensive care unit (NICU) hospitalization period. The availability of a supportive intervener who is proactive in reaching out to mothers and who provides information and reassurance may be important ingredients in the success of early interventions in the NICU; this warrants further investigation. Longer term follow-up is needed to determine whether intervention effects, on both mothers and their children, may be seen as the infant develops. |

| **Feeley et al. (2012)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | CUES program: The 6-session Cues program was designed to teach mothers to (1) recognize signs of their anxiety/distress, (2) use various strategies to alleviate their distress, (3) read their infant's communication cues, and (4) respond sensitively to their infant's cues and distress. |
| **Country** | Canada | **Exposure control group** | CARE program: were given general information about infant care, such as sleep position and crib safety |
| **Setting** | 2 tertiary care hospitals in Montreal | **Level of prematurity** | Birth weight < 1500 gr |
| **Sample size** | Intervention group: 46<br>Control group: 50 | | |
| **Time frame** | August 2006 – May 2009 | | |

| Newborn and parent characteristics | |
|---|---|
| **Eligibility criteria** | *Parents*<br>Mothers of singleton infants who spoke either English or French and resided within 90 min of the study sites were eligible. Mothers were excluded if they gave birth to multiples, would not be caring for the child after discharge, or their infant had a congenital anomaly or sensory handicap, or might be transferred or discharged in less than 4 weeks. |
| **Exclusion criteria** | *Parents*<br>Mothers were also excluded if their infant was hospitalized in a two-patient room with the infant of a mother already enrolled. |
| **Newborn and parent characteristics** | The mean length of the NICU hospitalization was greater in the Cues group. A greater percentage of the Cues infants had been rehospitalized, were on medication, and had contact with specialized health services after discharge. More Cues mothers were born in North America. A greater percentage of the Care mothers were partnered, and the proportion of male infants was greater in the Care group. |
| **Results** | |
| **Parent-infant interaction** | *Instrument: Global Rating Scales of Mother-Infant Interaction, videotaped and coded for sensitivity, intrusiveness, remoteness, and depression* |

**Comparison of Groups on Postintervention Mother Outcomes**

| Variable | Cues[a] ($n = 46$) | Care[a] ($n = 50$) | CI for difference | Cohen's $d$ | $p$[b] |
|---|---|---|---|---|---|
| Anxiety (STAI) | | | | | |
| Unadjusted $t$ test | 27.8 (7.9) | 30.5 (10.0) | [−0.9, 6.4] | 0.30 | .14 |
| Anxiety adjusted GEE regression[c] | | 0.89 (0.80 to 1.03); $p = .12$ | | | |
| | | | $r^2 = .15$ | | |
| | | | Wald chi-square = 17.4 | | |
| | | | $df = 5$ | | |
| | | | $p$ value (for model) = .0038 | | |
| Interactive behavior (GRS) | | | | | |
| Sensitivity unadjusted $t$ test | 3.9 (0.7) | 3.8 (0.6) | [−0.35, 0.17] | 0.15 | .49 |
| Sensitivity adjusted GEE regression[d] | | 1.01 (0.95 to 1.07); $p = .71$ | | | |
| | | | $r^2 = .34$ | | |
| | | | Wald chi-square = 44.6 | | |
| | | | $df = 5$ | | |
| | | | $p$ value (for model) < .0001 | | |
| Intrusive | 4.0 (0.7) | 3.9 (0.8) | [−0.41, 0.22] | 0.13 | .54 |
| Remote | 4.6 (0.6) | 4.5 (0.8) | [−0.42, 0.14] | 0.14 | .32 |
| Depressive | 4.4 (0.5) | 4.5 (0.4) | [−0.11, 0.29] | 0.22 | .38 |
| Overall interaction | 3.3 (0.8) | 3.3 (0.9) | [−0.43, 0.27] | 0.00 | .66 |
| Psychological distress | | | | | |
| PTSD symptoms total score (PPQ) | 2.4 (2.9) | 3.2 (3.3) | [−0.38, 2.12] | 0.26 | .17 |
| PTSD clinical score (PPQ) | 8 (17) | 11 (22) | [−13%, 23%] | — | .76[e] |
| Depressive symptoms total score (EPDS) | 5.2 (4.9) | 5.0 (4.6) | [−2.1, 1.8] | 0.04 | .86 |
| Depression score in clinical range (EPDS) | 6 (13) | 4 (8) | [−19%, 9%] | — | .51[f] |
| Beliefs about competence | 79.4 (8.7) | 80.4 (7.5) | [−2.27, 4.36] | 0.12 | .53 |

**Anxiety**

*Instrument: State-Trait Anxiety Inventory (STAI), measured at 2 months' and 6 months' corrected age*

The univariate analysis revealed that there was no significant difference in the mean anxiety scores of the Cues and Care mothers when the infants were 6 months of age. Similarly, the GEE regression analysis indicated no statistically significant difference between groups after adjusting for group, infant birth weight, mother's baseline anxiety, education, and place of birth. Furthermore, the mean anxiety scores for both groups were well below the clinical range (i.e., greater than 40). Mother's anxiety decreased significantly in both groups from baseline (46.9 [12.8] in the Cues group and 47.5 [13.9] in the Care group) to 6 months of age (27.8 [7.9] in the Cues group [−19.0], 95% CI of the difference = [−22.9, −15.2], p < 0.00; and 30.5 [10.0] in the Care group [−16.9], 95% CI of the difference = [−21.0, −12.9], p < 0.00).

**Depression**

*Instrument: Edinburgh Postnatal Depression Scale*

There were no significant differences between groups on any other mother outcomes examined.

*See results "Parent-newborn interaction"*

**Limitations and conclusion**

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| **Limitations** | Although the participants did not differ from nonparticipants, only 57.8% of eligible mothers participated. This limits the generalizability of the findings. Rates of attrition (24% Cues and 18% Care) were comparable between groups however; retention was just 79%. Thus, attrition may bias the findings (Orton et al., 2009). Trials testing sensitivity interventions with less than 20% attrition have greater effect sizes than those with more attrition (Bakermans-Kranenburg et al., 2003). Most of the attrition occurred soon after enrolment, a pattern also noted in our pilot study (Feeley et al., 2008). Although mothers were invited to participate after their infant was medically stable, five infants died, and other participants withdrew due to the deterioration of the infant's condition soon after enrolment. The variability of the course of VLBW infants' medical condition in the first few months of life poses feasibility challenges for both intervention and research with their mothers. |
| **Authors' conclusion** | There is no evidence that the Cues program has any differential positive effects on mothers or their infants. Further follow-up is underway to determine whether any effects emerge over time (Clarke & Clarke, 2003). It is imperative to evaluate the longer term impact of the Cues program on mother's sensitivity as empirical evidence suggests that consistency of sensitivity over the first 3 years is important to the development of VLBW children (Landry, Smith, Swank, Assel, & Vellet, 2001; Smith, Landry, & Swank, 2006; Taylor, Anthony, Aghara, Smith, & Landry, 2008). Without intervention, the negative impact of mothers' psychological distress on parenting behavior can persist (Korja et al., 2008), and mothers who are low in sensitivity during infancy are likely to remain so in early childhood (Taylor et al., 2008). Follow-up when the children are 2.5 years old will allow for an assessment of a broader range of child developmental outcomes. Trials are required that include two comparison groups—usual care and attention control. As well, future studies should test sensitivity interventions provided after discharge from the NICU, when attrition is likely to be lower and the intervention more effective. |

## *Appendix 2.3.7. Hospital to Home: Optimising the Infant's Environment (H-HOPE) program*

| **White-Traut et al. (2013)** | | | |
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| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | H-HOPE intervention |
| **Country** | USA | **Exposure control group** | Parent Education Program |
| **Setting** | Two-inner city Midwestern community hospitals with NICUs (one level II and one level III facility) | **Level of prematurity** | |
| **Sample size** | Intervention group: 96<br>Control group:102 | | |
| **Time frame** | NA | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Newborns*<br>Infants met eligibility criteria if they were born between 29 and 34 weeks gestation and had no other major health problems. Infants may have previously received ventilator support or other medical therapies for maintenance (e.g. IV therapy, or oxygen therapy via nasal cannula). However, they had to be deemed clinically stable at the time of enrolment. | | |

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| | *Parents*<br>Their mothers met eligibility criteria if they had at least 2 social-environmental risk factors such as minority status, less then high school education, less than 18 years of age, history of current mental illness e.g. depression, family income less than 185% of the federal poverty guidelines, more than one child under 24 months, four or more children under 4 years of age in the home, or resided in a disadvantaged neighbourhood. |
| **Exclusion criteria** | *Newborns*<br>Infant exclusion criteria included the presence of congenital anomalies, necrotizing enterocolitis, brain injury, chronic lung disease, history of prenatal illicit drug exposure or positive toxicology screen.<br>*Parents*<br>Mothers were excluded if they were illicit drug users, not the legal guardian of the infant or HIV positive. |
| **Newborn and parent characteristics** | Of the 142 mother-infant dyads in this analysis, there were no significant differences in baseline characteristics between the control and H-HOPE groups for any infant or maternal characteristics (See Tables 1 and 2). The sample included 47% female and 53% male infants overall. The average age of the infants was 32.4 weeks gestation at birth (SD = 1.6), and the mean birth weight was 1844 grams (SD = 407). The mean Apgar Score at 5 minutes was 8.3 (SD= 1.1). Infant health status at birth and throughout the infant's hospital stay was assessed by the Problem-Oriented Perinatal Risk Assessment System (POPRAS). The infants' mean POPRAS Score was 70.8 (SD= 19.9) (scores ranged from 36 to 136). At the six week CA follow up visit, mean chronological age was 13.4 weeks (SD = 1.9). Maternal ethnic/racial background was evenly distributed (50% Latina and 50% African American). Mean maternal age was 26 (SD = 6.6). The sample consisted of 41% primiparous mothers; 77% had an education appropriate for their age. The sample was largely homogeneous with respect to income level, with almost 90% of the sample having income <185% of the federal poverty level (FPL) guidelines (as measured by direct reporting of income and household size or, for those who could not report income, participation in the Women, Infants and Children Nutrition program which has an income eligibility level of <185% FPL in Illinois). In addition, 38% of mothers worked before the delivery, 59% lived with the baby's father, 43% screened high for depressive symptoms, and 26% had high trait anxiety. |
| **Results** | |
| **Parent-newborn interaction** | *Instrument 1 (mother-infant interaction during feeding): Nursing Child Assessment Satellite Training–Feeding Scale (NCAST-Feeding), at 6 weeks corrected age*<br>*The Feeding Scale (76 items) consists of six subscales: (a) maternal - sensitivity to cues; (b) maternal response to distress; (c) maternal social - emotional growth-fostering; (d) maternal cognitive were summed to yield a mother score, an infant score, and a total score. Infant clarity of cues includes alert behaviours and responses such as looking at the mother when the mother is looking at the baby, vocalizing to the mother, either initiation of a vocalization or responding to the mothers' vocalization, or touching the mother. An example of an unclear behavioural cue includes lack of signalling readiness to eat, a lack of alertness during the feeding, or lack of movement during the feeding. The NCAST has been widely used in parenting research and has well-established reliability and validity for term and preterm infants. For premature infants, the infant subscales are significantly correlated to later IQ (Barnard, 1989). Internal consistency is high for the total score (a = .86), the mother total score (α =.83) and for the infant total score (α =.73) (Barnard, 1989). The feeding interactions were video-recorded and later judged by a coder. Prior to data collection, two coders were re-trained to criterion of > 90% agreement. Interrater reliability between the primary and a secondary coder was assessed using NCAST manual guidelines throughout the study period and remained above 95% agreement. Both coders were blinded to the infant's group assignment.*<br><br>The mean total NCAST score was marginally ($p < 0.10$) higher for the H-HOPE group compared to the control group. The maternal subscale score for the H-HOPE group showed a mean score slightly higher than the control group, but these differences did not reach significance. The infant subscale score, specifically the infant clarity of cues subscale, was significantly higher for the H-HOPE compared to the control group (Table 3). In multivariable models controlling for significant covariates, H-HOPE dyads had more positive mother-infant interaction during feeding than control dyads, as |

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| | measured by the overall NCAST score, and differences were marginally significant (p = 0.06). For the infant subscale, H-HOPE dyads had significantly higher scores than control dyads (p = 0.05). For the maternal subscale, H-HOPE dyads had higher scores than control dyads, but this finding did not reach statistical significance. In general, dyads with mothers who were anxious performed worse on the NCAST than those with low trait anxiety and dyads with infants who had higher morbidity in the hospital performed better (Table 4).<br><br>*Instrument 2 (mother-infant interaction during play): Dyadic Mutuality Code (DMC), at 6 weeks corrected age*<br>*The DMC measures levels of mutuality in infant-adult interaction, e.g., the partners coordinate repetitive sequences of behavior as they move as a joint unit to higher levels of energy, heightened positive affects, and increased mutual attention (Censullo, Bowler, Lester, & Brazelton, 1987; Lester, Hoffman, & Brazelton, 1985). The DMC consists of six items that represent key components of mutuality: mutual attention, positive affect, mutual turn-taking, maternal pauses, infant clarity of cues, and maternal sensitivity to cues and responsiveness (each scored as 1 if none or very brief and 2 if half the time or more), for a total score (range 6–12). Mothers were given standardized instructions for the 5-minute play session. For analysis, scores were categorized into low (6–8), moderate (9–10), or high responsivity (11–12). DMC reliability and construct and concurrent validity have been established using healthy term and preterm infants (Censullo, no date; Coffman, 1991; Lester et al., 1985; Tronick, Als, & Brazelton, 1980) and in high risk infants (Tronick et al., 1980). Inter-rater reliability was .89 for the total score, with item reliabilities from .82 to .96. Two coders were trained to criterion of > 85% by the developer of the DMC instrument. Like the NCAST, the play sessions were video-recorded and later judged by a coder. Inter-rater reliability between the primary and a secondary coder remained above 98% agreement. Both coders were blinded to the infant's group assignment.*<br><br>Of the mothers and infants assigned to the H-HOPE group, 44.1% were identified as exhibiting high responsivity (11–12) on the Dyadic Mutuality Code (DMC) score, compared to only 28.8% of the control infants. In addition, fewer dyads in the H-HOPE versus control group exhibited low responsivity (score of 6–8), 23.5% vs. 34.2%, respectively (Table 3). The chi-square test for trend was marginally significant (p = 0.055). After adjustment for significant covariates, H-HOPE dyads had 2.37 times (95% CI: 0.97–5.80) higher odds of high versus low responsivity compared to control dyads. The H-HOPE group also had slightly higher odds of having moderate versus low responsivity, but the 95% CI was wide and contained the null value of one (Table 5). Covariates significantly associated with high responsivity included higher infant birthweight, older infant chronological age at the 6 week CA visit, and maternal employment before delivery, although 95% CIs were wide around all OR estimates. |
| **Limitations and conclusion** | |
| **Limitations** | There were a number of limitations to this study. The number of participants with complete data for mother-infant interaction at six weeks CA was diminished because some mothers moved out of the area or discontinued their telephone services and some mother-infant dyads were not able to complete both videos for a variety of reasons. We also failed to include a measure of maternal post-traumatic stress symptomology, which is increasingly recognized as a factor that may add to distress and anxiety for mothers of preterm infants (Forcada-Guex et al., 2011; Holditch-Davis et al., 2003; Pierrehumbert, Nicole, Muller-Nix, Forcada-Guex, & Ansermet, 2003). Finally, mothers in the study were all African American or Latina and predominately low income, limiting generalizability to other groups. A major strength of the study is the use of two different ways of examining mother infant interaction, during feeding and play. Videotaping interactions enabled us to verify the reliability of coding of mother-infant interactions, another strength of the study. |
| **Authors' conclusion** | Our results identified a trend toward more positive mother-infant interaction during both feeding and play for dyads who received the H-HOPE intervention compared to those in the attention control group, and these differences were significant or marginally significant when covariates were controlled. Moreover, the significantly higher score for H-HOPE infants on the infant clarity of cues subscale of the NCAST during feeding supports the effectiveness of the ATVV in helping the infant to organize his/her behaviours. The trend toward higher scores for the H-HOPE mothers on the |

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| | social-emotional growth fostering subscale supports the importance of the H-HOPE mother-focused education component. Mothers who received this education responded to their infant with greater warmth and sensitivity, a key component for infant social development. |

| White-Traut et al. (2015) | | | |
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| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | |
| **Country** | USA | **Exposure control group** | |
| **Setting** | Two inner city community hospitals, one with a Level II (with extended capabilities) and one with a Level III Special Care Nursery | **Level of prematurity** | 29 – 34 weeks of gestational age |
| **Sample size** | Intervention group: 88<br>Control group: 94 | | |
| **Time frame** | NA | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Newborns*<br>Infants were eligible if they were born between 29 and 34 weeks.<br>*Parents*<br>The infants' mothers were eligible if they had at least two social-environmental risk factors that included: self-identified as African-American or Latina, less than high school education, <18 years old, history of current mental illness, depression, family income <150% or poverty, more than one child under 24 months, ⩾4 children o4 years in the household, or residing in a disadvantaged neighbourhood. | | |
| **Exclusion criteria** | *Newborns*<br>Exclusion criteria included congenital anomalies, parenchymal brain injury, necrotizing enterocolitis, chronic lung disease, receiving oxygen via nasal canula, HIV and prenatal drug exposure.<br>*Parents*<br>Mother–infant dyads were excluded if the mother was positive for illicit drug use. | | |
| **Newborn and parent characteristics** | The enrolled sample was predominantly African American (n = 89) and Latina (n = 93). There were 87 male infants and 95 female infants. Mean infant gestational age at birth was 32.6 weeks (s.d. = 1.5). Mean birth weight was 1824.8 g (s.d. = 357.1). The mean chronological age of the infants at baseline was 9.2 days (s.d. = 6.5). The mean 5-min infant APGAR (Appearance, Pulse, Grimace, Activity and Respiration) score was 8.3 (s.d. = 1.0). Infant health status throughout the infant's hospital stay was calculated via the Problem-Oriented Perinatal Risk Assessment System (POPRAS). The mean infant health status score from the POPRAS was 68.1 (s.d. = 18.8). One hundred and twenty-seven mothers began milk expression. At hospital discharge, 48 (27% plus 2 missing milk types) mothers continued with breast milk expression. Of the H-HOPE babies, 55.8% were fed any breast milk and 64.6% of controls were fed breast milk (P = 0.23). The standard of care in both NICUs was to fortify all breast milk feedings when 50% of the feedings contained breast milk. There were no significant group differences. | | |

| Results | |
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| **LOS newborn** | *Measured by subtracting the date of birth from the discharge date*<br>Length of hospital stay did not differ for infants in the H-HOPE (mean = 21.3 days, s.d. = 10.4) and control (mean = 21.4 days, s.d. = 12.5) groups. |
| **Limitations and conclusion** | |
| **Limitations** | The number of infants decreased over the course of hospitalization and thus the number available for analysis after 20 days was reduced. The change in our protocol does not allow for comparison of these findings with our previous research. Finally, infants in this study were all African American or Latina and predominantly low income, limiting generalizability to other groups. |
| **Authors' conclusion** | For healthy preterm infants, the H-HOPE intervention appears to improve weight gain and length over time from birth to hospital discharge. |

## *Appendix 2.3.8. Creating opportunities for Parent Empowerment (COPE) program*

| Melnyk et al. (2001) | | | |
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| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | COPE program |
| **Country** | USA | **Exposure control group** | Audiotaped information |
| **Setting** | 52-bed NICU (level III) within a 720-bed academic medical center in upstate New York | **Level of prematurity** | 26 – 36 weeks of gestational age |
| **Sample size** | Intervention group: 20<br>Control group: 22 | | |
| **Time frame** | NA | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Parents*<br>Eligible mothers were those who: (a) could speak and read English; (b) delivered their infant at the medical center; (c) lived within a 1hr distance from the hospital; and (d) had a singleton birth. | | |
| **Exclusion criteria** | *Parents*<br>Mothers were excluded from the study if their infants had a positive drug screen or a life-threatening complication in the ®rst 24 hr after birth. | | |
| **Newborn and parent characteristics** | The ages of those in the final sample, which had 42 mothers, ranged from 18 to 38 years, with a mean of 27.9 years (SD=5.6). The racial composition of the sample was: 27 (64.3%) White; 11 (26.2%) African American; 2 (4.8%) Asian; 1 (2.4%) Hispanic; and 1 (2.4%) other. The majority of mothers (n=34, 81%) had completed high school. Nineteen (45.2%) mothers were in their first marriages. Household income for the majority (n=30, 71.4%) was at least $15,000 per year. There were no differences on maternal demographic variables between the two groups (Table 1). In addition, there were no differences on these variables between those subjects who completed the study and those lost to follow-up. | | |

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| | The mean gestational age of the premature infants was 31.7 weeks (SD=2.3, range=26±36 weeks) and the mean birth weight was 1613 g (SD=496 g, range=640±2500 g). Twenty-two (52.2%) of the infants were males, and 20 (47.8%) were females. |
| **Results** | |
| **Parent-newborn interaction** | *Instrument: Maternal-Infant Interaction Scale (MISS) and the Nursing Child Assessment Feeding Scale (NCAFS)*<br>There was a small positive effect size for the MIIS for the comparison group at the second observation.<br>MIIS<br>First observational follow-up 36.8 (8.1) 35.7 (9.8) .12<br>Second observational follow-up 40.5 (7.0) 42.1 (4.8) .28[b]<br>HOME scale |
| **LOS newborn** | There also were no significant differences between the length of time in days that the COPE and comparison infants were home before the 3 months' corrected age data collection visit (COPE, M=134.5, SD=19.9; comparison, M=132.8; SD=20.1) and the 6 months' corrected age data collection visit (COPE, M=232.5, SD=22.7; comparison, M=230.5, SD=28.6). |
| **Stress** | *Instrument: Parental Stressor Scale-Neonatal Intensive Care (PSS-NICU)*<br>Regarding emotional coping outcomes, COPE mothers reported significantly less stress on the sights and sounds subscale of the PSS:NICU than did mothers in the comparison program, t(40)=ÿ2.0, p=.05, at the first observational follow-up (Table 3). There was not a significant group difference in stress related to NICU sights and sounds at Phase III. In addition, there was a small positive effect for the COPE program on the PSS:NICU subscale that taps how stressed mothers are by their infants' looks and behaviours at the Phase III intervention contact. However, this difference also was not statistically significant (Table 3). Although there was a small positive effect for the COPE program on mothers' reports of general stress with the experience of having their infant hospitalized in the NICU at the first observational follow-up, the difference in mean scores on this variable was not statistically significant. |
| **Anxiety** | *Instrument: State-Trait Anxiety Inventory (STAI)*<br>There were no statistically significant differences between the study groups on maternal state anxiety, overall negative mood state, and depression during and following hospitalization (Table 3). However, there were small to medium positive effects for the COPE program on: (a) maternal state anxiety at the Phase II and Phase III interventions and (b) maternal depression at the Phase II and Phase IV interventions. |
| **Limitations and conclusion** | |
| **Limitations** | A limitation of this pilot study was the administration of the BSID-II early in infancy, at 3 months' and 6 months' corrected ages. It should be noted that although the BSID-II has been extensively used with infants 1±42 months of age, when administered early in the first year of life, it is better at correctly identifying children with later normal IQs than at identifying infants who would later be cognitively delayed (Harris & Langerkamp, 1994). However, the results of other studies have indicated that early mental development effects, smaller than those found in our study, leverage larger effects later in children's development (Bradley et al., 1997). Continued follow-up of these infants would be important to determine the intervention's longer-term effects on cognitive development.<br>Another limitation of this study was the low internal consistency reliability of the baby subscale of the Parental Beliefs Scale. Therefore, refinement of that subscale and further pilot testing would be important before use in future studies.<br>Finally, a major limitation of this study was its small sample size, which resulted in large variances and limited power to detect statistically significant differences between groups, even when clinically meaningful differences existed. To have yielded a power level of .80 to detect medium positive effects for the COPE program at a .05 level of significance, a sample of 144 mothers would have been necessary (Cohen, 1992). Therefore, it would |

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| | be important to conduct a full-scale study with a larger sample to determine whether the positive outcomes in this study could be replicated and statistically significant differences between the study groups could be detected. |
| **Authors' conclusion** | COPE mothers were significantly less stressed by the NICU sights and sounds and had significantly stronger beliefs about what behaviours and characteristics to expect from their premature infants. Findings from this study support the need for further testing of early NICU interventions with parents to determine their effectiveness on parental coping and infant developmental outcomes |

| **Melnyk et al. (2006)** | | | |
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| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | COPE intervention |
| **Country** | USA | **Exposure control group** | Information regarding hospital services and policies |
| **Setting** | 2 NICUs (a 52-bed NICU within a 720-bed academic medical center [University of Rochester Medical Center, Rochester, NY] and a 60-bed NICU within a 566-bed medical center [Crouse Hospital, Syracuse, NY]) | **Level of prematurity** | 26 – 34 weeks of gestational age |
| **Sample size** | Intervention group: 138<br>Control group: 109 | | |
| **Time frame** | September 2001 – October 2004 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Parents*<br>All mothers and fathers ≥18 years of age who could read and speak English, who had not had another infant admitted to the NICU, and whose infants met the following criteria were eligible for participation: (1) gestational age of 26 to 34 weeks inclusive; (2) birth weight of <2500 g and appropriate for gestational age; (3) anticipated survival; (4) singleton birth; (5) no severe handicapping conditions including grade III or IV intraventricular haemorrhage; and (6) born at the study sites. | | |
| **Exclusion criteria** | - | | |
| **Newborn and parent characteristics** | The 258 mothers ranged in age from 18 to 43 years (mean: 27.8 years; SD: 6.7 years). The racial and ethnic composition of the mothers included 174 (67.4%) white, not Hispanic, 58 (22.5%) black, not Hispanic, and 26 (10.1%) in "other" categories (10 Hispanic, 8 Asian, 1 American Indian, and 7 >1 race). The majority of mothers (n = 212 [82.2%]) completed at least high school. Household income for families was less than $20 001 for 82 (31.5%), between $20 001 and $40 000 for 52 (20.2%), and greater than $40 000 for 103 (39.6%), and 23 (8.8%) families did not report their household income. Eighty-six of the mothers (33.3%) reported being on public assistance. One hundred thirty-eight (53.4%) of the mothers were married, 98 (38.0%) had never been married, 11 (4.3%) reported some other status (divorced or separated), and 11 (4.3%) did not report their status. The ages of the 155 fathers/significant others ranged from 18 to 49 (mean: 30.6 years; SD: 7.4 years). The racial and ethnic composition of the fathers was: 115 (76.2%) white, not Hispanic, 23 (15.2%) black, not Hispanic, and 13 (8.6%) other (5 Hispanic, 4 Asian, 1 American Indian, and 3 >1 race). The majority of | | |

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| | fathers (n = 126 [83.4%]) completed at least high school. Ninety six (63.6%) of the fathers were married, 39 (25.8%) had never been married, 7 (3.2%) reported some other status (divorced or separated), and 9 (6.0%) did not report their status.<br>The mean gestational age of the premature infants was 31.3 weeks (SD: 2.4; range: 26.0–35.0 weeks). The mean birth weight was 1650 g (SD: 476 g), with 102 (39.2%) infants weighing <1500 g, 84 (32.3%) in the 1500- to 1999-g range, and 74 (28.5%) weighing <2000 g. One hundred twenty six (48.5%) of the infants were males, and 134 (51.5%) were females. The mean illness severity index level using the CRIB score was 1.7 (SD: 2.5; range: 0–12). Mean weight at discharge from the NICU was 2150.3 g (SD: 440.4 g; range: 955–4710 g). Total LOS in the NICU averaged 35.2 days (SD: 27.3 days; range: 5–163 days). Sixty-one infants (24.3%) were transferred to another hospital before discharge to home. |
| **Results** | |
| **LOS newborn** | *Reported as the number of days of hospitalization in the NICU. The total hospital LOS included NICU days plus convalescent care in a transfer hospital or step-down unit before being discharged to home.*<br>The total NICU infant LOS (n = 241) was 3.8 days shorter for those in the COPE group (mean: 31.86 days; SD: 22.54 days; 95% confidence interval [CI]: 29.32–34.41) than for those in the comparison group (mean: 35.63 days; SD: 26.85 days; 95% CI: 32.80–38.46) (P = .05; see Fig 3). In addition, the total hospital LOS, including days spent in transfer hospitals, was 3.9 days shorter for infants in the COPE group (mean: 35.29 days; SD: 22.40 days; 95% CI: 33.06–37.52) versus comparison infants (mean: 39.19 days; SD: 27.00 days; 95% CI:36.69–41.69) (P = .02). |
| **Stress** | *Instrument: Parental Stressor Scale-Neonatal Intensive Care (PSS-NICU)*<br>During the NICU hospitalization, mothers in the COPE program reported significantly less overall parental stress in the NICU than did mothers in the comparison group and specifically related to their general NICU stress, their infants' behaviors, and staff behaviors. There were no differences between the groups on fathers' reports of stress in the NICU. |
| **Anxiety** | *Instrument: State-Trait Anxiety Inventory (STAI)*<br>In addition, both mothers' and fathers' state anxiety and depressive symptoms decreased over time, without significant COPE- and comparison- group differences identified. |
| **Limitations and conclusion** | |
| **Limitations** | One of the limitations of this study is that it was conducted in only 2 level 3 NICUs located in hospitals within the northeast region of the United States. Potential differences in practice may exist in other institutions that may influence generalizability of our findings. Another potential limitation that should be noted is that this sample includes relatively healthy and larger premature infants (~60% of the infants were >1500 g). However, research has indicated that even larger and healthier preterm infants are likely to be treated differently by their parents on the basis of their perceptions of their preterm infant termed "prematurity stereotyping." Even having a relatively well infant in the NICU can be emotionally disturbing |
| **Authors' conclusion** | Interventions to enhance coping and mental health outcomes in parents of LBW premature infants to improve both parent and child health outcomes have lagged behind the rapid technologic advances to sustain survival in NICUs. However, evidence now has accumulated to support that the COPE program not only improves parent coping and mental health outcomes during, as well as shortly after, hospitalization but also reduces hospital LOS. Continued study of these infants and their parents is currently underway, through 3 years of age, to determine the more long-term effects of the COPE program. Although this study demonstrates considerable cost savings during the NICU stay, sustainable long-term effects could result in additional savings to a burdened health care system. More important is that the COPE program facilitates the development of critical parenting skills that are needed to shape the next generation of a high-risk group of families. |

## *Appendix 2.3.9. Psychological interventions*

### Early preventive attachment-oriented psychotherapeutic program

| Birsch et al. (2003) | | | |
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| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | Early preventive attachment-oriented psychotherapeutic program |
| **Country** | Germany | **Exposure control group** | Standard care |
| **Setting** | NICU and maternity ward of Children's Hospital University of Ulm | **Level of prematurity** | Birth weight ≤ 1500 gr |
| **Sample size** | Intervention group: 43<br>Control group: 44 | | |
| **Time frame** | November 1994 – November 1997 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | Mothers and fathers of premature infants (≤ 1500 grams of birthweight) were recruited from the NICU and from the maternity ward several days after their preterm was born. | | |
| **Exclusion criteria** | - | | |
| **Newborn and parent characteristics** | This is the data of singletons and of each firstborn infant from twins and from triplets, respectively. The birthweights of the infants in the control group (M = 987 grams, SD 254, range 460 – 1490) and in the intervention group (M = 919 grams, SD 290, range 440 – 1490) and the weeks of gestation in the control group (M = 27 weeks, SD 2.7, range 24 – 35) and in the intervention group (M= 27 weeks, SD 2.3, range 24 – 33) did not display significant statistical differences nor did the distribution of gender (20 male and 24 female infants in the control group and 27 male and 16 female in the intervention group). Thus, both groups were comparable for further statistical evaluation.<br>The mean age of the mothers was 30.9 years (SD 4.9, range = 18 – 40 years,) in the control and 30.9 years (SD 4.3, range = 23 – 42 years) in the intervention group. The control and the intervention group did not show significant differences in relevant control variables (marital status, years of school and professional education, mother's profession, loss of employment, separation from partner, severe illness of mother, severe illness of close relative, relatives to care for in the family, poor housing conditions, deaths of relatives, other important life events). | | |
| **Results** | | | |
| **Parent-newborn attachment** | *Instrument: Strange Situation Procedure, carried out at 14 months' corrected age by blinded coders*<br>Out of all infants who were seen in the Strange Situation Procedure with their mother (N = 71), n = 3 infants could not be classified in respect to their attachment quality. Out of the remaining sample (n = 68), 69.1% of the preterm infants were securely and 30.9% were insecurely attached. Within the control group, 77.8% of the preterm infants showed a secure attachment classification, 8.3% were insecurely avoidant and 13.9% insecurely ambivalent attached. In the intervention group only 59.4% of the preterms were securely attached, whereas a higher percentage than in the control | | |

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| | group was insecurely avoidant (31.3%) and a lesser percentage of 9.4% was insecurely ambivalent attached. Altogether, only n = 3 infants could not be classified (n = 2) in the intervention group and n = 1 in the control group). Infants who could not be classified were all neurologically impaired, but the reasons for no classification were different: one infant was severely disabled and was not able to show signs of an activation of the attachment system during separation, one infant was so extraordinarily strange in his behaviour that a classification was uncertain and could not be assigned, and one videotape recording displayed audio-technical problems so that the coders did not feel confident in assigning this infant to one of the groups of attachment patterns.<br>The group differences in the results between control and intervention group (see Table 1, computed only for a 262 table), did not reach a statistical significance, but showed a tendency (p = .084 in Fisher's Exact Test (1-tailed)) which – based on the adjusted residuals – was due to a high percentage of infants with a secure attachment representation in the control group and a high percentage of infants with a dismissing classification of attachment representation in the intervention group. |
| **Neuro-developmental impairment** | *Instrument: Classification of Grade of Neurological Impairment, neurological exam by a blinded child neurologist*<br>In the total sample there was no significant correspondence between neurological development and infants' attachment quality. Infants with secure attachment displayed a similar percentage of healthy (48.9%) as impaired (51.1%) neurological development. On the contrary, infants with insecure attachment showed 71.4% of impaired development. Although subjects were randomly assigned to the control and the intervention group, the data of the neurological development of the infants at 14 months (corrected for prematurity) revealed a significant difference in the two groups (Fisher's Exact Test (2-tailed) p = .009) with more infants being neurologically impaired in the intervention group (23.7% healthy vs. 76.3% impaired) than in the control group (54.1% healthy vs. 45.9% impaired).<br>This difference is reflected in the significant (p = .049 (2-tailed), Fisher's Exact Test (1-tailed) p = .058) correspondence of neurological development and attachment development of the infants in the control group revealing that infants with secure infant – mother attachment showed a high percentage of neurologically healthy development (64.3%), whereas those with insecure attachment were predominantly neurologically impaired (75%). However, in the intervention group, there was no significant correspondence between neurological development and infant – mother attachment quality. On the contrary, a high percentage of securely attached infants were disabled (73.7%), despite a significant higher percentage of disabled infants in the intervention group. |
| **Limitations and conclusion** | |
| **Limitations** | The drop-out rate in the control group and in the intervention group was comparable, however, more mothers in the intervention group (four out of five) dropped out because of postnatal death of their infants, whereas only one infants died in the control group. This could indicate that more neonatal complications and risk conditions in the sample of the intervention group interfered with the infants' development, which could not be foreseen, as the neonatal and postnatal course of somatic development is sometimes not predictable. |
| **Authors' conclusion** | There was no significant statistical difference in terms of quality of attachment of the preterm infants between the control group and the intervention group. However, only in the control group, impaired neurological development corresponded significantly with an insecure quality of attachment, but not in the intervention group, although there were significantly more neurologically impaired infants in the intervention group. |

### Triadic parent-infant Relationship Therapy (TRT)

| Castel et al. (2016) | | | |
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| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | Triadic parent-infant Relationship Therapy (TRT) |
| **Country** | France | **Exposure control group** | Standard care |
| **Setting** | Neonatal department of the University Hospital of Caen | **Level of prematurity** | 28 - 35 weeks gestational age + 6 days |
| **Sample size** | Intervention group: 33<br>Control group: 32 | | |
| **Time frame** | 1 June 2006 – 30 August 2008 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Newborns*<br>Enrolled children were required to be between 28 and 35 weeks gestational age + 6 days with no congenital anomalies or any other foreseeable disabilities during the neonatal period. Siblings were not excluded from the study.<br>*Parents*<br>As inclusion criteria, the parents were required to be French speakers, over 18 years old, without known psychiatric history and residing within a 50-km radius of the hospital. | | |
| **Exclusion criteria** | - | | |
| **Newborn and parent characteristics** | Statistically significant differences were observed for mother's trauma history and hospitalizations in the Kangaroo unit. The difference was close to significance for the father's level of education and the child's birth weight. | | |
| **Results** | | | |
| **Stress** | *Instrument: Parenting Stress Index Short Form (PSI-SF)*<br>*The PSI-SF contains 36 items and yields a Total Stress score indicative of the overall level of parenting stress in addition to three subscales: Parental Distress, Parent-Child Dysfunctional Interaction and Difficult Child. The PSI-SF Total Score constituted the study's primary assessment criterion.*<br><br>Regarding the overall level of parenting stress (PSI-SF global score), the group × time interaction was significant for the mothers, with a highly significant 16.6-point difference for the intervention group at 18 months relative to a non-significant difference at 3 months. This interaction was also significant for fathers, with a significant 11.7-point difference for the intervention group at 18 months relative to a non-significant difference at 3 months. The mothers' and fathers' respective overall PSI-SF scores were significantly and positively correlated at 3 and 18 months: r = 0.52 (95% CI: 0.27–0.71), p < 0.001 at 3 months and r = 0.63 (95% CI: 0.41–0.79), p < 0.001 at 18 months. Similar results were found for the mothers in the “Parent” and “Parent-Child Relationship” domains at 3 months, with significantly lower stress levels in the intervention group at 18 months (4.1 and | | |

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| | 7.1 points, respectively). A difference was also detected in favour of the intervention group for the "Child" domain (p b 0.001), with no difference in the magnitude of the gap between the two time points (no significant interaction). For the fathers, a "group effect" was observed for the "Child" domain at 18 months (a 3.6-point difference) but not at 3 months. Differences between the two groups were not significant for the "Parent" or "Parent-Child Relationship" domains, but the significance levels approached the threshold. |
| **Depression** | *Instrument: Edinburgh Postnatal Depression Scale (EPDS).*<br>*The cut-off we used for mother depression was N11 and for father depression N9.*<br><br>Parental mental health (EPDS and PTSD) was better at 18 months in the intervention group for both mothers and fathers. A significant 2.8-point difference on the EPDS score was observed for mothers of the intervention group in reference to the control group; a significant 2.6-point difference was observed for fathers. The proportion of mothers exceeding the cut-off for depression (EPDS > 11) remained stable in the control group (20.0% at baseline, 20.8% at 18 months) but decreased significantly in the intervention group (from 31.3% to 0%). The proportion of fathers exceeding the cut-off for depression (EPDS > 9) decreased from 14.3% at baseline to 10.5% at 18 months in the control group and from 10.0% to 0% in the intervention group, not significantly in both cases. |
| **Neurodevelopmental impairment** | *Instrument: Brunet-Lézine Revised Test*<br>*This test yields four developmental age sub-scores, for children aged 2 to 30 months, covering the domains of movement and posture, language, socialization, and coordination. The combination of these four sub-scores provides a global Developmental Quotient (DQ).*<br><br>Concerning the children's DQ, a significant and consistent over time difference was detected in favour of the intervention group (estimated mean score difference 7.8 points, p < 0.001). Similar results were found for the motor, language and socialization sub-scores, the strongest difference being observed for motor development, with an estimated mean score difference of nearly 12 points between the 2 groups (p < 0.001). The intervention effect was also strong for the language and socialization domains, with a nearly 8-point difference (p < 0.01). The difference was close to significance for the coordination sub-score. |
| **Limitations and conclusion** | |
| **Limitations** | Our study has some weaknesses. There was no a priori power calculation, and our target population was fairly small. The sample size was nevertheless sufficiently large to demonstrate an effect on the primary outcome and most of the secondary outcomes. Our study included a limited number of very preterm infants. However, in terms of public health, late prematurity is a major concern because it is overrepresented. In addition, we deliberately targeted children at low risk of sequelae because the aim of the intervention was to act on the family environment, a key factor in the optimal development of children. Despite randomization, the intervention group reported an increased frequency of maternal trauma history, lower parental education levels, lower mean birth weights and a lower number of hospitalization cases in mother-child care-units in comparison to the control group. Despite these four disadvantages, the intervention group showed benefits to the entire family. Furthermore, for each outcome, the results remained mainly unchanged after adjusting for baseline characteristics that differed between the 2 groups. Behavioural and emotional development data have been reported by parents. We cannot exclude a degree of interference with ratings due to parental mental health. A final limitation of our study, common to most of the other psychological intervention randomized trials, is that there was no control for the amount of attention received by the families of the intervention group, which could be achieved through the inclusion of an attention placebo control group. However, there is no gold standard for the choice of the type of attention to give to the subjects of the control group and a bad choice could lead to ethical problems and high drop-out rates. This issue warrants further study. In the field of early intervention programs for preterm infants and their parents, we only found two studies where such a control was implemented. |

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| **Authors' conclusion** | The TRT approach has proven to be effective in reducing parenting stress among both mothers and fathers, which is correlated with improvements in infant development assessed at 18 months. |

## *Appendix 2.3.10. Family-integrated care*

| O'BRIEN ET AL. (2018) | | | |
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| **Methods** | | | |
| **Design** | Multicentre, cluster-randomised controlled trial | **Exposure intervention group** | Family-integrated care |
| **Country** | Canada, Australia and New Zealand | **Exposure control group** | Standard care |
| **Setting** | 25 NICUs in Canada, Australia and New Zealand | **Level of prematurity** | ≤ 33 weeks of gestational age |
| **Sample size** | Intervention group: 895<br>Control group: 891 | | |
| **Time frame** | April 2013 – August 2015 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | Infants were eligible if born before or at 33 weeks' gestation with no or low-level respiratory support (i.e., oxygen by cannula or mask, or non-invasive ventilation such as continuous positive airway pressure [CPAP], biphasic CPAP, and nasal intermittent positive pressure ventilation). | | |
| **Exclusion criteria** | Infants were excluded if they received palliative care, had a major life-threatening congenital anomaly, had a critical illness and were unlikely to survive, were on high-level respiratory support (invasive ventilation), were scheduled for early transfer to another hospital, or were born to parents unable to participate because of health, social, or language barriers. | | |
| **Newborn and parent characteristics** | The age at enrolment was similar between the two groups, although a greater proportion of infants in the FICare group were born at a younger gestational age (22–28 weeks) than those in the standard care group (table 1). Also, more parents in the FICare group self-identified as being Caucasian in the demographic survey. | | |
| **Results** | | | |
| **LOS newborn** | There were no significant differences between groups in the secondary outcome duration of stay in hospital. | | |

| | FICare (n=895) | Standard care (n=891) | p value* | Adjusted difference (95% CI); p value† | Adjusted OR (95% CI); p value† |
|---|---|---|---|---|---|
| **Mean weight gain** | | | | | |
| Mean change in Z score at 21 days | 1·58 (0·51) | 1·45 (0·49) | <0·0001 | 0·11 (0·06–0·16); p<0·0001 | .. |
| Mean daily weight gain | 26·7 (9·4) | 24·8 (9·5) | <0·0001 | 2·03 (1·10–3·00); p<0·0001 | .. |
| Percentage change in weight at 21 days | 42·6% (15·1) | 38·9% (13·9) | <0·0001 | 3·47 (1·89–4·94); p<0·0001 | .. |
| **Mortality and morbidity** | | | | | |
| Mortality | 11/895 (1%) | 4/891 (<1%) | 0·21 | .. | 2·21 (0·64–7·68); p=0·21 |
| Necrotising enterocolitis | 23/891 (3%) | 15/887 (2%) | 0·25 | .. | 1·34 (0·73–2·45); p=0·27 |
| Bronchopulmonary dysplasia | 167/889 (19%) | 149/887 (17%) | 0·41 | .. | 0·80 (0·44–1·46); p=0·37 |
| Nosocomial infection | 49/895 (5%) | 44/890 (5%) | 0·69 | .. | 0·90 (0·47–1·75); p=0·76 |
| Retinopathy of prematurity‡ | 43/591 (7%) | 33/504 (7%) | 0·84 | .. | 0·94 (0·67–1·31); p=0·73 |
| Intraventricular haemorrhage‡ | 109/756 (14%) | 63/802 (8%) | 0·023 | .. | 1·63 (0·97–2·75); p=0·06 |
| Resource use | | | | | |
| Mean duration of hospital stay (days) | 50 (1·9) | 48 (2·3) | 0·19 | .. | 1·12 (0·81–1·54); p=0·51 |
| Median duration of oxygen support (days) | 4 ( 0–36) | 3 (1–33) | 0·67 | .. | 1·00 (0·75–1·27); p=0·86 |

Data are n/N (%), mean (SD), or median (IQR). FICare=Family Integrated Care. OR=odds ratio. *Based on generalised estimating equations to account for clustering. †Adjusted for gestational age, infant age at enrolment, small for gestational age, singleton status, surfactant use, and caesarean delivery. ‡Of stage 3 or higher.

*Table 3:* **Assessment of neonatal outcomes and resource use with univariate and multivariable analyses**

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| **Stress** | *Instrument: 34-item Parental Stress Scale: Neonatal Intensive Care unit (PSS:NICU), at enrolment and day 21*<br>At enrolment, total stress and anxiety scores among parents were similar in both groups (mean stress score 2·79 [SD 0·75] in FICare group vs 2·72 [0·78] in standard care group; p=0·091; mean anxiety score 83·7 [22·6] vs 81·5 [21·8]; p=0·062). The mean scores were lower in both study groups at day 21; however, the mean stress and anxiety scores for parents in the FICare group were significantly lower than those for parents in the standard care group by day 21 (figure 3; stress scores 2·3 [SD 0·8] vs 2·5 [0·8], p<0·00043; anxiety scores 70·8 [20·1] vs 74·2 [199], p=0·0045). |
| **Anxiety** | *Instrument: State-Trait Anxiety Inventory (STAI), at enrolment and day 21*<br>At enrolment, total stress and anxiety scores among parents were similar in both groups (mean stress score 2·79 [SD 0·75] in FICare group vs 2·72 [0·78] in standard care group; p=0·091; mean anxiety score 83·7 [22·6] vs 81·5 [21·8]; p=0·062). The mean scores were lower in both study groups at day 21; however, the mean stress and anxiety scores for parents in the FICare group were significantly lower than those for parents in the standard care group by day 21 (figure 3; stress scores 2·3 [SD 0·8] vs 2·5 [0·8], p<0·00043; anxiety scores 70·8 [20·1] vs 74·2 [199], p=0·0045). |
| **Breastfeeding** | *Measured by high-frequency breastfeeding at hospital discharge*<br>However, the rate of high-frequency breastmilk feeds (>6 times a day) at discharge home was higher in the FICare group than in the standard care group (279 [70%] of 396 infants vs 394 [63%] of 624]; p=0.016). Of infant receiving high-frequency breastmilk feeds, a greater proportion of those in the FICare group were fed at the breast, as opposed to bottle, than those in the standard care group (92 [33%] of 279 vs 37 [9%] of 394; p<0.0001). |
| **Limitations and conclusion** | |
| **Limitations** | Cluster-randomised controlled trials are more prone to bias than are individual patient randomised controlled trials because of variations in practice, unbalanced patient populations, and staff cultures that are not captured or measured during the study. For example, our study had a random imbalance in infants younger than 29 weeks' gestation (there were more in the FICare group) and singletons (more in standard care group). To address possible confounding factors in neonatal practice, we stratified sites by country and size before they were randomly assigned. We were unable to control for |

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| | nutritional policies or resource use. Specific to this study, FICare parents were asked to make a very different commitment than were standard care parents, resulting in the possibility that more committed parents enrolled in FICare; the proportion of families who participated at FICare sites (30%) was different than at the standard care sites (44%). However, our sensitivity analysis, which included family demographic data as well as the infant data, showed that the intervention effects remained significant, regardless of the family demographics. One last potential source of bias from the study design is that over the duration of the study, some standard care sites could have adopted local family-oriented practices that were not recorded and might have biased the results towards a less detectable difference.<br>Our study had other limitations that were independent of the study design. First, we have less information about the status of infants in the FICare group on discharge home than about infants in the standard care group. The increased rate of transfer of infants from FICare sites to level 2 NICUs before discharge home was not something that we anticipated when assigning sites. These missing data might have resulted in a type I error, which limits our conclusions about the success of breastfeeding in this population. Furthermore, we did not report the difference in weight gain at 36 weeks and at discharge home between infants in both groups because many of the data were missing. Second, some secondary outcomes (e.g., intraventricular haemorrhage, nosocomial infection, or bronchopulmonary dysplasia) either occur before trial enrolment or are predetermined at the time at enrolment. |
| **Authors' conclusion** | FICare improved infant weight gain, decreased parent stress and anxiety, and increased high-frequency exclusive breastmilk feeding at discharge, which together suggest that FICare is an important advancement in neonatal care. Further research is required to examine if these results translate into better long-term outcomes for families. |

| **Benzies et al. (2020)** | | | |
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| **Methods** | | | |
| **Design** | Cluster randomised controlled trial | **Exposure intervention group** | Alberta FICare™ |
| **Country** | Canada | **Exposure control group** | Standard care: NICU care as usual, with the addition of postpartum depression screening and referral to additional supports if needed. |
| **Setting** | 10 level II NICUs across 6 cities in Alberta | **Level of prematurity** | 32 – 35 weeks gestational age |
| **Sample size** | Intervention group: 353 infants/308 mother<br>Control group: 365 infants/306 mothers | | |
| **Time frame** | 15 December 2015 – 26 July 2018 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Newborns*<br>We included mothers and their preterm singleton or twin infants born between 32 0/7 and 34 6/7 weeks gestational age (GA) inclusive, with a primary admission or transfer within 72 h to a level II NICU.<br>*Parents*<br>At intervention sites, we included mothers who committed to spending a minimum of 6 h per day with their infant(s). | | |

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| **Exclusion criteria** | *Parents*<br>We excluded mothers (1) whose health, social, or language issues may have interfered with their ability to communicate with the health care team, (2) with triplets or higher order multiple births, and (3) whose infants required palliative care or had severe congenital or chromosomal anomalies. |
| **Newborn and parent characteristics** | Compared to the standard care group, the intervention group had a significantly higher proportion of mothers who were Caucasian and born in Canada (χ2 P = .01 for both variables). However, in univariate regression analyses, neither of these maternal variables were associated with infant LOS (born in Canada vs not: R2 = .000, P = .74; Caucasian vs non-Caucasian: R2 = .002, P = .24). |
| **Results** | |
| **LOS newborn** | *Measured from date and time of birth to date and time of discharge*<br>Mean LOS adjusted for site geographic area and infant risk factors was shorter for infants in the Alberta FICare™ group (17.62 days; 95% CI, 16.27 to 18.96) than the standard care group (20.16 days; 95% CI, 18.83 to 21.50), with a treatment effect of − 2.55 days in favor of Alberta FICare™ (95% CI, − 4.46 to − 0.66; P = .02; Table 3). A permutation test confirmed this result with P = .05. The forest plot in Fig. 2 summarizes the unadjusted and geographic area/risk-adjusted mean LOS for each site. |
| **Readmission newborn** | *Measured by hospital readmission withing 2 months' corrected age*<br>Groups were similar in proportions of infants with hospital readmissions (6.2% Alberta FICare™ vs 6.6% standard care; P = .85). |
| **Stress** | *Instrument: Parental Stress Scale: Neonatal Intensive Care unit (PSS:NICU), within 72h of infant being admitted and 72h prior to discharge of the infant*<br>Type of feeding and maternal outcomes at discharge were also not significantly different between groups. |

**Table 3** Infant outcomes

| Outcome | Alberta FICare™ (*n* = 353) | Standard care (*n* = 365) | Effect | *P* value | Permutation test *P* value |
|---|---|---|---|---|---|
| **Primary outcome** | **Mean (95% CI)** | **Mean (95% CI)** | **Mean difference (95% CI)** | | |
| Length of stay, days | | | | | |
| Unadjusted | 17.62 (15.23, 20.01) | 19.58 (17.23, 21.94) | −1.96 (−5.32, 1.40) | .22 | .28 |
| Adjusted for site geographic area | 18.06 (16.55, 19.58) | 20.47 (18.98, 21.96) | −2.40 (− 4.53, − 0.28) | .03 | .13 |
| Adjusted for site geographic area/ infant risk factors | 17.62 (16.27, 18.96) | 20.16 (18.83, 21.50) | −2.55 (− 4.44, − 0.66) | .02 | .05 |
| **Secondary outcomes** | ***n* (%)** | ***n* (%)** | **OR (95% CI)** | | |
| Hospital readmission to 2 months CA | 22 (6.2) | 24 (6.6) | 0.94 (0.52, 1.72) | .85 | – |
| Emergency department visit to 2 months CA | 83 (23.5) | 93 (25.5) | 0.90 (0.64, 1.26) | .54 | – |
| Feeding at discharge[a] | | | | | |
| Breastmilk only | 217 (70.0) | 175 (66.8) | – | .57 | – |
| Combination | 78 (25.2) | 76 (29.0) | | | |
| Formula only | 15 (4.8) | 11 (4.2) | | | |

*Abbreviations*: *FICare* Family Integrated Care, *CA* corrected age
[a] *n* = 310 for Alberta FICare group and *n* = 262 for standard care group due to missing data

**Table 4** Maternal outcomes

| Outcome measure | Baseline Alberta FICare™ Mean (*SD*) | Baseline Standard care Mean (*SD*) | Discharge Alberta FICare™ Mean (*SD*) | Discharge Standard care Mean (*SD*) | Model adjustment | Mean difference at discharge (95% CI) | *P* value |
|---|---|---|---|---|---|---|---|
| STAI-Trait[a] | 35.43 (9.36) | 34.85 (8.91) | – | – | | – | – |
| STAI-State[a] | 38.24 (12.01) | 37.22 (11.36) | 31.26 (10.00) | 32.62 (9.94) | None | −1.80 (−4.74, 1.13) | .20 |
| | | | | | Geographic area | −1.61 (−4.36, 1.13) | .21 |
| | | | | | Geographic area and infant risk factors | −1.43 (−4.23, 1.36) | .27 |
| EPDS[b] | 7.85 (4.76) | 8.01 (4.87) | 6.20 (4.34) | 7.03 (4.62) | None | −0.75 (−1.80, 0.30) | .14 |
| | | | | | Geographic area | −0.70 (−1.75, 0.36) | .17 |
| | | | | | Geographic area and infant risk factors | −0.61 (−1.66, 0.45) | .22 |
| PSS:NICU[c] | 2.59 (0.80) | 2.61 (0.82) | 2.43 (0.84) | 2.57 (0.85) | None | −0.13 (− 0.28, 0.02) | .09 |
| | | | | | Geographic area | −0.12 (− 0.27, 0.03) | .10 |
| | | | | | Geographic area and infant risk factors | −0.13 (− 0.29, 0.04) | .11 |
| PMP S-E[d] | 62.76 (10.71) | 63.53 (10.66) | 73.64 (6.25) | 72.35 (6.64) | None | 1.45 (−0.81, 3.71) | .16 |
| | | | | | Geographic area | 1.11 (−0.46, 2.68) | .14 |
| | | | | | Geographic area and infant risk factors | 0.96 (−0.57, 2.50) | .19 |

All models included admission scores as covariates. The models for state anxiety also controlled for trait anxiety, which was measured only at admission
*Abbreviations: FICare* Family Integrated Care, *STAI* State-Trait Anxiety Inventory, *EPDS* Edinburgh Postnatal Depression Scale, *PSS:NICU* Parental Stressor Scale: Neonatal Intensive Care Unit, *PMP S-E* Perceived Maternal Parenting Self-Efficacy
[a] *n* = 267 for Alberta FICare™ group and *n* = 215 for standard care group
[b] *n* = 268 for Alberta FICare™ group and n = 215 for standard care group
[c] *n* = 268 for Alberta FICare™ group and n = 217 for standard care group
[d] *n* = 266 for Alberta FICare™ group and *n* = 217 for standard care group

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| **Anxiety** | *Instrument: State-Trait Anxiety Inventory (STAI), within 72h of infant being admitted and 72h prior to discharge of the infant*<br>Type of feeding and maternal outcomes at discharge were also not significantly different between groups.<br>*For effect sizes, see table results "Stress"* |
| **Depression** | *Instrument: Edinburgh Postnatal Depression Scale (EPDS), within 72h of infant being admitted and 72h prior to discharge of the infant*<br>Type of feeding and maternal outcomes at discharge were also not significantly different between groups.<br>*For effect sizes, see table results "Stress"* |
| **Breastfeeding** | *Measured by type of feeding at discharge (breastmilk only, combination of breastmilk and formula, or formula only)*<br>Type of feeding and maternal outcomes at discharge were also not significantly different between groups.<br>*For effect sizes, see table results "LOS newborn"* |
| **Limitations and conclusion** | |
| **Limitations** | This study has several limitations. First, components of the Alberta FICare™ intervention (required time spent in NICU and parking passes) were intentionally designed to facilitate parental presence. Although parental presence may have increased parental confidence and shortened LOS, these |

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| | intervention components were designed as part of the Alberta FICare™ bundle; effects of individual components cannot be disentangled from the whole. Health system policy changes that provide parking passes to all parents of infants in NICU and repeated evaluation of Alberta FICare™ may identify the most effective components of the intervention. Although there was a statistically significant group difference in parental time spent in NICU (9.00 vs. 7.79 h for Alberta FICare™ and standard care groups, respectively), a 1.21-h difference is unlikely to be clinically relevant. Second, the rate of missing maternal data differed between groups; 87% of mothers in the intervention group completed both surveys versus 71% of mothers in the standard care group. Since data on type of feeding was reported by mothers on the discharge survey, this resulted in more missing infant feeding data for infants in the standard care group compared to infants in the Alberta FICare™ group. Third, Alberta has a single health services delivery system with many standardized structures and processes. Thus, results may not be generalizable to other systems of care. Fourth, there were insufficient sites in the province for a cRCT and this study was underpowered for the planned analysis. |
| **Authors' conclusion** | Alberta FICare™ in level II NICUs reduced hospital LOS in preterm infants born between 320/7 and 346/7 weeks GA, without concomitant increases in readmissions and emergency department visits. A small number of sites in a single jurisdiction and inclusion of a select group of mothers and infants limit generalizability of findings. Country-wide replication of the trial in all level II NICUs would increase generalizability. |

| **Church et al. (2020)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Cluster randomised controlled trial | **Exposure intervention group** | Family-integrated care approach |
| **Country** | Canada | **Exposure control group** | Non-family integrated care approach |
| **Setting** | 7 family-integrated sites and 7 control sites | **Level of prematurity** | < 33 weeks of gestational age |
| **Sample size** | Intervention group: 123<br>Control group: 62 | | |
| **Time frame** | NA | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | Families were approached for enrolment if their infant was born less than 33 weeks' gestation, they were enrolled in Canadian sites participating in the FICare cRCT, and were less than 18–21 months of age at the start of this follow up study. | | |
| **Exclusion criteria** | - | | |
| **Newborn and parent characteristics** | FICare infants were one week more mature at birth but were enrolled in the FICare study at a younger post-natal age. They were also less likely to be singletons, and their mothers were more likely to be employed. There were no significant differences appreciated in the major morbidities for the FICare and control infants. | | |

**Table 1**
Comparison of infant and maternal characteristics.

| Characteristics | Non-FiCare $n = 62$ | FiCare $n = 123$ | $p$-Value |
|---|---|---|---|
| Birth weight (g), mean (sd) | 1110 (350) | 1230 (411) | 0.054 |
| Gestational age at birth, median (IQ range) | 27 (26, 29) | 28 (27, 31) | 0.03 |
| Sex (male), % (n/N) | 67.7 (42/62) | 54.5 (67/123) | 0.08 |
| Gestational age group, % (n/N) | | | 0.04 |
| 22–28 weeks | 66.1 (41/62) | 50.4 (62/123) | |
| 29–33 weeks | 33.9 (21/62) | 49.6 (61/123) | |
| Weight at enrolment, mean (sd) | 1507 (487) | 1384 (347) | 0.08 |
| Age at enrolment(days), median (IQ range) | 21.5 (12, 35) | 13 (7, 29) | 0.002 |
| Small for gestational age, % (n/N) | 11.3 (7/62) | 8.1 (10/123) | 0.48 |
| Apgar score < 7 at 5 min, % (n/N) | 31.2 (19/61) | 25.2 (31/123) | 0.39 |
| Singleton, % (n/N) | 77.4 (48/62) | 61.8 (76/123) | 0.03 |
| Surfactant use, % (n/N) | 59.7 (37/62) | 56.1 (69/123) | 0.64 |
| Caffeine use, % (n/N) | 96.8 (60/62) | 91.1 (112/123) | 0.15 |
| Maternal age (years), mean (sd) | 31.7 (6.2) | 31.7 (5.1) | 0.96 |
| Cesarean, % (n/N) | 63.3 (38/60) | 59.4 (73/123) | 0.6 |
| Antenatal steroid use, % (n/N) | 85.3 (52/61) | 92.6 (113/122) | 0.11 |
| Employment, % (n/N) | 74.6 (44/59) | 87.2 (95/109) | 0.04 |
| Ethnicity (White vs others), % (n/N) | 69.5 (41/59) | 81.7 (89/109) | 0.07 |
| Education level groups, % (n/N) | | | 0.25 |
| ≤12 years | 18.6 (11/59) | 26.6 (29/109) | |
| > 12 years | 81.4 (48/59) | 73.4 (80/109) | |
| Marriage, % (n/N) | 91.5 (54/59) | 93.5 (100/107) | 0.75 |

Notes: the reported $p$-values were based on the comparisons between two groups using Chi-square, or Fisher exact test for categorical variables and Student's $t$-test or Wilcoxon Rank Sum test for continuous variables.

## Results

**Parent-newborn interaction**

*Instrument: Nursing Child Assessment Satellite Training (NCAST) Parent Child Interaction (PCI) Teaching Scale, at 12 months' CA by filming the observation of the parent-child dyad in a teaching episode, and was scored by two blinded independent observers*

FICare was significantly associated with the Child subtotal score of the NCAST and the Child Domain total score of the parent PSI (Table 5), suggesting these could serve as potential mediators of the effect of FICare in relation to the behavioural outcome of Dysregulation at 18 months.

As indicated in Table 5, the NCAST Child subtotal score was higher in the FICare infants than the non-FICare infants, meaning that these children, when assessed by blinded observers, demonstrated greater clarity with their cues and responsiveness to caregivers in parent-child teaching interactions.

**Stress**

*Instrument: Parenting Stress Index (PSI), completed at 12 months' CA*

The FICare infants also were found to have a lower total score on the PSI Child Domain versus non-FICare parents. This reflects that the FICare parents' assessment of their child's characteristics, such as the child's ability to adjust to social and physical changes, their more positive mood and

| | |
|---|---|
| | less demanding interactions, contributed to their lower overall experience of stress related to parenting. In multiple regression analyses, only the Child Domain total score of the PSI was identified as a potential mediator of the effect of FICare on child behaviour. The mediation effect was estimated to as 1.28 (−2.96, −0.02), p=0.044. |
| **Limitations and conclusion** | |
| **Limitations** | Limitations to this study were that we were unable to recruit the entire FICare study cohort for this follow up study. Many of the infants did not qualify for routine neonatal neurodevelopmental follow up based on their more mature gestational age at birth. In addition, at the time funding was awarded, many of the eligible infants were already too old for the study, attended a study site which did not provide follow up, declined the assessment, or were unable to be recruited at the sites due to travel distance. In addition, not all infants had both 12 and 18–21 months assessments limiting our interpretation of this data as only a small number in this cohort were still under 12 months of age at the time of funding. Despite this, however, we were able to demonstrate a significant effect on behaviour and this warrants further investigation. Another limitation was that of our cohort from the FICare study, which was predominantly in a secure relationship, high school graduate, and employed. While it limits generalizability, it does offer the potential of an easily teachable intervention that can be offered and the effect appears sustained across time. |
| **Authors' conclusion** | In conclusion, NICU interventions for the very preterm population, which include increased parent-infant interaction/proximity, reduced infant and parent stress and anxiety, and improved parent confidence in caring for their infant, have a lasting positive impact on parent child interactions and decreased parent stress into the first year of life, as well as greater infant self-regulatory capacity into the second year of life. This work highlights important pathways that promote and potentially alter later childhood behavioural outcomes common to the preterm population. |

## *Appendix 2.3.11. Music therapy*

| Schlez et al. (2011) | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Cross-over prospective randomised controlled trial | **Exposure intervention group** | KMC combined with live harp music therapy (for 30 minutes, each session began 30 minutes after feeding) |
| **Country** | Israel | **Exposure control group** | KMC only |
| **Setting** | NICU at the Meir Medical Center | **Level of prematurity** | 32 – 37 weeks gestational age |
| **Sample size** | 52 mother-infant dyads | | |
| **Time frame** | October 2008 – January 2008 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Newborns*<br>Inclusion criteria were clinically stable infants born between 32 and 37 weeks of gestation and having normal hearing confirmed by measurement of distortion product otoacoustic emission.<br>*Parents*<br>Maternal inclusion criteria were ability to hear, literary ability to read and answer an anxiety questionnaire, and no signs or medical history of postpartum depression. | | |
| **Exclusion criteria** | *Newborns*<br>Exclusion criteria were: a) observed hyper-responsiveness to live music therapy, as opposed to other sounds and noises, and defined as crying when music starts and relaxing when music stops; b) congenital anomaly that mainly affects hearing, such as craniofacial anomalies; c) medication intake such as phenobarbital, furosemide and gentamycin, which might interfere with the reaction to musical stimuli; and d) brain anomalies associated with neurological disorders such as: grade 3-4 intraventricular haemorrhage and periventricular leukomalacia. | | |
| **Newborn and parent characteristics** | There were 24 male and 28 female infants, with a median gestational age of 32 weeks (range 26–36 weeks) and a median postnatal age of 35 days (range 12–76 days). The median age of the mothers was 30 years (range 19–46 years). | | |

**Table 1.** Study population characteristics (N = 52)

| | |
|---|---|
| **Ethnic origin** | |
| Jews/Arabs (N) | 33/19 |
| **Infants*** | |
| Male/female (N) | 24/28 |
| Gestational age (wks) | 32 (26–36) |
| Postnatal age (days) | 35 (12–76) |
| Birth weight (g) | 1641 (760–2715) |
| AGA/SGA (N) | 46/6 |
| Weight at testing (g) | 1985 (1675–3210) |
| Bronchopulmonary dysplasia (N) | 1 |
| **Mothers** | |
| Age (yrs) | 30 (19–46) |
| Education (yrs, N) | |
| 1–8 | 18 |
| 8–12 | 22 |
| ≥ 13 | 12 |
| Affinity for music** (hrs, N) | |
| 1 | 10 |
| 2 | 12 |
| 3 | 17 |
| 4 | 7 |
| 5 | 6 |

*When applicable data are presented as median (range)

** A 5-point scale was initiated to measure the length of time spent a day listening to music.

AGA = appropriate for gestational age, SGA = small for gestational age

| Results | |
|---|---|
| **Anxiety** | *Instrument: State-Trait Anxiety Inventory Scale, completed at the beginning and the end of each intervention* |

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|---|---|
| | Compared with KC alone, KC combined with live harp music therapy had a significant beneficial effect on maternal anxiety state (before intervention: KC 53 ± SD 11.3 and KC combined with music therapy 55.3 ± SD 9.2; after intervention: 46.8 ± SD 10 vs. 27.7 ± SD 7.1, respectively, P < 0.01). The data showed that maternal age, ethnicity, education, and affinity for music did not correlate with the STAI scores (P = 0.2 to 0.5 for all four variables). |
| **Limitations and conclusion** | |
| **Limitations** | - |
| **Authors' conclusion** | In conclusion, applying live harp music during mother-infant kangaroo care and music therapy is feasible within the NICU milieu, and the combination significantly reduced maternal anxiety responses. However, it had no apparent effect on infants' physiological parameters and behavioural states. These outcomes may stem from the ability of KC to mask music or from the lack of a female voice added to harp music. No correlation was found between maternal age, ethnicity, education and affinity for music, and anxiety scores, implying that the soothing effect of KC combined with music therapy for mothers, who are in need of support at a stressful time for the family, is universal regardless of their characteristics and personal beliefs, traits or preferences. Further studies using music therapy to reduce anxiety should focus on finding the best combination of interventions for preterm infants and mothers/parents and should comply with a specific study design to measure the effect of music in the NICU setting. |

| **Arnon et al. (2014)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Prospective, randomised, within-subject, crossover, repeated-measures study | **Exposure intervention group** | Kangaroo mother care (KC) combined with live maternal singing: 10 min. KC only, 20 min. KC with live maternal singing, 10 min. KC only |
| **Country** | Israel | **Exposure control group** | Kangaroo mother care (KC): 30 min. KC only |
| **Setting** | NICU | **Level of prematurity** | 32 – 36 weeks of gestational age |
| **Sample size** | Of 116 preterm infants screened for the study, 10 were excluded for medical indications and 15 were excluded as the parents refused to participate. In another five dyads, data were incomplete. The study population comprised of 86 mother-infant dyads, belonging to 53 Jewish and 33 Arab families. | | |
| **Time frame** | 1 October 2011 – 31 March 2012 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Newborns*<br>Inclusion criteria were clinically stable infants at a postmenstrual age of 32–36 weeks, whose hearing was confirmed by distortion product oto-acoustic emissions. | | |
| **Exclusion criteria** | *Newborns* | | |

| | |
|---|---|
| | Exclusion criteria were a congenital anomaly that affected hearing and brain anomalies associated with neurological problems, such as grade 3-4 intraventricular haemorrhage and periventricular leukomalacia. Additional exclusion criteria were hyper alertness to maternal voice, defined as crying when the mother started singing and relaxing when the music stopped and medication that might have interfered with the reaction to musical stimuli, such as anti-convulsive or sedative drugs or oxygen. |
| **Newborn and parent characteristics** | **Table 1** Characteristics of study population (n = 86)*<br>Characteristic — Value<br>Ethnic origin<br>Jewish/Arabic (no.) — 53/33<br>Infants<br>Male/Female (no.) — 39/47<br>Postmenstrual age at birth (weeks) — 31 (25–33)*<br>Postnatal age at study onset (days) — 25 (14–61)<br>Birth weight (grams) — 1411 (640–2512)<br>AGA/SGA (no.) — 78/8<br>Weight at testing (grams) — 1885 (1620–2780)<br>Bronchopulmonary dysplasia (no.) — 1<br>Mothers<br>Age (years) — 27 (17–41)<br>Education (years) — 12 (6–20)<br>AGA = appropriate for gestational age; SGA = small for gestational age.<br>*Data are presented as median (range). |
| **Results** | |
| **Anxiety** | *Instrument: State-Trait Anxiety Inventory (STAI)*<br>*This is a well-validated self-report questionnaire comprising 20 descriptive statements of anxiety symptoms. Higher scores indicate higher levels of anxiety, with a range of 20-80 points. We choose this questionnaire because the Hebrew version has high reliability and validity, it takes only a few minutes to complete and our team was familiar with it after using it in previous studies.*<br><br>Compared with KC alone, KC with maternal singing had a significant beneficial effect on maternal anxiety: 56.2 ± 10.8 before and 42.8 ± 8 after KC alone (p = 0.09) versus 50.6 ± 12.3 before and 26.4 ± 8.2 after KC with maternal singing (p = 0.04). The mean difference in preintervention to postintervention STAI scores was significantly greater in KC with maternal singing compared with KC alone (p = 0.03). |
| **Limitations and conclusion** | |
| **Limitations** | - |
| **Authors' conclusion** | In conclusion, applying live maternal singing during KC therapy produced changes in HRV that indicated a better autonomic stability and had an apparent effect on the mothers' anxiety response as well. These safe, inexpensive and easily implemented therapies can be applied during daily neonatal care. They are especially advocated when singing might decrease an infant's restlessness and maternal anxiety associated with just providing |

| | |
|---|---|
| | KC. Given that maternal singing during KC improved the autonomic stability of the preterm infants during their stay in the NICU, further studies evaluating the long-term effects of this bimodal exposure, and whether continuing this therapy during infancy facilitates gross motor skills, mental processing, perceptual memory, social behaviour and learning, are warranted |

| **Chorna et al. (2014)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Prospective, parallel, randomised controlled trial | **Exposure intervention group** | Pacifier-activated music player (PAM) during non-nutritive sucking: 15 minutes daily for 5 consecutive days |
| **Country** | USA | **Exposure control group** | Standard care feeding procedures in the NICU, which include cue-based feeding, NNS support, skin-to-skin care, and graduated introduction of breastfeeding. |
| **Setting** | Vanderbilt University Medical Center NICU | **Level of prematurity** | 34 – 36 weeks of gestational age |
| **Sample size** | Intervention group: 46<br>Control group: 48 | | |
| **Time frame** | April 2012 – May 2013 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Newborns*<br>Infants were eligible if their postmenstrual age was 34 0/7 to 35 6/7 weeks at study start, they were receiving .50% enteral feeds and,50% oral feeds in the 3 days before the study start, and they were cared for in private or semiprivate rooms. | | |
| **Exclusion criteria** | *Newborns*<br>Infants were excluded if they were receiving assisted ventilation, continuous positive airway pressure, or high-flow nasal cannula .2 L/min, or if the medical team/feeding specialists considered them medically unsafe to feed orally. | | |

**Newborn and parent characteristics**

TABLE 1 Patient Characteristics

| | Intervention, $n = 46$ | Control, $n = 48$ | $P$ |
|---|---|---|---|
| GA, wk, median (IQR) | 30 (28–32) | 30 (28–32) | .15[b] |
| PMA 34 completed wk at study start,[a] % | 93 | 98 | .29[b] |
| Birth weight, g, median (IQR) | 1495 (1122–1742) | 1405 (1057–1684) | .35[b] |
| Gender, % girls | 48 | 52 | .70[b] |
| White matter injury, all types, % | 17 | 19 | .86[c] |
| White matter injury, severe, % | 4 | 6 | .69[c] |
| Feeding rate at study start, day 0 | 0.6 (0.4–0.8) | 0.6 (0.1–0.8) | .27[b] |
| No. of oral feedings/d at study start (IQR) | 2 (1–5) | 2 (0.7–4) | .27[b] |

IQR, interquartile range (25th–75th).
[a] Versus PMA 35 completed weeks, respectively 7% and 2% in intervention and control groups.
$P$ determined by using GEE linear regression controlling for [b] twins and [c] Pearson $\chi^2$ test.

## Results

**LOS newborn**

The trend to decreased length of hospital stay was not significant (P = .07).

TABLE 3 Hospitalization Outcomes

| Measure | Intervention, $n = 46$ | Control, $n = 48$ | $P$ |
|---|---|---|---|
| Time to full oral feeds, d | 31 (17–54) | 38 (24–69) | .04 |
| Length of hospital stay, d | 41 (25–69) | 50 (31–86) | .07 |
| Discharge weight, g | 2000 (1892–2228) | 1990 (1902–2120) | .62 |

Values are median (interquartile range).
All $P$ determined by using GEE linear regression controlling for twins.

## Limitations and conclusion

**Limitations**

Our study has several limitations. Our findings may have been strengthened by inclusion of a third group treated with the PAM device with either a female voice that was not the mother's or an instrumental lullaby. We chose not to include such a group, as this stimulus had been conclusively studied by Standley et al. Additionally, our purpose was to study an intervention supported by the developmental approach in the NICU to promote family-centered care. Documenting the timing and duration of mother's singing at the bedside each day for comparison with the duration of the PAM intervention would have been optimal. However, this would have unmasked the study group assignment to nursing and medical staff.

**Authors' conclusion**

Our study showed that a relatively simple, short, and reproducible intervention with a PAL sung by the infant's mother improves oral feeding skills in preterm infants, including those with brain injury. Larger studies are needed to determine whether this intervention can decrease length of hospitalization for preterm infants. Whether this therapeutic approach is applicable to other populations at risk for poor oral feeding, such as infants with congenital heart disease, prolonged respiratory illness, or neuromuscular disease, requires additional research.

| Ranger et al. (2018) | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Prospective, two-center, randomised crossover trial | **Exposure intervention group** | Live music, played on a children's harp |
| **Country** | Germany | **Exposure control group** | No music |
| **Setting** | NICU (level II) of the Children's Hospital of the University of Tübingen, and in the NICU (Level 2) of the Filderklinik, Filderstadt, | **Level of prematurity** | 26 – 35 weeks of gestational age |
| **Sample size** | Intervention group: 38<br>Control group: 38 | | |
| **Time frame** | July – October 2013 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Newborns*<br>Inclusion criteria were GA of 26+0–34+6 weeks and days at birth in room air and in an open crib at time of study. | | |
| **Exclusion criteria** | *Newborns*<br>Exclusion criteria were heart defect or cardiac arrhythmia; significant disease (e.g. neonatal infection), genetic or congenital anomalies or documented or suspected hearing problems. Concerning the neonates' mothers no additional exclusion criteria were defined. | | |

**Newborn and parent characteristics**

Table 1
Characteristics of the study population.

| Variable | *n (%)* | *M (SD)* | *Minimum* | *Maximum* |
|---|---|---|---|---|
| *Infants* | 21 (100) | | | |
| GA birth (weeks + days) | – | 32 + 1 (1 + 6) | 27 + 6 | 34 + 3 |
| GA measurement (weeks + days) | – | 35 + 0 (1 + 3) | 32 + 1 | 38 + 5 |
| Postnatal age (weeks + days) | – | 2 + 6 (1 + 4) | 1 + 1 | 7 + 0 |
| Birthweight (g) | – | 1586 (325) | 980 | 2350 |
| Weight at measurement (g) | – | 1983 (419) | 1421 | 3282 |
| Delivery mode | | | | |
| Vaginal birth | 5 (23.8) | – | – | – |
| Caesarean section | 16 (76.2) | – | – | – |
| Apgar-Score | | | | |
| 1 minute | – | 7.2 (1.5) | 4 | 9 |
| 5 minutes | – | 8.6 (1.0) | 7 | 10 |
| 10 minutes | – | 9.2 (0.6) | 8 | 10 |
| *Mothers* | 15 (100) | | | |
| Age | 15 (100) | 32.9 (4.9) | 24 | 40 |
| Primiparae | 12 (80) | – | – | – |

Note: GA = gestational age, Apgar-Score = score to evaluate the vital functions of a newborn.

## Results

**Anxiety**

*Instrument: German version of the State-Trait Anxiety Inventory (STAI), before and after the intervention*

The largest within-effect was shown on the STAI-X1. Mothers reported less anxiety after listening to the music intervention than beforehand (ΔSTAI-X1=- 4, z = −2.53, p= 0.01). Because the STAI-X1 was administered only twice in the CC, no comparison of the pre-post-difference between the conditions could be conducted. The mother-reported neonate emotional state did not change over time.

## Limitations and conclusion

**Limitations**

Since blinding of the parents concerning the intervention was not feasible in the current study mothers might have given socially desirable answers. It also must be taken into account that parents in general have high expectations about the effects of music on their neonates. In a survey with parents in the NICU, Pölkki and colleagues found out, their neonates' feeling of security and decrease the neonates' experienced stress. Still more than 80% considered that music would improve their neonates' sleep as well as console a crying neonate.

A second limitation of the current study is inherent in its design: In the CC the STAI-X1 was answered only twice, namely before and after the intervention phase; thus, the results must be interpreted with caution. Mothers were asked to refrain from interacting with their child during the

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|---|---|
| | measurement. Therefore many mothers decided to leave the NICU during the actual measurements. Only the mothers, who were interested in the music intervention itself decided to stay in the NICU. Thirdly, given that the sample size was estimated on the basis of a meta-analysis, that identified large overall music intervention effects 8 the small sample size of the current study did not allow identification of smaller effects. Moreover, it must be noted that correction of the multiple test p-values was not performed. Due to the effectiveness approach of the study design it can be assumed, that the results found are generalizable to other NICU setting. |
| **Authors' conclusion** | Given, that preterm-born children still show impaired autonomic nervous system activity and reactivity at the age of 9–10 years corrected age, it seems to be particularly important to support ANS development from early on. Despite no changes were found in the primary outcome parameter, with the reported heart rate variability changes in mind, the use of music might, nevertheless, play an important role in the NICU. |

| **Corrigan et al. (2021)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Prospective, randomised, parallel group trial | **Exposure intervention group** | Two music interventions: recorded maternal singing and heartbeat for the intervention and recorded infant heartbeat with mother-preferred music for her the mother's personal use |
| **Country** | USA | **Exposure control group** | Standard care |
| **Setting** | NICU | **Level of prematurity** | NA (mean gestational age of 34.8 weeks in intervention group and 34.5 weeks in control group) |
| **Sample size** | Intervention group: 43<br>Control group: 54 | | |
| **Time frame** | NA | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Parents*<br>Mothers met inclusion for participation if they were the legal guardian, were of adult legal age (≥18 years), and had a preterm infant in the NICU scheduled for an retinopathy of prematurity (ROP) examination. | | |
| **Exclusion criteria** | - | | |
| **Newborn and parent characteristics** | Participants were similar across all baseline characteristics. Mothers in both groups had the same average age of 31 years. In addition, breakdown of ethnicity was similar between groups and there was virtually identical representation of different marital statuses between groups. Furthermore, participants averaged the same gravida and parity in both groups (MT: gravida = 2.3, parity = 2.5; SC: gravida = 1.8, parity = 1.7). Infants were also demographically similar at baseline, though parents were more often present for ROP examinations in the SC group. | | |
| **Results** | | | |

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|---|---|
| **Parent-newborn attachment** | *Instrument: Mother-to-Infant Bonding Scale (MIBS), completed at baseline and 1 week post-enrolment*<br>Mean MIBS score at baseline was slightly higher in the MT group (0.49) than in the SC group (0.28), but this was not statistically significant (see Table 3). The survey response rate was 44.3%, as 43 of 97 participants returned the post-MIBS survey and one<br>participant only partially completed the post-MIBS survey. Therefore, analysis of post-MIBS score compared 42 participants total (MT: n = 14, 33.3% response rate; SC: n = 28, 66.7% response rate).<br>When covarying out the effect of baseline MIBS score, the one-way ANCOVA found no statistical difference between groups for MIBS scores 1 week postenrollment (MT: mean = 0.64, SD = 1.6; SC: mean = 0.57, SD = 1.5); F1,39= 0.29, P = .60. However, effect size in post hoc shows an underpowered analysis.<br>There were 4 mothers (9.4%) in the MT group with a baseline MIBS score of 2 or more compared with 3 (5.7%) in the SC group. For post-MIBS scores, 2 mothers (14.2%) in the MT group had a score of 2 or more compared with 3 (10.8%) in the SC group. Of the 2 mothers in the MT group with a post-MIBS score of 2 or more, they also had a baseline MIBS score of 2 or more with a difference of only one between the baseline and post-MIBS scores for each (baseline MIBS = [3,5] and post-MIBS = [2,6], respectively). However, of the 3 mothers in the SC group with a post-MIBS score of 2 or more, 2 had a baseline MIBS score of less than 2 and for the mother with an MIBS score of 2 or more at baseline and post-MIBS 1 week, their score increased |
| **Limitations and conclusion** | |
| **Limitations** | However, low MIBS scores at baseline in this study precluded significant positive changes over time. Other explanations of low effect size may derive from cultural limitations of the MIBS, study design, and study intervention use. This study included equal representation of African American, Hispanic, and White participants, and the MIBS has shown to have cultural limitations affecting score reliability. Apart from addressing the limitations of the tool itself, increasing MT sessions with mothers, providing more opportunities for verbal support and processing of thoughts/feelings toward their infant, and chances to individualize the heartbeat music further and counsel more on its use could improve bonding even more. Also, future studies could only include mothers with clinically impaired bonding at baseline, making it easier to see potential positive changes in bonding and offer intervention to those most in need. Still, it appeared the intervention as presented in this study helped prompt some mothers to think more positively about their infants, a clear indicator of positive bonding. |
| **Authors' conclusion** | NICUs have a responsibility to include parents in the care of their infants. This is difficult without concrete interventions to address parental psychosocial concerns and involve parents in a tangible task. Heartbeat-music interventions engage mothers on several levels, supporting them emotionally and creating something concrete that supports physical comfort. Music therapists offer a unique perspective on the care of preterm infants and support of parents. With close collaboration with nurses, MT services could elevate family-integrated care toward more practical application. |

| Menke et al. (2021) | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Randomised controlled trial (pilot study) | **Exposure intervention group** | Interactive live-improvised music therapy (for 30 minutes, twice a week, started at the 21st day of life) |
| **Country** | Germany | **Exposure control group** | Standard care (EFIB®) |
| **Setting** | NICU (level III), Department of Neonatology at the University Children's Hospital, Heidelberg | **Level of prematurity** | ≤ 30 weeks of gestational age |
| **Sample size** | Intervention group: 24<br>Control group: 26 | | |
| **Time frame** | June 2016 – December 2016 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | Inclusion criteria applied were gestational age at birth ≤ 30 weeks, chronological age ≥10 days of life, clinical stability (at the time of inclusion) as well as sufficient German language skills and informed consent of the parents. | | |
| **Exclusion criteria** | *Newborns*<br>Exclusion criteria applied were genetically defined syndrome, neurological diseases (e.g., high-grade intraventricular haemorrhage, periventricular leukomalacia), severe sepsis (necrotizing enterocolitis), clinically relevant malformations as well as malformations that potentially impaired the development of the child up to the age of two years. Preterm infants with need for palliative care were also excluded from the study. | | |
| **Newborn and parent characteristics** | **Table 1. Baseline demographic and clinical characteristics of the study sample.** | | |

| Variable | MT (n = 24) | CG (n = 26) |
|---|---|---|
| Sex (female) | 12 (50.0%) [a] | 8 (30.8%) [a] |
| Gestational age (days) | 196.29 8.36) [b] | 187.46 (14.80) [b] |
| Birth weight (grams) | 1072.08 (346.47) [b] | 858.85 (334.97) [b] |
| Length (cm) | 36.75 (3.86) [b] | 33.81(4.32) [b] |
| Head circumference (cm) | 25.40 (2.45) [b] | 24.01 (2.72) [b] |
| Mother's age (years) | 33.50 (5.48) [b] | 34.96 (7.51) [b] |

MT = music therapy group; CG = control group
[a] = frequency
[b] = mean and standard deviation.

| **Results** |
|---|

**LOS newborn**

Table 2. Differences between groups in physiological development of the infants at time of discharge.

| Variable (at discharge) | MT (n = 24) | CG (n = 26) | p | Cohen's d |
|---|---|---|---|---|
| Weight (grams)[a] | 2,560.63 (220.09) | 2,602.69 (467.72) | .852[b] | -0.11 |
| Length (cm)[a] | 45.40 (2.01) | 45.00 (2.76) | .852[b] | 0.16 |
| Head circumference (cm)[a] | 32.73 (0.96) | 32.66 (1.51) | .852[b] | 0.05 |
| Duration of caffeine therapy (till dol)[a] | 53.46 (20.87) | 64.58 (24.02) | .205[b] | -0.49 |
| Duration of nasogastric/ orogastric tube feed (till dol) [a] | 63.89 (21.94) | 75.92 (25.53) | .205[b] | -0.51 |
| Duration of hospitalization (days)[a] | 70.79 (21.12) | 86.27 (25.44) | .072[b] | -0.66 |

dol = day of life; MT music therapy group; CG control group

[a] = mean (SD)

[b] = t-test with Bonferroni-Holm correction.

**Stress**

*Instrument: Parental Stress Questionnaire (PSQ), baseline (21st day of infant's life) to postintervention (day of discharge)*

Mixed ANOVAs on each stress factor revealed a decrease of stress levels ($F(1,45) = 20.33$, $p < .001$, $\eta 2\ p = 0.34$), state anxiety ($F(1,45) = 11.70$, $p = .001$, $\eta 2\ p = 0.21$), trait anxiety ($F(1,45) = 9.63$, $p = .003$, $\eta 2\ p = 0.18$) and postpartum depression ($F(1,45) = 29.16$, $p < .001$, $\eta 2\ p = 0.39$) at the time of discharge compared to baseline measurement, while resources ($F(1,45) = 5.10$, $p = .029$, $\eta 2\ p = 0.11$) and skills as primary caregivers ($F(1,45) = 23.66$, $p < .001$, $\eta 2\ p = 0.37$) increased. Contrary to expectations, no difference between intervention and control group and no interactions between the two factors were found.

As for maternal stress factors, parental stress factors were also compared between time points T1 and T2 (within factor) as well as between intervention and control group (between factor). As in mothers, the mixed ANOVAs show a decrease of stress levels ($F(1,28) = 25.10$, $p < .001$, $\eta 2\ p = 0.47$) and state anxiety ($F(1,28) = 4.89$, $p = .034$, $\eta 2\ p = 0.12$) in fathers at the time of discharge compared to baseline measurement, but no changes in trait anxiety ($F(1,28) = 2.85$, $p = .010$, $\eta 2\ p = 0.08$), resources ($F(1,28) = 0.02$, $p = .965$, $\eta 2\ p<0.01$) and skills as primary caregivers ($F(1,28) = 0.84$, $p = .368$, $\eta 2\ p = 0.03$) were observed between the two points in time. Again, no difference between intervention and control group and no interactions between the two factors were found.

**Anxiety**

*Instrument: German version of the State-Trait Anxiety Inventory (STAI), baseline (21st day of infant's life) to postintervention (day of discharge)*

*See results in for "Stress"*

**Depression**

*Instrument: Edinburgh Postnatal Depression Scale (EPDS), baseline (21st day of infant's life) to postintervention (day of discharge)*

*See results in for "Stress"*

## Limitations and conclusion

**Limitations**

The study shows several limitations. First: One challenge is related to the complexity of family-centered interventions, encompassing many different procedures making it difficult to draw explicit conclusions. Still, the findings of the presents study suggest benefits for premature infants from a music therapy intervention. For future investigations, an improvement of statistical power is recommended as well as adding further measurements at predefined points in time. Using such fixed-time measurements, it should be possible to disentangle possible effects of music therapy on both physiological development of the infant and the therapy durations needed to achieve these developments. As the reduction of parental stress factors may be influenced by the infants' development rather than therapy duration, such a change in research design might also reveal positive effects of music therapy on these stress factors.

| | |
|---|---|
| | Second: Although both parents were invited to participate in the music therapy session, the participation of both was not feasible in all cases due to clinical practice. This limits the significance of the conclusions about the influence of the music therapy intervention on the reduction of stress, especially for fathers.<br>Third: The music therapy intervention was offered over the entire inpatient period. Even being beneficial for establishing a therapeutic relationship, this process-oriented approach is very vulnerable to different influencing in- and outpatient factors such as condition of the infant, varying parental engagement as well as demanding expectations of other family members, friends and colleagues. |
| **Authors' conclusion** | This pilot study suggests that a live-improvised interactive music therapy intervention for extremely and very preterm infants and their parents has a beneficial effect on the therapy duration needed for premature infants before discharge from hospital is possible. The results show that the study protocol could be implemented successfully, which demonstrates the feasibility of the study. The pilot study provides valuable information regarding the recruitment process as well as compliance of parents, which can be used for sample size calculation and planning of a future RCT study. Further studies should assess both short-term and long-term effects on premature infants as well as on maternal and paternal health outcomes, to determine whether a family-centered music therapy actually experienced as an added value to developmental care should be part of routine care at the NICU. |

## *Appendix 2.3.12. Video interaction guidance (VIG)*

| **Hoffenkamp et al. (2015)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | Hospital-based video interaction guidance |
| **Country** | Netherlands | **Exposure control group** | Standard care |
| **Setting** | 2 NICUs and 7 maternity wards | **Level of prematurity** | 25 – 37 weeks of gestational age |
| **Sample size** | Intervention group: 75<br>Control group: 75 | | |
| **Time frame** | September 2009 – September 2012 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Parents*<br>Parents were eligible to participate if they had had a preterm hospital delivery. | | |
| **Exclusion criteria** | *Parents*<br>A poor understanding of the Dutch language and previous experience with a video-feedback intervention were exclusion criteria. | | |

**Newborn and parent characteristics**

Table 1
*Demographic and Clinical Characteristics of Sample by Treatment Condition*

| Demographic | Intervention group $n$ = 75 families | Control group $n$ = 75 families |
|---|---|---|
| Infant medical data, *n* | 75 | 75 |
| Male sex, % | 57.3 | 54.7 |
| Twins, % | 13.3 | 24.0 |
| GA at birth, wk | 32 (3.1) | 32 (3.1) |
| GA at birth, range | 25–37 | 25–37 |
| Birth weight, g | 1828 (735) | 1770 (663) |
| Birth weight, range | 556–4280 | 592–3770 |
| 5-min APGAR | 8.7 (1.4) | 8.3 (1.7) |
| Incubator, d | 22.5 (20.7) | 23.4 (24.8) |
| Mortality, % | 4.0 | 1.3 |
| Maternal demographic data, *n* | 75 | 75 |
| Maternal age at birth, year | 31.1 (4.9) | 30.8 (5.4) |
| Birth order | 1.4 (0.6) | 1.2 (0.5) |
| Dutch nationality % | 92.0 | 93.3 |
| Education level[a] | 2.2 (0.7) | 2.2 (0.8) |
| Paternal demographic data, *n* | 74 | 70 |
| Paternal age at birth, year | 34.1 (5.4) | 33.6 (5.5) |
| Birth order | 1.5 (0.7) | 1.3 (0.7) |
| Dutch nationality % | 89.2 | 92.9 |
| Educational level[a] | 2.1 (0.9) | 2.3 (0.8) |
| Single/divorced parents[b], *n* | 2 | 5 |

*Note.* GA = gestational age; values are expressed as mean (*SD*) unless otherwise indicated.
[a] Educational level was classified as *low*, 1; *medium*, 2; *high*, 3. [b] Single/divorced parents: i.e., one divorced couple (both mother and father participated in the study), and six single mothers (only the mothers participated in the study).

## Results

**Parent-newborn attachment**

*Instrument: 25-item Postpartum Bonding Questionnaire (PBQ), completed by parents at month 1 and month 6*

In sum, VIG had a significantly positive effect on several aspects of parent–infant bonding, in particular for fathers. While dissipation of the behavioral intervention effects occurred across time, the effects on paternal bonding were maintained until M6 follow-up.

**Parent-newborn interaction**

*Instrument, mother-infant interaction and father-infant interaction videotaped at day 1, day 6, 1 month, and 6 months postpartum*

In sum, VIG significantly changed parents' levels of sensitivity (i.e., more sensitive and positive behaviour) and detachment (i.e., less withdrawn and detached behaviour) during parent–infant interaction. The effect sizes were small to moderate for mothers, and moderate to large for fathers. The intervention positively altered parental interactional behaviour after two review sessions, but the effect faded over time. VIG was not found to change explicit intrusiveness in parents (i.e., intrusive and negative behaviour).

| | |
|---|---|
| **Stress** | *Instrument: 34-item Parental Stress Scale: Neonatal Intensive Care unit (PSS:NICU), completed by parents at week 1*<br>The comparative analyses revealed no statistically significant intervention effects. |
| **Anxiety** | *Instrument: State-Trait Anxiety Inventory (STAI), completed at month 1*<br>Regarding parental feelings of postnatal depression (EPDS), state anxiety (STAI-State), or state anger (STAXI2-State); also no differences between treatment groups were detected. |
| **Depression** | *Instrument: Edinburgh Postnatal Depression Scale (EPDS), completed at month 1*<br>Regarding parental feelings of postnatal depression (EPDS), state anxiety (STAI-State), or state anger (STAXI2-State); also no differences between treatment groups were detected. |
| **Limitations and conclusion** | |
| **Limitations** | First, it is not clear which part of the intervention program actually accounts for the effects. The change generating component could be parents' self-observations via video recordings, the provided information on the infant's initiatives and responsiveness, or the positive feedback by the VIG nurses. To gain understanding about the precise mechanisms that generate behaviour change in parents, future research should focus on units smaller than the intervention effects. Second, we neither can provide information about the optimal number of VIG review sessions. Although the study's intervention consisted of three sessions in the first postpartum week, VIG already positively altered parental interactional behaviour after two review sessions. However, the behavioural intervention effects dissipated over time. Further research is needed on the exact rate of decay of intervention effects, the effects on infant development and behaviour, as well as the long-term outcomes in parents. Perhaps booster sessions (in hospital or at home) can increase the long term effects. In addition, some methodological restrictions of the study must be noted. First, a disadvantage of the applied method of intention to treat is that it generally provides a more conservative estimate of the intervention effect compared with what would be expected with full compliance. In addition, increased levels of intervention adherence in a trial setting may challenge the generalizability of the results to clinical practice. Second, our results may suggest that the effects of VIG are stronger for fathers than for mothers, but a direct comparison between the outcomes of mothers and fathers was not conducted. Additional research on gender differences is necessary to further validate this notion. Third, the interrater agreement for the observational coding of parental behaviour appears to be somewhat less than desirable. A final methodological limitation concerns the relatively small sample size of mothers who met the trauma criteria (n = 31). |
| **Authors' conclusion** | The results indicate that VIG is a useful addition to standard hospital care, reducing the possible negative impact of preterm birth on the parent–infant relationship. VIG appeared particularly beneficial for fathers, and for mothers with traumatic birth experiences. High levels of parental intrusiveness, however, need complementary intervention. |

| Twohig et al. (2021) | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Pragmatic randomised controlled trial | **Exposure intervention group** | Video interaction guidance (VIG) |
| **Country** | Ireland | **Exposure control group** | Standard care |
| **Setting** | Tertiary level III NICU in Dublin | **Level of prematurity** | < 32 weeks of gestational age |
| **Sample size** | Intervention group: 29<br>Control group: 32 | | |
| **Time frame** | NA | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | Parents of preterm infants born at <32 weeks gestation, inborn and out-born, admitted to the NICU were eligible for inclusion in the study. Multiple births were included. | | |
| **Exclusion criteria** | Exclusion criteria were infants born with major congenital anomaly and mothers whose level of fluency in English precluded completion of the interview. | | |
| **Newborn and parent characteristics** | The study sample included families from a range of socioeconomic, educational and ethnic backgrounds and was representative of Irish sociocultural demographics50 (Table 1). Mothers in the intervention group had attained a higher level of education than mothers in the standard care group (p = 0.008). There were no significant differences between the groups in other sociodemographic variables. There were no statistically significant differences in sociodemographic variables, baseline parental measures of psychological well-being between families who were lost to follow-up and those who completed the study.<br>There were no statistically significant differences between the intervention and standard care groups in mean gestational age, birth weight, birth order or sex of the infant (Table 2). There was a greater number of pregnancies conceived following in vitro fertilisation (p = 0.001) and infants of multiple births (p = 0.02) in the intervention group. Eight (16%) infants in the intervention group compared with 1 (2.6%) infant in the standard care group developed necrotising enterocolitis (NEC) (p = 0.03) (Table 3). There were no significant differences in the rates of intraventricular haemorrhage (IVH) or periventricular leukomalacia (PVL). | | |
| **Results** | | | |
| **Parent-newborn interaction** | *Instrument: The Child Adult Relationship Evaluation (CARE)-index, observed at 9 months' corrected age*<br>There was no statistically significant difference between the intervention and standard care groups in maternal sensitivity (p = 0.8 [CI = −1.4 to 1.1]). Adjusting for maternal education, the mean difference between intervention and standard care remained non-significant (p = 0.2 [CI = −2.8 to 0.7]). The mean sensitivity for both groups fell >7, the cut-off previously established for the CARE-Index indicating the need for clinical intervention. In the secondary analysis, there was no statistically significant difference in maternal sensitivity (F = 0.02, d.f. = 2, p = 0.9) between the three groups, mothers in the intervention group who had received VIG those who did not and with mothers in the standard care group. | | |
| **Limitations and conclusion** | | | |
| **Limitations** | The study was generally welcomed by parents, with only 15% of families who were eligible declining to participate. There was also a moderately high attrition rate of 22% to complete follow-up. Despite the loss to follow-up, additional recruitment allowed appropriate numbers for statistical analysis. Approaching parents necessitated sensitivity to the infant's medical difficulties and awareness of the parents' emotional state. Therefore, despite the | | |

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| | often chaotic and challenging emotional environment of the NICU, many parents found space to take part with their infants. Informal feedback from parents during and at the end of the intervention attested to the perceived benefit of the intervention. The process of reflecting on their own and their infant's experiences and of making the video, specifically creating a space for mother and father to attend to their infant's cues and communications, with no other expectation, and which in turn was attended to, reflected on and thought about by the researcher, was experienced as very important to the parents (personal communication, anonymous study participant feedback, 2016). Nine (26%) families did not receive the VIG session as part of the intervention. Partial engagement was inevitable due to factors that were extraneous to the study, such as the infant being transferred from the hospital to a specialist paediatric centre or to a district hospital for ongoing care.60 This was understandably very stressful for the parents of these babies and may be reflected in the findings of the study.<br>Consideration of the impact of the everyday interactions with NICU staff, nurses, doctors, social workers and allied health professionals, which contributes to each infant's and parent's experience in the NICU, is important in interpreting the findings. It was not possible to blind parents or staff to the intervention allocation resulting in a secondary effect of focusing attention to the infant–parent relationship. However, the pragmatic nature of the study was envisaged as a valid way of studying the impact of this brief attachment-focussed intervention with preterm infants and their parents within the NICU. A limitation of the study design is the single researcher engaged in recruitment and delivery of the intervention, having contact with parents in both the intervention and control groups. This may have introduced biases, such as the Hawthorne effect. The design of the study attempted to control for this through randomisation and blinded rating of primary outcome data.<br>Furthermore, there is the limitation of conducting secondary analyses and lack of adequate power of the study to draw definitive conclusions from these analyses. The analyses of the secondary outcomes may be subject to bias given the self selected nature of the groups presented. However, these represented the real experience of the participants of the study. These analyses are exploratory in nature and presented to stimulate further research. |
| **Authors' conclusion** | While the intervention did not yield an effect on the primary outcome as hypothesised, the exploratory, preliminary findings relating to the secondary outcome measures indicate further exploration of the effects of VIG as an attachment-focussed intervention in the NICU for preterm infants and their parents is warranted. Integrating VIG with other evidenced-based approaches may prove beneficial and contribute to the multi-modal interventions needed to support parent–infant interaction and developing relationship. Furthermore, this study evaluated the intervention in a 'real-world' setting, and may therefore be generalisable to patients of other tertiary referral NICUs. Further evaluation of VIG would be beneficial in a larger sample, with methodological adjustments to control for the limitations described. Further evaluation an modification of the approach used in this study may help to optimise the intervention and also the feasibility of delivering such interventions within the challenging environment of the NICU. |

## *Appendix 2.3.13. Other*

### Baby CareLink

| Gray et al. (2000) | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | Access to Baby CareLink |
| **Country** | USA | **Exposure control group** | Usual practice in the NICU |
| **Setting** | NICU at Beth Israel Deaconess Medical Center (Boston, Massachusetts) | **Level of prematurity** | Birth weight < 1250 g |
| **Sample size** | | | |
| **Time frame** | November 1997 – April 1999 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | - | | |
| **Exclusion criteria** | Infants were excluded if ISDN access was not available at their family's primary residence or if the infants expected length of stay in the study NICU was expected to be ,14 days (e.g. because of need for transfer for surgical care at the nearby Children's Hospital, or because of planned transfer back to a referring community hospital for infants born weighing > 1250 g). In addition, infants were excluded if their family lacked a permanent residence, did not speak English, or if discharge to other than the biological family was expected. Lack of basic telephone service in the family residence was not used as an exclusion criterion. | | |
| **Newborn and parent characteristics** | The 2 groups were similar in birth weight, gestational age, plurality, maternal race, and educational level, as well as insurance status. Infants in the Baby CareLink group were more likely to have been delivered by caesarean section (92.3% vs 63.3%; P <0.05) and to be born to a single mother (38.5% vs 13.3%; P < 0.05). Similar percentages of parents of each group lived together in the same home (88.5% vs 90.0%; P ≥ 0.85). | | |
| **Results** | | | |
| **LOS newborn** | Infants in the CareLink group remained hospitalized for a shorter time than those in the usual care group although this difference was not significant (68.5 ± 28.3 vs 70.6 ± 35.6 days; P ≥ 0.05). | | |
| **Parent satisfaction** | Instrument: Picker Institute's Neonatal Intensive Care Unity Family Satisfaction survey, administered between 1 and 4 months after discharge of the newborn<br>CareLink usage was associated with significant improvements in family satisfaction in the overall quality of care and environment and visitation dimensions. CareLink families also reported higher scores in all other dimensions except in coordination of care. Within the dimension of overall quality, CareLink families were 85% less likely to report problems with the duration of their child's hospitalization (6.7% vs 43.8%; P = 0.04). Of those reporting problems most noted that their NICU stay was shorter than they felt necessary. Interestingly, even though the same visitation policies applied to both groups, CareLink families were also less likely to report problems when asked if the unit's visitation policy met the needs of their other family members | | |

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| | (13.3% vs 50%; P = 0.02; Fig 3B). CareLink families also showed a trend toward fewer problems related to receiving practical support from the NICU (33.3% vs 68.7%; P = 0.08). |
| **Limitations and conclusion** | |
| **Limitations** | The small size of our study group limits the power of our analyses to detect differences. |
| **Authors' conclusion** | CareLink significantly improves family satisfaction with inpatient VLBW care and definitively lowers costs associated with hospital to hospital transfer. Our data suggest the use of telemedicine and the Internet support the educational and emotional needs of families facilitating earlier discharge to home of VLBW infants. We believe that further extension of the Baby CareLink model to the post-discharge period will significantly improve the coordination and efficiency of care. |

### Co-bedding of premature multiple-gestation newborns

| **Byers et al. (2003)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Randomised, repeated measures experimental trial | **Exposure intervention group** | Co-bedded infants received care using the institution's co-bedding care protocol |
| **Country** | USA | **Exposure control group** | Traditional NICU standard of care |
| **Setting** | A southeastern medical centers' 78-bed NICU. The unit has 44 licensed level III beds and 34 level II beds and is set up in seven separate rooms | **Level of prematurity** | NA (mean 29 weeks of gestational age) |
| **Sample size** | Intervention group: 16<br>Control group: 21 | | |
| **Time frame** | NA | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | Inclusion criteria included a neonatologist's approval, parental ability to read and write English, and the physiological stability of the infant (normal vital signs for the previous 24 hours and last white blood count within normal limits). For triplets, the first two infants to achieve physiological stability were co-bedded. | | |
| **Exclusion criteria** | Exclusion criteria included the infants having a known infection, being on mechanical ventilation, and having a combined weight too great to be safely co-bedded in an incubator. | | |
| **Newborn and parent characteristics** | The average infant was born at 29 weeks gestation, weighed between 1,100 and 1,200 g, and had a 26- to 29- year-old mother. Thirty-three of the participating infants were twins, and four were triplets. There were no differences between groups for any of the demographic variables, with the exception of gender ($\chi 2 = 8.05$, p = .005). | | |

## Results

**Parent-newborn attachment**

*Instrument: Maternal Attachment Inventory, at baseline and repeated at the conclusion of the 5 days of data collection*

*This is a 28-item tool that ranks items on a 4-point Likert-type scale. This tool had established construct validity and good reliability (Cronbach's alpha = .85) in previous work with mothers prenatally and postnatally.*

The Maternal Attachment Inventory had poor reliability in this sample, with a Cronbach's alpha of .44 at baseline and .60 at post–data collection.

Paired t tests found no differences in the co-bedded infants' parental scores from pretesting to posttesting for state anxiety, maternal attachment, or parental satisfaction. Parents of infants in the control group demonstrated increased state anxiety (t = 2.25, p = .05) and decreased maternal attachment scores (t = 6.79, p = .0001) over time.

Independent t tests comparing the co-bedded and control group parental scores found no significant differences in their total state anxiety, maternal attachment, and parental satisfaction scores, except for higher baseline parental satisfaction scores (t = 2.67, p = .029) in the cobedded group (see Table 4).

**TABLE 4**
***Parental Variable Scores***

| *Variable* | *Co-Bedded Group Baseline* | *Co-Bedded Group Post-Intervention* | *Control Group Baseline* | *Control Group Post-Intervention* |
|---|---|---|---|---|
| State anxiety inventory | 37.83 (13.37) | 35.5 (3.16) | 33.00 (6.93) | 34.6 (3.37) |
| Maternal attachment inventory | 104.86 (3.25) | 101.80 (1.55) | 107 (4.20) | 100.90 (4.38) |
| Parental satisfaction survey | 51.00 (5.07) | 50.75 (4.68) | 41.00 (0) | 51.13 (4.08) |

*Note.* Mean (standard deviation).

**Anxiety**

*Instrument: State-Trait Anxiety Inventory, at baseline and repeated at the conclusion of the 5 days of data collection*

The Cronbach's alpha for the state portion of the State-Trait Anxiety Inventory was .92 at baseline and .54 at post–data collection.

*See results "parent-newborn attachment"*

**Parent satisfaction**

*Instrument: NICU's standard 11-item parental satisfaction tool (uses a 5-point Likert-type scale), at baseline and repeated at the conclusion of the 5 days of data collection*

*See results "parent-newborn attachment"*

## Limitations and conclusion

**Limitations**

Because of its small sample, the study may have had inadequate power to demonstrate significant differences on some variables, thus increasing the risk of a type II error. A type II error is erroneously determining no significant differences when statistically significant differences actually exist (Burns & Groves, 2001). However, review of the descriptive data found the differences in infant physiological and behavioral variables between groups not to be clinically significant. The desired sample size was not obtained because of the increase in multiple gestation birth weights during the period of data collection as well as multiple-gestation infants not being stable at the same time. The interpretation of parental variables is limited by the poor reliability of the tools used to measure state anxiety and maternal attachment in this sample. Resource utilization could not be compared because several control group infants were co-bedded at parental request after the 5-day data collection period.

| | |
|---|---|
| **Authors' conclusion** | This research demonstrated the safety of co-bedding multiple-gestation infants in incubators but did not find any significant clinical improvement in infant or parental outcomes with cobedding. Neonatal intensive-care unit providers should educate staff and parents about the potential benefits of co-bedding and consider developing policies and procedures for co-bedding in both incubators and cribs. Co-bedding of multiple-gestation infants may be provided as an adjunctive developmental care strategy if parents desire this intervention. |

### Assessment of the Preterm Infant Behaviour (APIB): guided interaction and education

| **Browne et al. (2005)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | Demonstration and interaction, according to the systematic administration of the Assessment of the Preterm Infant Behaviour (APIB) (intervention group 1), and education (intervention group 2) |
| **Country** | USA | **Exposure control group** | Standard care (control group) |
| **Setting** | 1 NICU | **Level of prematurity** | ≤ 36 weeks of gestational age |
| **Sample size** | Intervention group 1: 28<br>Intervention group 2: 31<br>Control group: 25 | | |
| **Time frame** | NA | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | All mother–infant dyads admitted to the University Hospital were eligible candidates for the study. Infant characteristics determined inclusion of mothers in the study. Mothers whose infants were born at or before 36 weeks post-conceptional age and expected to be hospitalized 2 weeks or more, had no documented congenital anomalies, nor did their condition necessitate surgery, were approached for consent. Additional maternal criteria included the mother's age over 17 years, documented presence with their infant prior to discharge, no major medical complications associated with delivery, English speaking, and reading ability at least at a fifth grade level, as assessed by administration of the reading subscale of the Wide Range Achievement Test Reading Scale (WRAT). | | |
| **Exclusion criteria** | - | | |
| **Newborn and parent characteristics** | *Newborns*<br>Because inclusion criteria required the infants' hospital stay to be of at least 2 weeks duration, the number of hospital days ranged from a minimum of 14 days to a maximum of 80 days, with a mean of 33.16 days (SD = 16.98). A severity score was assigned based on review of medical record data reflecting length of stay, severity of illness, and complicating factors. The mean severity score for the infants was 54.64 (SD = 45.12) at discharge. Infant distribution to the three treatment groups was not statistically different for weight, Apgar score, gender, or severity of illness score.<br>*Parents* | | |

Racial composition was as follows: 75% white (n = 63), 15% African American (n = 13), and the remaining 9% comprised of Latina (n = 2), American Indian (n = 5), and Asian American (n = 1) women. Nine of the couples were racially mixed. Mothers reported that in most homes, the father was present regardless of marital status. Income and source of payment for the mothers' medical services were consistent with the referral pattern to the University Hospital, which was reported to be approximately 85–90% indigent. Eighty-seven percent of the study mothers had an income of less than $19,999, and 77% reported receiving public assistance for medical payment. The majority of mothers were unemployed (85%) and reported a highschool education or less. These data indicate that the participants studied were almost entirely from a low socioeconomic, low education background, and thus were a high-risk population. After establishing parity, participating mothers were randomly divided into one of three treatment groups by card draw to assure even distribution of parity in each group. No statistical differences between groups were found for mothers' age (M = 24.02, SD = 5.51), education, $\chi2(10, N = 83) = 9.83$, $p = .501$, or marital status, $\chi2(6, N = 84) = 8.42$, $p = .209$. The three groups did not differ by racial composition.

## Results

**Parent-newborn interaction**

*Instrument: Nursing Child Assessment Feeding Scale (NCAFS)*

Treatment group main effects were also found for the NCAFS, $F(2, 80) = 3.25$, $p < .05$), with scores for the control group significantly higher, indicating lower relationship quality, than scores for the intervention groups.

**Table II.** Mean Scores ± Standard Deviations of Outcome Measures by Experimental Group

| Measure | Total | Group 1 | Group 2 | Group 3 | *F* |
|---|---|---|---|---|---|
| Knowledge of Preterm Infant Behavior | 23.16 ± 5.94 | 23.32 ± 5.88* | 25.90 ± 5.30* | 19.58 ± 5.01* | 9.04 |
| Nursing Child Assessment Feeding Scale | 47.31 ± 7.06 | 45.65 ± 6.20** | 47.43 ± 7.36** | 48.88 ± 7.41** | 3.25 |

*Differ at $p < .0001$.
**Differ at $p < .05$.

**Stress**

*Instrument: Parenting Stress Index (PSI)*

A multivariate analysis of variance (MANOVA) with group as the between-subject factor was used to analyse the PSI, with severity of illness as a covariate. The MANOVA revealed a significant effect for group, multivariate $F(2, 76) = 1.71$, $p < .05$. Planned contrasts, using the Student Newman Keuls correction, indicated a marginally significant difference between groups in the child acceptability subscale, $F(2, 76) = 2.86$, $p = .056$, with control group mothers scoring higher, which indicated more perceived stress with parenting their infant at 1 month after discharge, than mothers in Groups 1 and 2. A large proportion (38%) of mothers in this highrisk population scored outside the published high and low normative ranges on the PSI regardless of group assignment. High and low scores are based on the 80$^{th}$ and 15th percentile ranks, respectively. Twenty-eight percent of the mothers scored higher than 250, whereas 10% scored lower than 180.

## Limitations and conclusion

**Limitations**

Engaging mothers in this high-risk population was challenging. Significant accommodation for their lack of transportation and financial resources to be with their infants in the hospital, care in providing culturally appropriate educational approaches, and patience in their lack of trust in the hospital system was warranted.

Other challenges to engaging mothers in the intervention included the lack of individualization of treatment to the mother's particular learning or coping style. These factors may have affected the extent to which mothers were able to engage in the intervention, and thus influenced outcomes.

| | |
|---|---|
| **Authors' conclusion** | This study provides evidence that even short-term intervention may have positive outcomes with a high-risk, low socioeconomic sample of mothers and infants. This population is reportedly at highest risk for parenting dysfunction, and yet appears to benefit most from both long-term or, as now documented, short-term intervention. These data demonstrate that an intervention that utilizes easy to administer educational materials may be as effective as a more time consuming and labour intensive intervention such as demonstration of the infant's behaviour. |

### Parent Baby Interaction Programme (PBIP)

| **Glazebrook et al. (2007)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Cluster-randomised controlled trial | **Exposure intervention group** | Parent Baby Interaction Program |
| **Country** | UK | **Exposure control group** | Standard care |
| **Setting** | 6 NICUs, three from each region (South West and Trent region) | **Level of prematurity** | < 32 weeks of gestational age |
| **Sample size** | Intervention group: 112<br>Control group: 121 | | |
| **Time frame** | July 2002 – January 2003 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Newborns*<br>The inclusion criteria for the study were that infants should be born at less than 32 weeks' gestation and admitted to one of the six neonatal centres in the study. | | |
| **Exclusion criteria** | *Newborns*<br>Exclusion criteria were an illness incompatible with life and residence outside the study catchment areas. | | |
| **Newborn and parent characteristics** | - | | |
| **Results** | | | |
| **Parent-newborn interaction** | Instrument: Nursing Child Assessment Teaching Scale (NCATS), videotaped a week prior to discharge and at home when the infant reached 3 months' corrected age<br>Scores for caregiver total interaction in the intervention and control groups did not differ. Over a quarter (25 (26.6%)) of mothers in the intervention group and 21 (20.6%) in the control group had scores below the 10$^{th}$ centile, which are considered worrisome.<br>Total NCATS caregiver scores in the intervention and control groups did not differ significantly. At three months' follow-up, 21 (22.6%) in the intervention and 21 (19.9%) in the control group had caregiver scores below the 10th centile cut-off. | | |

**Stress**

*Instrument: Parenting Stress Index Short Form (PSI-SF), completed by parents at 3 months' corrected age*

Total parenting stress in the intervention and control groups did not differ significantly. High levels of parenting stress (scores above the 85th centile) were found in mothers of 23 (25.3%) babies in the intervention group and 21 (19.4%) mothers in the control group, compared with the expected 15% in the normative population. Subgroup analyses with the primary outcome measure found no significant difference in intervention effect between first born and other infants (p=0.72) or between more and less premature infants (p=0.64).

**Table 3** Intervention effects on outcome variables measured before discharge and at 3 months corrected age*)

| | Intervention mean (SD) | n | Control mean (SD) | n | Adjusted intervention–control difference (95% CI)† |
|---|---|---|---|---|---|
| Before discharge | | | | | |
| *NAPI scores at 35 weeks (average of 7 z scores)* | *0.40 (0.54)* | *101* | *0.35 (0.65)* | *110* | *0.09 (−0.06 to 0.23), p=0.17* |
| NCATS cognitive growth fostering | 9.5 (3.3) | 94 | 10.1 (3.0) | 102 | |
| NCATS maternal sensitivity to cues | 9.4 (1.2) | 94 | 9.2 (1.2) | 102 | |
| NCATS emotional and social growth fostering | 7.9 (1.6) | 94 | 8.1 (1.5) | 102 | |
| NCATS maternal response to distress | 9.8 (1.6) | 94 | 10.0 (1.6) | 102 | |
| *NCATS total caregiver score* | *36.6 (5.1)* | *94* | *37.4 (4.9)* | *102* | *−0.7 (−2.7 to 1.4)., p=0.43* |
| 3 months corrected age | | | | | |
| NCATS cognitive growth fostering | 10.2 (2.9) | 93 | 10.7 (3.2) | 106 | |
| NCATS maternal sensitivity to cues | 9.6 (1.1) | 93 | 9.5 (1.1) | 106 | |
| NCATS emotional and social growth fostering | 7.5 (1.5) | 93 | 8.0 (1.6) | 106 | |
| NCATS maternal response to distress | 10.0 (1.5) | 93 | 10.2 (1.3) | 106 | |
| NCATS total caregiver score | 37.4 (4.8) | 93 | 38.3 (5.2) | 106 | −0.8 (−3.6 to 1.9), p=0.45 |
| PSI Difficult child | 23.6 (7.1) | 91 | 21.4 (6.8) | 108 | |
| PSI Parental distress | 27.2 (7.9) | 91 | 26.3 (9.2) | 108 | |
| PSI Dysfunctional interaction | 21.0 (6.4) | 91 | 19.4 (6.0) | 108 | |
| *PSI total score* | *71.9 (18.9)* | *91* | *67.1 (19.6)* | *108* | *3.8 (−4.7 to 12.4), p=0.28* |
| *HOME responsiveness* | *8.8 (1.1)* | *92* | *9.1 (1.5)* | *107* | *−0.2 (−0.9 to 0.5) , p=0.46* |

HOME, Home Observation for Measurement of the Environment; NAPI, Neurobehavioral Assessment of the Preterm Infant; NCATS, Nursing Child Assessment Teaching Scale; PBIP, Parent Baby Interaction Programme; PSI, Parenting Stress Index.
*Primary and secondary outcomes in italics.
†Adjusted for cluster-crossover design and for baseline variables (maternal age, maternal education, marital status, parity, gestational age, birth weight, number of fetuses, infant sex and index of multiple deprivation).

| | |
|---|---|
| **Neuro-developmental impairement** | *Instrument: Neurobehavioural Assessment of the Preterm Infant (NAPI), administered by two trained research nurses at 35 weeks' gestation*<br>The average NAPI z scores or neurophysiologic function in the groups, as measured by the average standardised NAPI scores, did not differ significantly.<br>*See Table in "Stress"* |
| **Limitations and conclusion** | |
| **Limitations** | There is a possibility of recruitment bias in a cluster-randomised design as recruitment happens after randomisation, but the high recruitment rates, baseline balance and lack of differences in response rates between the two groups are all evidence against such a bias. |
| **Authors' conclusion** | This study confirmed the difficulties that mothers of very preterm infants experience in relation to the provision of sensitive and responsive interaction. The intervention we tested made no difference to maternal stress, responsivity or infant neurobehaviour. It is possible that the impact of the intervention becomes apparent later in the study when cognitive function is assessed at 2 years adjusted age. |

### Family-centred unit in NICU

| **Örtenstrandt et al. (2010)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | Family-centred ward (FC) |
| **Country** | Sweden | **Exposure control group** | Standard care ward (SC) |
| **Setting** | 2 NICUs (both level II): 1 NICU at the Sachs' Children's Hospital and 1 NICU at the Karolinska University Hospital Danderyd | **Level of prematurity** | < 37 weeks of gestational age |
| **Sample size** | Intervention group: 177<br>Control group: 168 | | |
| **Time frame** | September 2006 – October 2008 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | Inclusion criteria were preterm birth (< 37 weeks), no major congenital malformation diagnosed on admission, and a need for in-hospital care in a level 2 NICU. | | |
| **Exclusion criteria** | - | | |
| **Newborn and parent characteristics** | Infant and maternal characteristics did not differ statistically between the FC and SC groups except for a higher median postconceptional age at randomization in the 300/7 to 346/7 group, and a lower proportion of women with a non–Swedish-speaking background in the FC group. A comparison between infants exposed to FC and SC gave almost identical results. | | |
| **Results** | | | |

| | |
|---|---|
| **LOS newborn** | *Defined as number of days from birth to discharge*<br>Total length of hospital stay was a mean of 5.3 days shorter in the FC group (mean: 27.4 days compared with 32.8 days in the SC group [P = 0.05]). The median difference, which was not adjusted for possible confounders, was -2 days (P = 0.25). The reduction of total length of stay was mainly explained by differences between the most preterm infants: mean -10.1 days (P = 0.26) and median -16 days (P = 0.02). Table 2 also shows that the smaller number of days in the hospital in the FC group was explained by a shorter stay in intensive care: mean -4.7 days (P = 0.02) and median -3 days (P = 0.02). Table 3 provides details of care in a level 3 NICU, such as admission directly from the delivery ward or later, and length of stay. The total length of stay was also calculated after excluding infants with congenital diseases diagnosed after randomization (2 infants in the FC group: Down syndrome, nonketotic hyperglycinaemia; and 5 in the SC group: Williams syndrome, Prader-Willi syndrome, myotubular myopathy, congenital pulmonary stenosis, and congenital liver disease), and was 27.3 days in the FC group and 31.8 days in the SC group, respectively (P = 0.05). |
| **Limitations and conclusion** | |
| **Limitations** | A limitation of our study was that the number of hours that 1 or both parents spent with their newborn during the intensive care period was not specifically recorded. However, our observation was that at least 1 of the parents in the FC group was present on the ward most of the time, except for a maximum of a few nights. The presence of parents in the SC group was limited by the fact that they usually could not stay overnight in the hospital, neither during the period of intensive care nor during rest of the stay. We did not find any evidence suggesting that SC infants were sicker, despite a slightly larger number of infants admitted to a level 3 NICU from the delivery ward. |
| **Authors' conclusion** | This study demonstrated a reductio of total length of hospital stay for infants born prematurely by providing facilities for parents to stay in the NICU 24 hours/day from admission to discharge. Analyses of secondary outcomes also suggested a reduction in pulmonary morbidity, such as moderate-to-severe BPD. However, this finding needs additional investigation. |

### Free parking for parents of hospitalised newborns

| **Northrup et al. (2016)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Randomised controlled trial | **Exposure intervention group** | Free parking (FP): received 7 parking vouchers at a time (value: $10/each) |
| **Country** | USA | **Exposure control group** | Usual care (UC): did not receive vouchers |
| **Setting** | NICU at the Memorial Hermann Hospital (Houston, Texas) | **Level of prematurity** | ≤ 1000 grams birth weight |
| **Sample size** | Intervention group: 72<br>Control group: 66 | | |
| **Time frame** | November 2007 – February 2011 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | Eligibility criteria included birth weight ≤1000 grams, age 7–14 days, and deemed "likely to survive." | | |

| | |
|---|---|
| **Exclusion criteria** | Exclusion criteria were uncertain custody status or anticipated hospital transfer. Participants who did not own a car were eligible if they reported reliable automobile access from another household member or family/friends. Infants were randomized using opaque, consecutively numbered, sealed envelopes stratified by birth weight (≤750g; >750g) and mechanical ventilation status (yes/no) on postnatal day seven. |
| **Newborn and parent characteristics** | Mean gestational age was 25.8 weeks and mean birth weight was 782g. Half of the infants were female (48.5%); 24.3% were White, 34.6% Black, 30.2% Hispanic, 3.7% Asian, and 7.4% identified as "Other" races/ethnicities. On postnatal day seven, 46.7% of the infants were receiving mechanical ventilation. Participants (most often mothers') average age was 29 years, 82.5% had a high school diploma/GED, 35.5% reported an annual income ≤$20,000, and 50.4% were married. No significant differences were found across group characteristics at baseline. |
| **Results** | |
| **LOS newborn** | There was no significant difference between FP and UC groups with respect to mean LOS (FP=89 [SD=37], UC=102 [SD=66] days; F=2.44, p=0.22), median LOS (FP=82, UC=84 days; non-parametric [2-sided] t-test approximation: p=0.30) or proportion of days that parents visited (FP=0.69 [SD=0.27], UC=0.72 [SD=0.21]; F=0.59, p=0.47). |
| **Satisfaction** | The groups also did not differ significantly with respect to satisfaction. |

**Parental Satisfaction**

| | % (n) | | |
|---|---|---|---|
| Family involvement[A,C] | | | 0.07 |
| Not enough | 7.5%(n=3) | 0.0%(n=0) | |
| Just right | 85.0%(n=34) | 81.4%(n=35) | |
| Too much | 7.5%(n=3) | 18.6%(n=8) | |
| | *M(SD)* | | |
| NICU support[A,D,E] | 28.7(3.7) | 30.0(2.7) | 0.07 |
| Emotional connection[A,D,F] | 12.3(1.7) | 12.3(1.7) | 0.96 |

| | |
|---|---|
| **Breastfeeding** | The groups also did not differ significantly with respect to breast or bottle feeding. |

**Care-by-Parent Measures (Per Day), *M(SD)***

| | | | |
|---|---|---|---|
| Breast milk fed (%) | 32.1%(36.5%) | 30.7%(36.8%) | 0.78 |
| Feeds at the breast (#) | 0.1(0.3) | 0.3(1.2) | 0.24 |
| Breast pumping (#) | 0.1(0.3) | 0.1(0.3) | 0.62 |
| Bottle feeds (#) | 0.2(0.2) | 0.2(0.2) | 0.99 |

| | |
|---|---|
| **Limitations and conclusion** | |
| **Limitations** | - |
| **Authors' conclusion** | More potent interventions than FP are needed to increase parental visits and reduce LOS for ELBW infants in disadvantaged urban populations. |

### Parenting intervention Baby Triple P (BTP)

| Evans et al. (2017) | | | |
|---|---|---|---|
| **Methods** | | | |
| Design | Randomised controlled trial | Exposure intervention group | Baby Triple P intervention |
| Country | Australia | Exposure control group | Standard care |
| Setting | 2 NICUs at the Royal Brisbane and Women's Hospital (RBWH) and the Mater Mothers' Hospital (MMH) | Level of prematurity | < 32 weeks of gestational age |
| Sample size | Intervention group: 61<br>Control group: 59 | | |
| Time frame | February 2012 – July 2013 | | |
| **Newborn and parent characteristics** | | | |
| Eligibility criteria | - | | |
| Exclusion criteria | Exclusion criteria included (i) infants born with major congenital abnormalities; (ii) families who were unwilling to complete assessment requirements at 24-months CA; and (iii) parents who could not speak English | | |
| Newborn and parent characteristics | There was a difference between groups at baseline for maternal age, t (118) = 2.18, p = .031, such that, the CAU mothers were younger in age (see Table 2). Controlling for maternal age by entering the variable into the GEE analysis as a covariate did not change the results. Therefore, the original data were reported at 6-weeks CA. Due to an attrition rate of 21% for BTP families and 25% for CAU families, the participant characteristics were again examined for families that completed the assessment measures at 12-months CA. There was a significant difference between groups for first-time mothers, such that, there were more first-time mothers in the CAU group, $\chi 2$ (1) = 8.22, p = .004. Controlling for this variable again did not change the results, therefore the original data were again reported at 12-months CA. | | |
| **Results** | | | |
| Parent-newborn attachment | Instrument: Maternal Postnatal Attachment Scale (MPAS)<br>The MPAS is a 19-item self-report questionnaire that measures a mother's emotional response to her infant. The range is 19–95, with each item scored from '1' low attachment to '5' high attachment. The scale has high internal consistency (α = 0.78, 0.79 and 0.78 at 4-weeks, 4-months, and 8-months respectively) and high test-retest reliability (α = 0.70).<br>At 6-weeks CA and 12-months CA, linear regression revealed no difference in self-reported maternal responsiveness between the BTP and the CAU mothers, $\chi 2$ (1) = 0.01, p > .05 and $\chi 2$ (1) = 2.02, p > .05, respectively. | | |
| **Limitations and conclusion** | | | |

| | |
|---|---|
| Limitations | - |
| Authors' conclusion | In conclusion, Baby Triple P did not improve the quality of the mother-preterm infant relationship, maternal attachment or responsiveness at 6-weeks CA or 12-months CA. Self-reported maternal attachment was significantly higher at 12-months CA for the CAU group. It is possible that BTP may impact on child behaviour, emotional problems, cognitive development, language and motor abilities at 24-months CA. |

### Parent participation improvement program

| **Heo et al. (2019)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Parallel, two-group randomised controlled trial | **Exposure intervention group** | Parent participation improvement program for parents (2 weeks) |
| **Country** | South-Korea | **Exposure control group** | Usual care according to open unit policy |
| **Setting** | NICU in hospital in Seoul | **Level of prematurity** | < 37 weeks of gestational age |
| **Sample size** | Intervention group: 33 dyads<br>Control group: 33 dyads | | |
| **Time frame** | February – August 2017 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Newborns*<br>The inclusion criteria for infants were (a) <37 weeks gestation, (b) receiving high-flow nasal cannula or less respiratory support, and (c) no expected to be discharged within one month.<br>*Parents*<br>The inclusion criteria for parents were (a) willingness to spend time with the infants according to the program's plan, and (b) informed consent for participation. | | |
| **Exclusion criteria** | - | | |
| **Newborn and parent characteristics** | In total, 62 infants and their 124 parents (62 mother-father dyads) were enrolled in this study. The intervention group consisted of 30 infants and their 30 mother-father dyads; the control group consisted of 32 infants and their 32 mother-father dyads. The demographic and clinical characteristics of these two groups are shown in Table 1, and no significant differences were found between the two groups. Additionally, no significant differences in the dependent variables were found between the two groups. | | |
| **Results** | | | |
| **Parent-newborn attachment** | *Instrument: Maternal Attachment Inventory* | | |

**Table 3**
Comparison of dependent variables in mothers and fathers of the two groups.

| Outcome measures | Intervention (N=30) | | | Control (N=32) | | | Mann-Whitney U | p |
|---|---|---|---|---|---|---|---|---|
| | Pre Mean(SD) | Post Mean(SD) | Diff Mean(SD) | Pre Mean(SD) | Post Mean(SD) | Diff Mean(SD) | | |
| Mothers | | | | | | | | |
| Attachment | 3.66(0.02) | 3.91(0.01) | 0.25(0.02) | 3.62(0.02) | 3.73(0.02) | 0.11(0.01) | 146.5 | < .001 |
| Partnership | 3.93(0.06) | 4.43(0.05) | 0.5(0.05) | 3.96(0.06) | 4.21(0.04) | 0.25(0.03) | 212.5 | < .001 |
| Fathers | | | | | | | | |
| Attachment | 3.50(0.03) | 3.84(0.01) | 0.33(0.03) | 3.50(0.03) | 3.57(0.02) | 0.07(0.02) | 84.5 | < .001 |
| Partnership | 3.83(0.1) | 4.31(0.07) | 0.48(0.05) | 3.89(0.09) | 4.04(0.07) | 0.15(0.03) | 152.5 | < .001 |

Diff=Difference.
Attachment scores were converted to 4 points.
Partnership scores were converted to 5 points.

## Limitations and conclusion

**Limitations**

This study has some limitations. Although this paper presents a description of parents' experiences of participating in neonatal care through interviews, parental attachment was evaluated with quantitative data. As there are limitations in understanding parental attachment and experiences of participation through quantitative data, further qualitative studies are needed for in-depth exploration of attachment and experiences of parents.

**Authors' conclusion**

The aim of this study was to develop the Parent Participation Improvement Program for parents in neonatal care and to evaluate its effects. This program was proven effective for increasing attachment and partnership in both mothers and fathers. The program, developed in accordance with King's goal attainment theory, will serve as a useful reference in developing standardized guidelines for promoting parent participation in neonatal care, and it is expected to bridge the gap between theory and practice by applying family-centered care to the practical base of neonatal care. Although the effectiveness of the program on partnerships and attachment has been identified, it may have been conducted over too short a period of time for parents and nurses to form a true partnership and to enable accurate measurements. In addition, the study period may be too short to assessing changes in the weight of premature infants due to parent participation. Therefore, future research needs to increase the duration of interventions and assess the effectiveness of the program on the partnership between nurses and parents through long-term follow-up studies.

Another limitation is the lack of a baseline assessment of the level of parent participation that may have potentially affected partnership and attachment. However, in this study, the researcher attempted to control the assessment through random assignment of participants to groups and found no significant difference in the scores at baseline.

Furthermore, the generalization of the program's effectiveness is limited because the study was conducted with parents of premature and immature infants in a single hospital in Seoul, Korea.

### Financial support for mother of hospitalised newborns

| Andrews et al. (2020) | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Non-blinded randomised controlled trial | **Exposure intervention group** | Received financial support during newborn's hospitalisation |
| **Country** | USA | **Exposure control group** | Received informational pamphlets on SSC and breastfeeding, and supported them in obtaining a Medicaid-sponsored breast pump. In order to facilitate breastmilk production, we also offered all participants a hospital-grade breast pump on loan to take home while their infant was in the NICU. Hospital staff (who were blinded to treatment status) followed existing hospital policies for NICU visitation, breastfeeding support and skin-to-skin care. Women received a gift (a baby hat) at the point of completion of the study (3 months after discharge) but received no other compensation for participating in the study. |
| **Setting** | Tufts Medical Center, NICU (level IIIb), Boston, Massachusetts<br>Lowell General Hopsital, special care nursery (level IIb), Lowell, Massachusetts | **Level of prematurity** | 30 – 36 weeks of gestational age |
| **Sample size** | Intervention group: 25<br>Control group: 21 | | |
| **Time frame** | January 2017 – June 2018 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | We enrolled English- or Spanish-speaking Medicaid-eligible mothers of preterm infants born between 30 and 36 completed weeks of gestation without any contraindications to breastfeeding (which would have included mothers with documented substance abuse that would interfere with breastfeeding, HIV infections, breast surgeries, or certain medications). We assessed Medicaid-eligibility using electronic medical records, which listed women's insurance. | | |
| **Exclusion criteria** | - | | |
| **Newborn and parent characteristics** | Most women (89%) were enrolled at the main referral hospital. Mean maternal age was 32 years. The sample was racially diverse: 30% were white non-Hispanic, 20% were black, 36% were Hispanic and the remaining 13% reported another race. Approximately a third of the participants (36%) were first-time mothers. Five sets of twins were born to women in the treatment group, and two sets of twins were born to women in the control group. At | | |

| | |
|---|---|
| | birth, infants in the treatment group were about 1 week older, 122 g heavier and one cm longer on average than infants in the control group. Across groups, mean gestational age at birth was 33.4 weeks and mean birthweight was 1919 g. |
| **Results** | |
| **Parent-newborn interaction** | mothers receiving the transfer were 1.85 times as likely to practice SSC (95% CI 1.25–2.75), 1.23 times as likely to visit the NICU (95% CI 1.02–1.49) and 1.36 times likely to provide breastmilk (95% CI 1.10–1.69) on any given day compared to the control group. The average share of maternal behaviours performed (adjusted mean difference [percentage points]: 0.25; 95% CI 0.12–0.38) and the average number of minutes of STSC provided daily (adjusted mean difference [minutes]: 33.36; 95% CI 13.38–53.34) were also statistically significantly higher in the treatment group versus the control group. |
| **LOS newborn** | Within the context of this small trial, we found no statistically significant differences for observed LOS. |

**Table 3** Infant outcome measures by treatment group

| | Unadjusted treatment group mean | Unadjusted control group mean | Unadjusted mean difference | Unadjusted OLS estimate of treatment effect | Adjusted OLS estimate of treatment effect | n |
|---|---|---|---|---|---|---|
| Length of stay at enrollment hospital (days) | 12.30 | 18.17 | − 5.87 | − 5.94 (− 12.06–0.17) | − 1.66 (− 6.54–3.21) | 53 |

| | |
|---|---|
| **Breastfeeding** | *See results "Parent-newborn interaction"* |
| **Limitations and conclusion** | |
| **Limitations** | First, the small sample size limits our ability to detect small effects and warrants interpreting the statistically significant effects with caution (Button et al. 2013). While we designed this small trial to establish feasibility, enrollment in the study was slower than expected because of low hospital volumes and the propensity of Tufts Medical Center to attract highrisk pregnancies (and consequently deliver infants who were either too premature or too sick to be eligible). Within this small sample, we experienced some chance imbalance, though estimates of treatment impacts on maternal behaviors are robust to adjusting for baseline imbalance.<br>Second, our evidence comes from Massachusetts, a setting where numerous quality improvement programs have been implemented to encourage provision of breastmilk and STSC for infants in the NICU (Leeman et al. 2018). Our results are therefore most relevant to contexts in which NICUs are prepared to support breastfeeding and skin-to-skin care behaviors and where mothers are able to secure access to a high quality breast pump in accordance with the most recent guidance (American Academy of Pediatrics 2019). Further work is needed to understand how the intervention effects would translate to other settings and populations. Relatedly, we conducted our trial among a group of later preterm infants, with relatively short NICU stays. Even within this context, we limited our cash transfer to three weeks, which may have blunted its ability to support families with younger preterm infants for whom the transfer stopped prior to their discharge. Future work could consider the impact of similar transfers paid over a longer period within a population of more medically vulnerable, younger preterm infants with more associated health challenges.<br>Furthermore, this study does not provide conclusive evidence about the amount and frequency of the financial transfer needed to support maternal caregiving. Future work on the optimal amount, frequency, and target population for the financial transfer would be extremely valuable.<br>Finally, we were not able to track mothers and newborns to community hospitals to record maternal behaviors, and our conclusions are limited by incomplete data for some outcomes. However, we expect these data limitations would affect both the treatment and control groups equally, as there were no statistically significant differences in the transfer rate to community hospitals or differences in postmenstrual age at discharge between treatment groups. |

| | |
|---|---|
| **Authors' conclusion** | Because of persistent disparities in preterm birth, the burden of preterm birth falls disproportionately on families with limited economic resources. We find evidence that labelled financial support can increase SSC and the provision of breastmilk among Medicaid-eligible families of preterm infants. More evidence is needed to understand the potential impacts on neonatal and maternal outcomes in a representative population. |

### Virtual family-centred rounds

| **Rosenthal et al. (2021)** | | | |
|---|---|---|---|
| **Methods** | | | |
| **Design** | Two-arm randomised controlled pilot trial | **Exposure intervention group** | Participation of parents in virtual family-centred rounds: using Zoom® |
| **Country** | USA | **Exposure control group** | Standard care: had the option to participate in FCR in person or not to participate in FCR |
| **Setting** | NICU (level IV) in a quaternary care children's hospital in North Carolina | **Level of prematurity** | NA (35.6 mean gestational age intervention group and 34.7 in control) |
| **Sample size** | Intervention group: 74<br>Control group: 36 | | |
| **Time frame** | 1 March 2020 – 31 August 2020 | | |
| **Newborn and parent characteristics** | | | |
| **Eligibility criteria** | *Newborns*<br>Eligible neonates had one or more non-incarcerated, English-speaking parent or guardian (referred to as "caregiver" hereafter) aged ≥18 years. | | |
| **Exclusion criteria** | *Newborns*<br>We excluded neonates if they had restrictions placed by child protective services, including visitation restrictions or parental restricted access to patient information. | | |
| **Newborn and parent characteristics** | The intervention and control groups were similar in regards to each measured neonatal and maternal characteristic. | | |
| **Results** | | | |
| **LOS newborn** | *Obtained from HER*<br>As shown in Table 3, the median subject length of stay was 12 (IQR 5.5−29) and 20 (IQR 13.5−30.5) days for the intervention and control group, respectively. The probability that a randomly chosen length of stay from the control arm was at least as long as one from the intervention arm was 0.62 (95% CI 0.496−0.75). | | |

**Table 3.** Length of Stay and Breast Milk Feeding by Intervention Versus Control Group

| Exploratory Outcome | Intervention | Control | Effect Size |
|---|---|---|---|
| Breast milk feeding at discharge, % | Mean (95% CI) | | Percentage point difference (95% CI) |
| Any breast milk | 88.5 (79.8–97.1) | 78.6 (63.4–93.8) | 9.9 (−7.6 to 27.4)* |
| Exclusive breast milk | 30.8 (18.2–43.3) | 10.7 (−0.7 to 22.2) | 20.0 (3.1–37.0)* |
| | Median (IQR) | | C-statistic (95% CI) |
| Length of stay, *days* | 12 (5.5–29) | 20 (13.5–30.5) | 0.62 (0.496–0.75)† |

CI indicates confidence interval; IQR, interquartile range.
*Wald CI for the difference in proportion.
†The point and CI for the C-statistic was calculated by transforming the corresponding Somers' D point and interval estimates using the transformation C=0.5(D+1).

| | |
|---|---|
| **Breastfeeding** | *Measured by breastmilk feeding at discharge, obtained from HER*<br>The between arm differences (intervention arm minus control arm) in proportion were 9.9% (95% CI -7.6 to 27.4%) and 20.0% (95% CI 3.1−37.0%) for receiving any breast milk and exclusive breast milk, respectively, at the time of discharge (Table 3). |
| **Limitations and conclusion** | |
| **Limitations** | This pilot trial was not designed to detect intervention efficacy. Rather, we included the exploratory outcomes to determine feasibility of data collection and to obtain empirical estimates of statistical parameters. Caution must be used when interpreting the effect sizes estimate from our pilot trial, as we might have overestimated or underestimated the true effect size. This limitation must be taken into consideration before generalizing these findings.<br>Another limitation of our study was the restriction to subjects with an English-speaking caregiver. However, the use of a homogeneous sample for this pilot trial was a necessary first step; future trials will include other languages. Our study was conducted at a level IV NICU within a teaching children's hospital; feasibility of conducting a virtual FCR trial may differ in other settings.<br>Furthermore, we specified five a priori feasibility objectives; however, other relevant measures of feasibility were not included. Despite these limitations, our pilot trial provides useful data to enhance the design and implementation of future virtual FCR trials. |
| **Authors' conclusion** | We conclude that a randomized trial to compare virtual FCR to standard of care in NICU patients is feasible in regard to intervention technical feasibility, intervention burden on the medical team, and caregiver survey data collection. Efforts to improve recruitment of intervention arm caregivers are needed. Outcomes to measure in the future hypothesis testing trial should include FCR caregiver attendance, length of stay, breast milk feeding at discharge, caregiver experience, and medical errors and adverse events. |

## Appendix 2.4. Assessment of risk of bias in included studies

| | | D1 | D2 | D3 | D4 | D5 | D6 |
|---|---|---|---|---|---|---|---|
| 1 | **Gray et al. (2000)** | + | ? | ? | ? | − | − |
| 2 | **Roberts et al. (2000)** | + | + | − | ? | + | ? |
| 3 | **Westrup et al. (2000)** | + | + | + | + | ? | ? |
| 4 | **Melnyk et al. (2001)** | − | + | + | − | − | − |
| 5 | **Feldman et al. (2002)** | + | + | + | + | + | + |
| 6 | **White-Traut et al. (2002)** | − | − | + | + | − | − |
| 7 | **Byers et al. (2003)** | + | − | + | − | ? | − |
| 8 | **Als et al. (2003)** | + | ? | + | + | ? | ? |
| 9 | **Birsch et al. (2003)** | + | + | + | + | ? | ? |
| 10 | **Feldman et al. (2003)** | + | + | + | + | + | + |
| 11 | **Browne et al. (2005)** | + | + | + | + | + | + |
| 12 | **Feijó et al. (2006)** | + | ? | + | ? | ? | ? |
| 13 | **Kaaresen et al. (2006)** | + | + | + | + | ? | ? |
| 14 | **Melnyk et al. (2006)** | − | + | + | − | − | − |
| 15 | **Miles et al. (2006)** | ? | + | + | + | + | ? |
| 16 | **Glazebrook et al. (2007)** | + | + | + | − | + | − |
| 17 | **Kleberg et al. (2007)** | + | ? | + | + | ? | ? |
| 18 | **Van der Pal et al. (2007)** | ? | − | + | + | ? | − |
| 19 | **Chiu et al. (2009)** | + | + | + | + | ? | ? |
| 20 | **Newnham et al. (2009)** | + | ? | + | + | ? | ? |
| 21 | **Peters et al. (2009)** | + | ? | + | + | ? | ? |
| 22 | **Örtenstrandt et al. (2010)** | + | + | + | + | ? | ? |
| 23 | **Zelkowitz et al. (2011)** | + | + | + | + | + | + |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 24 | **Feeley et al. (2012)** | 🟢 | 🟢 | 🟢 | 🟢 | 🟢 | 🟢 |
| 25 | **Ravn et al. (2011)** | 🟠 | 🟢 | 🟢 | 🟢 | 🟠 | 🟠 |
| 26 | **Ravn et al. (2012)** | 🟠 | 🟢 | 🟢 | 🟠 | 🟠 | 🟠 |
| 27 | **Ravn et al. (2012)** | 🟠 | 🟢 | 🟢 | 🟢 | 🟠 | 🟠 |
| 28 | **Schlez et al. (2011)** | 🟢 | 🟢 | 🟢 | 🟢 | 🟠 | 🟠 |
| 29 | **Holditch-Davis et al. (2013)** | 🟢 | 🟢 | 🟢 | 🟢 | 🟠 | 🟠 |
| 30 | **Matricardi et al. (2013)** | 🔴 | 🟢 | 🟢 | 🟢 | 🟠 | 🔴 |
| 31 | **Welch et al. (2013)** | 🟢 | 🔴 | 🟢 | 🟢 | 🟢 | 🔴 |
| 32 | **White-Traut et al. (2013)** | 🟢 | 🟠 | 🟢 | 🟢 | 🟠 | 🟠 |
| 33 | **Arnon et al. (2014)** | 🟠 | 🟢 | 🟢 | 🟢 | 🟠 | 🟠 |
| 34 | **Chorna et al. (2014)** | 🟢 | 🟢 | 🟢 | 🟢 | 🟢 | 🟢 |
| 35 | **Holditch-Davis et al. (2014)** | 🟠 | 🟠 | 🟢 | 🟢 | 🟠 | 🟠 |
| 36 | **Cong et al. (2015)** | 🟢 | 🟠 | 🟢 | 🔴 | 🟠 | 🔴 |
| 37 | **Mörelius et al. (2015)** | 🟢 | 🟠 | 🟢 | 🟢 | 🟠 | 🟠 |
| 38 | **Hoffenkamp et al. (2015)** | 🟢 | 🟠 | 🟢 | 🟢 | 🟠 | 🟠 |
| 39 | **Samra et al. (2015)** | 🟢 | 🟢 | 🟢 | 🟢 | 🟢 | 🟢 |
| 40 | **White-Traut et al. (2015)** | 🟢 | 🟢 | 🟢 | 🟢 | 🟢 | 🟢 |
| 41 | **Castel et al. (2016)** | 🟢 | 🟢 | 🟢 | 🔴 | 🟠 | 🔴 |
| 42 | **Nörthrup et al. (2016)** | 🟢 | 🟢 | 🟢 | 🟢 | 🟠 | 🟠 |
| 43 | **Welch et al. (2016)** | 🟠 | 🟠 | 🟢 | 🟢 | 🟢 | 🟠 |
| 44 | **Evans et al. (2017)** | 🟠 | 🟠 | 🟢 | 🟢 | 🟠 | 🟠 |
| 45 | **Beebe et al. (2018)** | 🟢 | 🟢 | 🟢 | 🔴 | 🟢 | 🔴 |
| 46 | **O'Brien et al. (2018)** | 🟠 | 🟠 | 🟠 | 🟠 | 🟢 | 🟠 |
| 47 | **Ranger et al. (2018)** | 🟢 | 🟢 | 🔴 | 🔴 | 🔴 | 🔴 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 48 | **Vittner et al. (2018)** | 🟢 | 🟢 | 🟢 | 🟢 | 🟠 | 🟠 |
| 49 | **Heo et al. (2019)** | 🟢 | 🟢 | 🟢 | 🔴 | 🟠 | 🔴 |
| 50 | **Andrews et al. (2020)** | 🟢 | 🟢 | 🟢 | 🟢 | 🟠 | 🟠 |
| 51 | **Benzies et al. (2020)** | 🟢 | 🔴 | 🟢 | 🔴 | 🟠 | 🔴 |
| 52 | **Church et al. (2020)** | 🟠 | 🟢 | 🔴 | 🟢 | 🟠 | 🔴 |
| 53 | **Coşkun et al. (2020)** | 🟢 | 🟠 | 🟢 | 🟢 | 🟠 | 🟠 |
| 54 | **Mehler et al. (2020)** | 🟢 | 🟢 | 🟢 | 🟢 | 🟢 | 🟢 |
| 55 | **Sahlen Hemler et al. (2020)** | 🟢 | 🟢 | 🟢 | 🟢 | 🟠 | 🟠 |
| 56 | **Corrigan et al. (2021)** | 🟢 | 🟠 | 🟢 | 🔴 | 🟠 | 🔴 |
| 57 | **Menke et al. (2021)** | 🟢 | 🟠 | 🟢 | 🟢 | 🟠 | 🟠 |
| 58 | **Rosenthal et al. (2021)** | 🟢 | 🟠 | 🟢 | 🟢 | 🟠 | 🟠 |
| 59 | **Twohig et al. (2021)** | 🟠 | 🟠 | 🟢 | 🟢 | 🟠 | 🟠 |

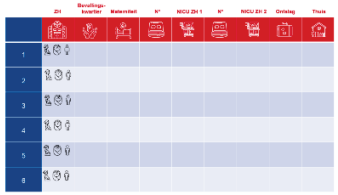
D1: randomisation process; D2: deviations from intended interventions; D3: missing outcome data; D4: measurement of the outcome; D5: selection of the reported result; D6: overall bias.

A green bullet refers to “low risk of bias”, an orange one to “some concerns”, and the red bullet to “high risk of bias”.

# APPENDIX 3. ANNEX TO CHAPTER 5

## Appendix 3.1. Interview guide

### *Appendix 3.1.1. Dutch version*

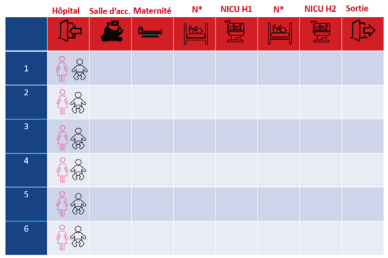
| VRAGEN | FOLLOW-UP VRAGEN |
|---|---|
| **IJSBREKER** | |
| **1. Kan u kort het hospitalisatietraject van bevalling tot terugkeer naar huis beschrijven van uw baby en uzelf (eventueel partner)?** | **Open de PowerPoint**<br><br>Bij elke episode<br>**Eigen kamer voor mama en kind(eren) of aparte plaats voor mama en kind?**<br>**Hoe werd het verblijf van de andere ouder geregeld?**<br>(rooming-in met de baby of de mama)<br>**Hoe lang verbleef uw kind op elke afdeling voor hij naar huis ging?**<br>**Hoe was het verblijf geregeld nadat de mama uit het ziekenhuis was ontslagen?**<br>(kamer in het ziekenhuis, hotel, gemeenschappelijke ruimte voor ouders, badkamer, bezoekuren)<br>**Als uw baby naar een ander ziekenhuis werd overgebracht, hoe was de accommodatie in dit tweede ziekenhuis?**<br>**Was dit uw eerste ervaring met de neonatologie (N* en/of NICU)?** (e.g. eerdere bevalling of kinderen van familie die op een neonatologie-afdeling weren gehospitaliseerd) |
| **2. Kan u ons iets meer vertellen over de eerste uren na de bevalling?** | **Had je de kans om je baby te zien na de geboorte? Hoe was je eerste ontmoeting met je baby('s)?**<br>**Wanneer heb je de kans gehad om je baby voor de eerste keer vast te houden** (ook een vraag voor de papa)**? Wat vind je van deze timing?**<br>**Hoe verliep de opname van uw kind op de neonatologie?** (onmiddellijk na de geboorte versus na een paar uur/dagen)<br>**Hoe was het eerste bezoek aan uw baby georganiseerd?** (aanwezigheid van een zorgverlener/uitleg door zorgverleners …) |
| **DEEL I: HECHTING** | |

| | | |
|---|---|---|
| 3. | **Hoe heeft u de fysieke scheiding van uw baby ervaren? (geen knuffel kunnen geven, in bed stoppen, etc.)**<br><br>**Note for the interviewer: question for both parents, pay attention to make a link between responses and services - NICU, N*.** | **Hoe werden de bezoeken aan uw baby georganiseerd?** (24h24, 7d/7?)<br>**Hoe zou je deze momenten omschrijven?** (Hoe voelde je je? Welke moeilijkheden heb je ondervonden? Hoe heb je die kunnen overwinnen?)<br>**Hoe werd het lichamelijk contact met uw baby('s) georganiseerd?** (toestemming nodig van verpleegkundigen, volgens een vast schema (bv: enkel tijdens bezoek), vrij (dag en nacht), Werd dit aangemoedigd? Zo ja, hoe en door wie?)<br>**Wie zorgde voor uw baby tijdens uw afwezigheid?** (verpleegkundigen, partner, etc?)<br>**In welke mate had u hulp nodig bij het huid-op-huid contact ?** (bv. verpleegkundige, partner, etc.)<br>**In welke mate hadden andere personen huid-op-huid contact met uw baby ? Hoe werd dit georganiseerd? Regeling COVID?** (verpleegkundigen, partner, andere familieleden, vrijwilligers, etc.)<br>**In welke mate verschilde deze organisatie tussen de afdelingen?** |
| 4. | **In welke mate was uw rol als ouder verschillend dan dat u verwacht had vóór de geboorte?**<br><br>**Note for the interviewer: question for both parents. If only one present please ask the perception of the other parents' role** | **In welke mate hebt u tegenstrijdige informatie gekregen in vergelijking met de informatie die u prenataal kreeg?**<br>**In welke mate was u voorbereid op de mogelijkheid van een hospitalisatie in de neonatologie? Zo ja, hoe?** |
| **DEEL II: VERZORGING** | | |
| 5. | **In welke mate was u betrokken bij de verzorging van uw baby (bad geven, verschonen, voeding, etc.)**<br><br>**Note for the interviewer: question for both parents pay attention to make a link between responses and services - NICU, N*.** | **Hoe werd je geholpen om voor je baby te zorgen?** (+ organisatorische en/of architecturale elementen)<br>**Van wie kreeg je hulp in de zorg voor je baby?** (artsen versus verpleegkundigen?)<br>**Wat maakte het voor u moeilijk om te betrokken te worden in de zorg voor je baby?** (organisatorische en/of architecturale elementen (ex. meubilair) + gezondheid van de mama)<br>**Heeft u alle hulp gekregen die u nodig had?**<br>**Welke hulp zou je nodig hebben gehad?** (professionelen/familie en vrienden/sociaal assistenten)<br>**In welke mate was u betrokken bij de voedingskeuze van uw baby?**<br>**Hoe was u betrokken bij de voeding van uw baby?** (beide ouders)<br>***Bij borstvoeding:***<br>**In welke mate werd u ondersteund tijdens de borstvoeding?** (respect voor uw ritme en dat van de baby, privacy, beschikbaarheid van een lactatiedeskundige, artsen, melkbank, beschikbaarheid van kolven in een privéruimte)<br>**Wat waren de barrières voor borstvoeding?**<br>***Bij flesvoeding:***<br>**In welke mate werd u ondersteund bij het voorbereiden van de flesjes?** (voorbereiding, reiniging, etc.) |
| 6. | **Hoe ging u om met de angst en/of bezorgdheid over de gezondheid van uw baby?** | **Door wie, wanneer, waar en hoe werd u ondersteund in uw angst en bezorgdheid ?** |

| | | |
|---|---|---|
| | **Note for the interviewer: question for both parents.** | |
| 7. | **Hoe voelde u zich toen u de medische apparatuur zag in de kamer van u baby/uw kamer?**<br><br>**Note for the interviewer: question for both parents pay attention to make a link between responses and services - NICU, N*.** | **In welke mate begreep u het doel en de functie van de medische apparatuur?** (uitleg door verpleegkundigen, artsen, ...)<br>**In welke mate was u zelf betrokken bij het gebruiken van deze medische apparatuur?** (zelfstandig gebruik/controle van sommige apparatuur) |
| **DEEL III: SAMENWERKING MET ZORGVERLENERS** | | |
| 8. | **In welke mate was de gezondheidsinformatie van uw baby duidelijk?** | **Wie gaf u de informatie over de behandelingen van uw baby('s)?**<br>**In welke mate was de informatie die u kreeg over de behandelingen duidelijk voor u?** (Was er een verschil tussen artsen-verpleegkundigen? Was er een verschil tussen de afdelingen?)<br>**In welke mate was de informatie duidelijk over de reden waarom uw baby('s) naar de neonatale afdeling overgeplaatst werden? Wie gaf u deze uitleg?** (Was er een verschil tussen artsen-verpleegkundigen? Was er een verschil tussen de afdelingen?)<br>**In welke mate was de informatie duidelijk die u kreeg over de medische onderzoeken en de resultaten? Wie gaf u deze uitleg?** (Was er een verschil tussen artsen-verpleegkundigen? Was er een verschil tussen de afdelingen?)<br>**In welke mate had u de mogelijkheid om al uw vragen te stellen?** (Was er een verschil tussen artsen-verpleegkundigen? Was er een verschil tussen de afdelingen?) |
| 9. | **Hoe evalueert u de beschikbaarheid van het verplegend en medisch personeel?**<br><br>**Note for the interviewer: question for both parents, comparison between services.** | **Hoe heeft het personeel u betrokken bij de zorgverlening van uw baby('s)?**<br>**In welke mate werd je ondersteund in je autonomie als ouder?** (Empowerment van opvoding en zorg ? Verschil tussen artsen-verpleegkundigen?)<br>**Hoe evalueert u de relatie met de verpleegkundigen/vroedkundigen in elke afdeling/ziekenhuis waar u verbleven hebt?**<br>**Hoe evalueert u de relatie met de artsen in elke afdeling/ziekenhuis waar u verbleven hebt?**<br>**Was dit wat je nodig had?**<br>(Note for the interviewer: check if the situation was the same in all hospitals the baby was admitted) |
| **DEEL IV: TRANSFER VAN N* NAAR NICU/NAAR EEN ANDER ZIEKENHUIS** | | |
| 10. | **Hoe verliep de transfer van uw baby naar de neonatale intensieve zorgen (in een ander ziekenhuis)?** | **Hoe bent u geïnformeerd over deze transfer?**<br>**In welke mate voelde je je voorbereid voor deze transfer?**<br>**In welke mate voelde je je ondersteund?**<br>**Welke moeilijkheden heb je ondervonden?** |
| 11. | **Hoe verliep de terugkeer van uw baby naar het ziekenhuis waar hij/zij geboren is?** | **Hoe bent u geïnformeerd over deze transfer?**<br>**In welke mate voelde je je voorbereid voor deze transfer?** |

| | |
|---|---|
| **This question is not relevant for participants where a NICU ward is available in the maternity where the baby is born** | **In welke mate voelde je je ondersteund?**<br>**Welke moeilijkheden heb je ondervonden?** |
| **DEEL V: DAGELIJKS LEVEN** | |
| **12. In welke mate heeft de organisatie van het leven buiten het ziekenhuis uw beschikbaarheid voor uw baby in de weg gestaan?**<br><br>**Note for the interviewer: question for both parents.** | **Welke moeilijkheden heb je ondervonden?**<br>**In welke mate voelde je je ondersteund?**<br>**In welke mate werd u ondersteund voor de broers en zussen van uw baby?** (inden van toepassing)<br>**Wat kan er verbeterd worden op dit gebied?**<br>**In hoeverre was het zwangerschaps-/vaderschapsverlof toereikend?**<br>**In welke mate had de ziekenhuisopname van uw baby een invloed op uw werk en financiële situatie?** |
| **DEEL VI: TERUGKEER NAAR HUIS** | |
| **13. Hoe was de terugkeer naar huis voor de mama georganiseerd?**<br><br>**Note for the interviewer: question for both parents, pay attention if the mother is return home before the baby, pay attention comparison between all settings.** | **Welke moeilijkheden heb je ondervonden?**<br>**In welke mate was je voorbereid op de thuiskomst?** (beide ouders)<br>**In welke mate voelde je je ondersteund?**<br>**Hoe waren de bezoeken aan uw baby('s) georganiseerd?**<br>**Hoe zou u deze organisatie evalueren?** |
| **14. Hoe was de terugkeer naar huis voor uw baby georganiseerd?** | **Welke moeilijkheden heb je ondervonden?**<br>**In welke mate was je voorbereid op de thuiskomst van je baby?**<br>**In welke mate voelde je je ondersteund?** |
| **DEEL VII: SLOT** | |
| **15. Hebt u zelf nog suggesties om de ervaring van ouders met premature baby's in de neonatologie te verbeteren?**<br><br>**Note for the interviewer: question for both parents.** | **Note for the interviewer: does the second researcher has additional questions? Check notes taken if clarification are needed for the previous discussions** |

## *Appendix 3.1.2. French version*

| QUESTIONS | FOLLOW-UP QUESTIONS |
|---|---|
| **QUESTION BRISE-GLACE** | |
| **1. Afin de bien comprendre votre parcours de soins, nous allons retracer avec vous les différents lieux que vous avez fréquentés depuis votre arrivée à l'hôpital jusqu'à votre retour à la maison ?** | **Ouvrir le PowerPoint**<br><br>A chaque étape<br>**Chambre particulière pour la mère et le(s) bébé(s) ou lieu séparé pour la mère et l'enfant ?**<br>**Comment était organisé l'hébergement de l'autre parent ?** (rooming-in avec le bébé ou la maman)<br>**Combien de temps votre enfant est-il resté à dans chaque service avant de rentrer à la maison ?**<br>**Comment était organisé votre hébergement après la sortie de la maman de l'hôpital ?** (chambre dans l'hôpital, hôtel, présence d'une pièce commune pour les parents, salle de bain, heure d'ouverture)<br>**Si votre bébé a été transféré dans un autre hôpital, comment était organisé l'hébergement dans ce second hôpital ?**<br>**Était-ce votre première expérience en néonatologie (NICU/N*) ?** (accouchement précédent ou enfants de proche ayant été pris en charge dans un service de néonatologie) |
| **2. Racontez-nous comment s'est passé l'arrivée de votre bébé / vos bébés ?** | **Avez-vous eu l'occasion de voir votre bébé après l'accouchement ? Comment s'est passé votre première rencontre avec votre bébé / vos bébés ?**<br>**Quand avez-vous eu l'occasion de prendre le bébé sur vous ?** (question aussi pour le papa) **Comment jugez-vous ce timing ?**<br>**Comment s'est passé l'admission de votre enfant en néonatologie ?** (directement après l'accouchement versus après quelques heures / jours)<br>**Comment s'est passé la première visite auprès de votre enfant ?** (présence de soignant / explication des soignants…) |
| **PARTIE I: L'ATTACHEMENT** | |

| | |
|---|---|
| **3. Comment avez-vous vécu la séparation physique d'avec votre bébé ? (ne pas pouvoir lui donner un doudou, ne pas pouvoir le cajoler, mettre votre enfant au lit)**<br><br>**Note for the interviewer: question for both parents, pay attention to make a link between responses and services - NICU, N*.** | **Comment étaient organisées les visites auprès de votre enfant ?** (24h24, 7j/7 ?)<br>**Comment décririez-vous ces moments?** (Comment vous sentiez-vous ? Quelles difficultés rencontriez-vous ? Comment avez-vous pu les surmonter ?)<br>**Comment étaient organisés les contacts physiques avec votre bébé / vos bébés ?** (besoin de permission des infirmières, selon un timing fixe (p. ex. : seulement pendant les visites), librement (jour et nuit), Était-ce encouragé ? Si oui, comment et par qui ?)<br>**Qui s'occupait de votre bébé en votre absence? (**l'infirmière, le partenaire, rôle de la fratrie)<br>**Dans quelle mesure avez-vous eu besoin d'aide lors des contacts peau-à-peau ?** (p. ex. : infirmière, le partenaire, autre)<br>**Dans quelle mesure d'autres personnes ont eu des contacts peau-à-peau avec votre bébé ? Comment était-ce organisé ? Dans quelle mesure cette organisation était différente à cause du COVID ? Qu'en pensez-vous ?** (infirmières, partenaire, autres membres de la famille, volontaires)<br>**Dans quelle mesure cette organisation était différente entre les services que vous avez fréquentés ?** |
| **4. Dans quelle mesure votre rôle de parents était différent de celui auquel vous vous attendiez avant l'accouchement ?**<br><br>**Note for the interviewer: question for both parents. If only one present please ask the perception of the other parents' role.** | **Avez-vous reçu des informations contradictoires par rapport à aux informations reçues en prénatal ?**<br>**Aviez-vous été préparé à l'éventualité d'un séjour en néonatologie ? Si oui, comment ?** |
| **PARTIE II: LES SOINS** | |
| **5. Dans quelle mesure avez-vous été impliqué(s) dans les soins de votre bébé (le bain, le change, l'alimentation) ?**<br><br>**Note for the interviewer: question for both parents pay attention to make a link between responses and services - NICU, N*).** | **Comment avez-vous été aidé(s) pour prendre soin de votre bébé ?** (+ éléments organisationnels et architecturaux)<br>**Par qui avez-vous été aidé(s) pour prendre soin de votre bébé ?** (médecins versus infirmières)<br>**De quel genre d'aide auriez-vous eu besoin ?** (des professionnels / de la famille et des proches / des assistants sociaux)<br>**Quels sont les éléments qui ont compliqué votre implication dans les soins de votre bébé ?** (éléments organisationnels et architecturaux (ex. le mobilier) + santé de la maman)<br>**Avez-vous reçu toute l'aide dont vous aviez besoin ?**<br>**Dans quelle mesure avez-vous été impliqué(s) dans le choix d'alimentation de votre bébé?**<br>**Comment participiez-vous à l'alimentation de votre bébé ?** (maman + père)<br>***Si allaitement :***<br>**Dans quelle mesure avez-vous été soutenue lors de l'allaitement ?** (respect de votre rythme et de celui de votre bébé, intimité, disponibilité d'une consultante en lactation, médecins, banque de lait, disponibilité de tire-lait dans un local privé)<br>**Quels ont été les freins à l'allaitement ?**<br>***Si biberon :*** |

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| | | **Dans quelle mesure avez-vous été soutenue dans la préparation des biberons ?** (mise à disposition de biberons, nettoyage, préparation) |
| **6.** | **Comment avez-vous surmonté la peur et/ou l'anxiété liées à la santé de votre bébé?**<br><br>**Note for the interviewer: question for both parents.** | **Par qui, quand, où et comment avez-vous été soutenus pour surmonter ces difficultés ?** |
| **7.** | **Qu'avez-vous ressenti lorsque vous avez vu les différents appareils médicaux qui équipaient la chambre de votre bébé / votre chambre ?**<br><br>**Note for the interviewer: question for both parents pay attention to make a link between responses and services - NICU, N*.** | **Dans quelle mesure aviez-vous compris l'utilité et le fonctionnement des différents appareils médicaux reliés à votre bébé / vos bébés ?** (explications des infirmières, des médecins…)<br>**Dans quelle mesure étiez-vous impliqué(s) dans l'utilisation des différents appareils médicaux ?** (utilisation en autonomie / contrôle de certains appareils) |
| **PARTIE III: PARTENARIAT AVEC LES SOIGNANTS** | | |
| **8.** | **Dans quelle mesure avez-vous compris les informations relatives à la santé de votre bébé ?** | **Qui vous donnait les informations en relation avec les traitements de votre bébé / vos bébés?**<br>**Dans quelle mesure les informations reçues par rapport aux traitements de votre bébé / vos bébés étaient-elles suffisamment claires pour vous ?** (y avait-il une différence entre les médecins et les infirmières ? y avait-il des différences entre les différents services fréquentés ?)<br><br>**Dans quelle mesure les informations reçues par rapport aux éléments qui ont conduit votre enfant (vos enfants) en néonatologie étaient-elles suffisamment claires pour vous ? Qui vous a donné ces explications ?** (y avait-il une différence entre les médecins et les infirmières ? y avait-il des différences entre les différents services fréquentés ?)<br>**Dans quelle mesure les informations reçues par rapport aux tests médicaux réalisés sur votre enfants/ vos enfants et leurs résultats étaient-elles suffisamment claires pour vous ? Qui vous a donné ces explications ?** (y avait-il une différence entre les médecins et les infirmières ? y avait-il des différences entre les différents services fréquentés ?)<br>**Dans quelle mesure avez-vous l'occasion de poser toutes vos questions ?** (différence entre médecins et infirmiers) |
| **9.** | **Comment évaluez-vous la disponibilité du personnel infirmier et médical ?**<br><br>**Note for the interviewer: question for both parents, comparison between services.** | **Comment les personnels vous impliquaient dans les soins de votre bébé / vos bébés ?**<br>**Dans quelle mesure avez-vous été aidé(s) dans votre autonomie par rapport à votre bébé ?** (empowerment de la parentalité et des soins) (différence entre médecins et infirmiers)<br>**Comment évalueriez-vous vos relations avec les infirmiers/sages-femmes dans chaque service / hôpital que vous avez fréquenté ?**<br>**Comment évalueriez-vous vos relations avec les médecins dans chaque service / hôpital que vous avez fréquenté ?**<br>**Était-ce ce dont vous aviez besoin ?** |

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| | Note for the interviewer: check if the situation was the same in all hospitals the baby was admitted |
| **PARTIE IV: LE TRANSFERT VERS DE N* VERS NICU / VERS UN AUTRE HOPITAL** | |
| **10. Comment s'est passé le transfert de votre bébé vers le service de néonatologie intensive (de l'autre hôpital) ?** | **Comment avez-vous été informé de ce transfert ?**<br>**Dans quelle mesure vous êtes-vous senti préparé(s) à ce transfert ?**<br>**Dans quelle mesure vous êtes-vous senti soutenu(s) ?**<br>**Quelles difficultés avez-vous rencontré ?** |
| **11. Comment s'est passé le retour de votre bébé dans l'hôpital où il est né ?**<br><br>**This question is not relevant for participants where a NICU ward is available in the maternity where the baby is born.** | **Comment avez-vous été informé(s) de ce transfert ?**<br>**Dans quelle mesure vous êtes-vous senti préparé(s) à ce transfert ?**<br>**Dans quelle mesure vous êtes-vous senti(s) soutenu(s) ?**<br>**Quelles difficultés avez-vous rencontré ?** |
| **PARTIE V: GESTION DE LA VIE QUOTIDIENNE** | |
| **12. Dans quelle mesure l'organisation de la vie en dehors de l'hôpital a interféré avec votre disponibilité pour votre bébé ?**<br><br>**Note for the interviewer: question for both parents.** | **Quelles difficultés avez-vous rencontré ?**<br>**Dans quelle mesure vous êtes-vous senti soutenu(s) ?**<br>**Comment avez-vous été soutenu(s) par rapport à la fratrie de votre bébé ?** (si pertinent)<br>**Que pourrait-on améliorer dans ces domaines ?**<br>**Dans quelle mesure le congé de maternité / paternité était adapté à vos besoins ?**<br>**Dans quelle mesure l'hospitalisation de votre bébé a affecté votre situation professionnelle et financière ?** |
| **PARTIE VI: RETOUR A LA MAISON** | |
| **13. Comment s'est organisé le retour à domicile de la maman ?**<br><br>**Note for the interviewer: question for both parents, pay attention if the mother is return home before the baby, pay attention comparison between all settings.** | **Quelles difficultés avez-vous rencontré ?**<br>**Dans quelle mesure avez-vous été préparé(s) au retour à domicile ?** (les 2 parents)<br>**Dans quelle mesure vous êtes-vous senti soutenu(s) ?**<br>**Comment étaient organisées les visites à votre bébé / vos bébés ?**<br>**Comment évalueriez-vous cette organisation ?** |
| **14. Comment s'est organisé le retour à domicile de votre bébé ?** | **Quelles difficultés avez-vous rencontré ?**<br>**Dans quelle mesure le retour de votre bébé à la maison a-t-il été préparé ?**<br>**Dans quelle mesure vous êtes-vous senti soutenu(s) ?** |
| **PARTIE VII: QUESTION DE CLÔTURE** | |
| **15. Avez-vous des suggestions à nous soumettre pour améliorer le vécu des parents de bébés prématurés en néonatologie ?**<br>**Note for the interviewer: question for both parents.** | **Note for the interviewer: do the second researcher has additional questions? Check notes taken if clarification are needed for the previous discussions.** |

# APPENDIX 4. ANNEX TO CHAPTER 6

## Appendix 4.1. Interview guide

### *Appendix 4.1.1. Dutch version*

| VRAGEN | BIJVRAGEN | TOPIC | TIMING |
|---|---|---|---|
| **1. Wat is volgens u gezinsgerichte neonatale zorg? Hoe pakken jullie dit aan op jullie afdeling/ziekenhuis?** | **Welke initiatieven nemen jullie?**<br>**Wat vinden jullie belangrijk?**<br>**Wat is het doel van de initiatieven die jullie nemen? Wat willen jullie bereiken?**<br>**Welke aspecten zijn belangrijk om gezinsgerichte zorg te verlenen (voeding, huid-op-huid, etc.)?**<br>*Deelaspecten te bevragen:*<br>- *Hoe draagt de architectuur daartoe bij?*<br>- *Hoe vertaalt het zich in de voeding van de baby (borst en/of flesvoeding)?*<br>- *Hoe wordt er gewerkt aan empowerment van de ouders?*<br>  o *Aanwezigheid*<br>  o *Participatie in de verzorging*<br>  o *Participatie in decision making*<br>- *Is er sprake van coupled care?*<br>- *Welke opleidingen worden voorzien voor het personeel?*<br>- *Hoe worden ouders ondersteund? (psychologen, gespreksgroepen, etc.)*<br>*Hoe wordt het ontslag naar huis georganiseerd?* | Definition of family-centred care concept en hoe het in de praktijk wordt gebracht. | 30 min |

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| **2. Welke factoren bevorderen de implementatie van gezinsgerichte neonatale zorg?** | **Wat loopt goed?**<br>**Waarom loop het goed? Reden (facilitatoren)?**<br>*Deelaspecten te bevragen:*<br>- *Architectuur?*<br>- *Financiering?*<br>- *Voeding van de baby (borst en/of flesvoeding)*<br>- *Verpleegkundige personeel(normen)?*<br>- *Medische personeel(snormen)?*<br>- *Attitude van verplegend en/of medische personeel?*<br>- *Empowerment van de ouders*<br>  ○ *Aanwezigheid*<br>  ○ *Participatie tijdens verzorging*<br>  ○ *Participatie in decision making*<br>- *Coupled care*<br>- *Ondersteuning van de ouders (psychologen, gespreksgroepen, etc.)*<br>- *Ontslag naar huis* | Facilitators to provide family-centred care | 30 min |
| **3. Welke factoren belemmeren de implementatie van gezinsgerichte neonatale zorg?** | **Wat loopt niet goed?**<br>**Waarom loopt het niet goed? Reden (barrières)?**<br>**In welke mate heeft de COVID-19 crisis (en bijhorende maatregelen) een invloed op de implementatie van gezinsgerichte neonatale zorg?**<br>*Deelaspecten te bevragen:*<br>- *Architectuur?*<br>- *Financiering?*<br>- *Voeding van de baby (borst en/of flesvoeding)*<br>- *Verpleegkundige personeel(normen)?*<br>- *Medische personeel(normen)?*<br>- *Attitude van verplegend en/of medische personeel?* | Barriers to provide family-centred care | 30 min |

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| | - *Empowerment van de ouders*<br>  o *Aanwezigheid*<br>  o *Participatie tijdens verzorging*<br>  o *Participatie in decision making*<br>- *Coupled care*<br>- *Ondersteuning van de ouders (psychologen, gespreksgroepen, etc.)*<br>- *Ontslag naar huis* | | |
| **4. Hoe zouden de belemmerende factoren kunnen worden opgelost?** | | Solutions for barriers | 15 min |
| **5. Tenslotte, welke oplossing zou volgens jou prioriteit moeten krijgen?** | | Priorities | 15 min |
| **6. Zijn er zaken die nog niet aan bod gekomen zijn maar waarvan u vindt dat ze toch belangrijk zijn voor het onderzoek?** | | Completeness? | |

## *Appendix 4.1.2. French version*

| QUESTIONS | SOUS-QUESTIONS | SUJET | TIMING |
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| **7. Selon vous, que signifient soins centrés sur la famille ? Comment intégrez-vous ce concept dans votre service ou de votre hôpital ?** | **Quel genre d'initiatives prenez-vous?**<br>**Que trouvez-vous important?**<br>**Quel est l'objectif que vous souhaitez atteindre grâce à ces initiatives ?**<br>**Quels aspects sont importants pour offrir des soins centrés sur la famille (alimentation, peau à peau, etc.)?**<br>*Questions spécifiques :*<br>*- Comment l'architecture y contribue-t-elle?*<br>*- Comment cela se traduit-il dans l'alimentation du bébé (allaitement au sein et / ou au biberon)?*<br>*- Comment l'autonomisation des parents est-elle encouragée?*<br>• *Présence*<br>• *Participation aux soins*<br>• *Participation à la prise de décision*<br>*- Comment les soins sont-ils couplés ?*<br>*- Quelles formations sont proposées au personnel?* | Definition of family-centred care concept en hoe het in de praktijk wordt gebracht. | 30 min |
| **8. Quels les facteurs facilitent la mise en œuvre des soins centrés sur la famille ?** | **Qu'est-ce qui fonctionne bien?**<br>**Pourquoi cela fonctionne-t-il bien ? Raisons (facilitateurs)?**<br>*Qu'estions spéficiques:*<br>- *Architecture?*<br>- *Financement?*<br>- *Alimentation du nouveau-né (allaitement et/ou biberon)*<br>- *Le personnel infirmier (normes)?*<br>- *Le personnel médical (normes)?*<br>- *Attitude du personnel infirmier et/ou médical?*<br>- *Autonomisation des parents* | Facilitateur à la mise en place de soins centrés sur la famille | 30 min |

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| | ○ *Présence*<br>○ *Participation aux soins*<br>○ *Partcipation à la prise de décision*<br>- *Comment les soins sont-ils couplés ?*<br>- *Soutien des parents (psychologues, groupes de paroles, etc.)*<br>- *Retour à la maison* | | |
| **9. Quels les facteurs entravent la mise en œuvre des soins centrés sur la famille ?** | **Qu'est-ce qui ne fonctionne pas bien?**<br>**Pourquoi cela ne fonctionne-t-il pas bien? Raisons (barrières)?**<br>**Dans quelle mesure la crise du COVID-19 (et les mesures associées) affecte-t-elle la mise en œuvre des soins néonatals centrés sur la famille??**<br>*Qu'estions spéficiques:*<br>- *Architecture?*<br>- *Financement?*<br>- *Alimentation du nouveau-né (allaitement et/ou biberon)*<br>- *Le personnel infirmier (normes)?*<br>- *Le personnel médical (normes)?*<br>- *Attitude du personnel infirmier et/ou médical?*<br>- *Autonomisation des parents*<br>○ *Présence*<br>○ *Participation aux soins*<br>○ *Partcipation à la prise de décision*<br>- *Soins couplés*<br>- *Soutien des parents (psychologues, groupes de paroles, etc.)* | Barrières à la mise en place des soins centrés sur la famille | 30 min |

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| | - *Retour à la maison* | | |
| **10. Quelles solutions pourrait-on apporter pour résoudre les problèmes liés à la mise en œuvre des soins couplés?** | | Solutions pour les barrières | 15 min |
| **11. En conclusion, selon vous, quelle solution est prioritaire ?** | | Priorités | 15 min |
| **12. Y a-t-il des choses qui n'ont pas encore été abordées mais que vous jugez importantes pour la recherche?** | | Exhaustivité? | |