**Supplemental Figures and Tables**

Supplemental Figure 1. Critical care settings among included studies

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Supplemental Figure 2. Classification of (a) intervention stage, (b) critical care setting, (c) enrolled caregivers, (d) duration of intervention1, (e) last time point of follow-up, and (f) attrition of enrolled caregivers2

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1Total duration of intervention; studies where duration depended on length of stay were categorized according to median length of stay

2Percent of enrolled caregivers lost to last time point of study (i.e., last day of intervention duration or last point of follow-up)

Supplemental Figure 3. Meta-analysis of caregiver (a) PTSD and (b) distress. Parentheses following study reference denote intervention type: (E), caregiver experience; (R), caregiver role; (S), caregiver support. Asterisk indicates adult ICU.

**(a) PTSD**

**A close up of a map

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**(b) distress**

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Supplemental Figure 4. Meta-analysis of caregiver courage, Parentheses following study reference denote intervention type: (E), caregiver experience; (R), caregiver role; (S), caregiver support. Asterisk indicates adult ICU.

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Supplemental Figure 5. Heat map characterizing intervention type and significant effects on (a) negative and (b) positive psychological outcomes among quasi-experimental and uncontrolled studies not amenable to meta-analysis

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Supplemental Table 1. Preferred Reporting Items for Systematic review and Meta-Analyses (PRISMA) Checklist

|  |  |  |  |
| --- | --- | --- | --- |
| **Section/topic** | **#** | **Checklist item** | **Reported on page #** |
| **TITLE** | | |  |
| Title | 1 | Identify the report as a systematic review, meta-analysis, or both. | 1 |
| **ABSTRACT** | | |  |
| Structured summary | 2 | Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number. | 4 |
| **INTRODUCTION** | | |  |
| Rationale | 3 | Describe the rationale for the review in the context of what is already known. | 5 |
| Objectives | 4 | Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS). | 5 |
| **METHODS** | | |  |
| Protocol and registration | 5 | Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number. | 5 |
| Eligibility criteria | 6 | Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale. | 6 |
| Information sources | 7 | Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched. | 6-7 |
| Search | 8 | Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated. | S. Table 3 |
| Study selection | 9 | State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis). | 7 |
| Data collection process | 10 | Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators. | 7-8 |
| Data items | 11 | List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made. | 8-9  S. Table 1 |
| Risk of bias in individual studies | 12 | Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis. | 8-9 |
| Summary measures | 13 | State the principal summary measures (e.g., risk ratio, difference in means). | 9 |
| Synthesis of results | 14 | Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I2) for each meta-analysis. | 9 |

|  |  |  |  |
| --- | --- | --- | --- |
| **Section/topic** | **#** | **Checklist item** | **Reported on page #** |
| Risk of bias across studies | 15 | Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies). | 9 |
| Additional analyses | 16 | Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified. | 9 |
| **RESULTS** | | |  |
| Study selection | 17 | Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram. | 9  Figure 1 |
| Study characteristics | 18 | For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations. | 10-13  S. Table 3 |
| Risk of bias within studies | 19 | Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12). | 14  S. Results  S. Table 10  S. Table 11 |
| Results of individual studies | 20 | For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot. | 10-13  Figure 4  Figure 5  Figure 6  Figure 7  Figure 8  S. Figure 3  S. Figure 4 |
| Synthesis of results | 21 | Present results of each meta-analysis done, including confidence intervals and measures of consistency. | 10-14  Figure 2  Figure 3  S. Table 7 |
| Risk of bias across studies | 22 | Present results of any assessment of risk of bias across studies (see Item 15). | 14  S. Results  S. Table 12 |
| Additional analysis | 23 | Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]). | 14  S. Table 5  S. Table 6  S. Table 8  S. Table 9 |
| **DISCUSSION** | | |  |
| Summary of evidence | 24 | Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers). | 14-18 |
| Limitations | 25 | Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias). | 18 |
| Conclusions | 26 | Provide a general interpretation of the results in the context of other evidence, and implications for future research. | 18 |
| **FUNDING** | | |  |
| Funding | 27 | Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review. | 3 |

*From:*  Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

Supplemental Table 2. Classification framework for intervention type, stage of intervention, and caregiver psychological outcomes

|  |  |
| --- | --- |
| **Intervention type1** | **Operational Definition** |
| Caregiver experience | Interventions aimed at caregiver distress and negative emotions, difficulty or deteriorating relationships, balancing the need to relieve suffering with the desire to communicate, or helplessness versus control. |
| Caregiver role | Interventions aimed at caregiver detection and prevention of patient delirium, monitoring patient symptoms, or advocating for the patient. |
| Caregiver support | Interventions aimed at caregiver knowledge on delirium, advice on how to respond to the patient, caregiver support systems, or patient outcomes. |
| **Stage of Intervention6** | **Operational Definition** |
| Development | Identifying the evidence base; identifying/developing theory; modelling process and outcomes. |
| Piloting & Feasibility | Testing procedures; estimating recruitment/retention; determining sample size. |
| Evaluation | Assessing effectiveness; understanding change process; assessing cost-effectiveness. |
| Implementation | Dissemination; surveillance and monitoring; long-term follow up. |
| **Negative Psychological Outcome** | **Operational Definition** |
| Anxiety2 | An emotion characterized by feelings of tension, worried thoughts, physical changes like increased blood pressure. People with anxiety disorders usually have recurring intrusive thoughts or concerns; avoid certain situations out of worry; have physical symptoms such as sweating, trembling, dizziness, or a rapid heartbeat. |
| Depression2 | People with depression may experience a lack of interest and pleasure in daily activities; significant weight loss or gain; insomnia or excessive sleeping; lack of energy; inability to concentrate; feelings of worthlessness or excessive guilt; and recurrent thoughts of death or suicide. |
| PTSD2 | An anxiety problem that develops after extremely traumatic events. People with PTSD may relive the event via intrusive memories, flashbacks and nightmares; avoid anything that reminds them of the trauma; and have anxious feelings they didn’t have before that are so intense their lives are disrupted. |
| Psychological distress3 | The unique discomforting, emotional state experienced by an individual in response to a specific stressor or demand, that results in temporary or permanent harm to the person. People who experience psychological distress may be unable to effectively cope; rapidly change emotional status; have difficulty communicating; experience feelings of discomfort or harm. |
| Psychological burden4 | Emotions such as concern or uneasiness due to a person’s worry about the success or failure of their role, which are affected by the workload and work conditions of their role. People who experience psychological burden often feel the need to do more. |
| **Positive Psychological Outcome5** | **Operational Definition** |
| Courage | Bravery, coping, resilience, persistence, integrity, vitality, or zest. |
| Humanity | Love, kindness, or social intelligence. |
| Justice | Citizenship, fairness, or leadership. |
| Temperance | Forgiveness and mercy, humility, prudence, or self-control. |
| Transcendence | Appreciation of beauty and excellence, gratitude, hope, humor, spirituality, or satisfaction. |
| Wisdom & Knowledge | Creativity, curiosity, open-mindedness, love of learning, perspective, or innovation. |

1Adapted from Finucane et al., 2017

2As defined by American Psychological Association

3As defined by Ridner et al., 2003

4As defined by Kim et al., 2018

5Adapted from the Character Strengths and Virtues by Peterson and Seligman et al., 2004

6Adapted from the Medical Research Council and National Institutes of Health Research 2019 joint publication on "Developing and Evaluating Complex Interventions to Improve Health"

Supplemental Table 3. Complete MEDLINE search strategy

|  |  |  |  |
| --- | --- | --- | --- |
| Population  (Informal or Family Caregivers) | Setting  (Critically Ill) | Interventions  (Psychological) | All |
| 1. Exp Caregivers/  2. Exp Family/  3. Family.mp  4. Families.mp.  5. Caregiv\*.mp.  6. “care giv\*”.mp.  7. Carer\*.mp.  8. Spouse.mp.  9. “next of kin".mp.  10. Support person.mp.  11. “loved one\*”.mp.  12. “Significant other\*”.mp.  13. Partner.mp.  14. Relative.mp.  15. Proxy.mp.  16. Surrogate.mp.  17. Friend.mp.  18. Or/1-17 | 19. Exp Intensive Care Unit/  20. “intensive care”.mp.  21. ICU.mp.  22. Critical\* ill.mp.  23. “critical care”.mp.  24. Or/19-23 | 25. exp Psychological Tests/  26. exp Resilience, Psychological/  27. exp Stress, Psychological/  28. Psychol\*.mp  29. Or/25-28  30. “postintensive care syndrome-family”.mp.  31. “postintensive care syndrome family”.mp.  32. Or/30-31  33. “psychological distress”.mp.  34. “psychological stress”.mp.  35. Or/33-34  36. exp Depressive Disorder/  37. Depressive disorder\*.mp.  38. Depress\*.mp  39. Major depressive disorder.mp.  40. MDD.mp.  41. Or/36-40  42. Exp Posttraumatic stress disorder/  43. (Post adj2 traumatic stress).mp.  44. (Post adj2 traumatic syndrome).mp.  45. Posttraumatic stress.mp.  46. PTSD.mp.  47. Or/42-46  48. Exp Anxiety disorders/  49. Anxiety disorder\*.mp.  50. Anxiety\*.mp.  51. Generalized anxiety.mp.  52. Generalized anxiety disorder\*.mp.  53. GAD.mp.  54. Or/48-53  55. “positive aspects of care”.mp.  56. “positive appraisal”.mp.  57. “positive experienc\*”.mp.  58. “positive perception\*”.mp  59. “positive impact\*”.mp.  60. “personal growth”.mp.  61. Enjoyment.mp.  62. Satisfaction\*.mp.  63. Benefit\*.mp.  64. Hope.mp.  65. Gratification.mp.  66. Pleasure\*.mp  67. Gain\*.mp.  68. Uplift\*.mp.  69. Strength.mp.  70. Reward\*.mp.  71. Or/55-70  72. 29 or 32 or 35 or 41 or 47 or 54 or 71 | 73. 18 and 24 and 72  74. Exp animals/ not humans.sh  75. 73 not 74 |

mp=title, abstract, original title, name of substance word, subject hearing word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier

Supplemental Table 4. Characteristics of included studies according to intervention type

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Caregiver Experience** | | | | | | | | | |
| **Source** | **Design1** | **Sites (N)** | **Setting** | **Intervention** | **Stage** | **Duration2** | **Follow-Up** | **Caregivers3 (N)** | **Attrition4 (%)** |
| Agren, 2015(1) | RCT | 1 | Surgical | Patient-Partner Psychoeducational Support | Piloting & Feasibility | 6 months | 3 months, 12 months | 42 | 23.81 |
| Barnato, 2017(2) | RCT | 3 | Mixed | Storytelling | Piloting & Feasibility | 2 hours | 3 months, 6 months | 32 | 12.50 |
| Bernard, 2011(3) | RCT | 1 | Neonatal | Brief Cognitive-Behavioral Therapy | Piloting & Feasibility | 2 weeks | 1 month | 56 | 3.57 |
| Bohart, 2019(4) | RCT | 10 | Mixed | Recovery Programme | Evaluation | 3 months | 3 months, 12 months | 181 | 38.67 |
| Cano Gimenez, 2015(5) | RCT | 1 | Neonatal | Five-Step Individualized Psychology Program | Evaluation | 4 weeks | None | 134 | N/A |
| Carvalho, 2009(6) | RCT | 1 | Neonatal | Psychological Support with Education | Evaluation | NICU stay | First Preterm Infant Appointment | 59 | N/A |
| Chiang, 2016(7) | Quasi-experimental | 1 | Mixed | Brief Cognitive-Behavioral Therapy | Evaluation | 2 hours | 5 days | 45 | 0.00 |
| Chiang, 2017(8) | RCT | 1 | Mixed | Family Education | Evaluation | 2 hours | None | 74 | N/A |
| Clarke-Pounder, 2015(9) | RCT | 1 | Neonatal | Decision-Making Tool | Piloting & Feasibility | 3 days | 2 weeks | 20 | 0.00 |
| Colville, 2010(10) | RCT | 1 | Pediatric | Pediatric Follow-Up Clinic | Evaluation | Single visit | 2 months, 5 months | 154 | 31.82 |
| Combe, 2005(11) | Uncontrolled | 1 | Not reported | Patient and Family Diaries | Implementation | Up to 12 months | 2 months, 6 months, 12 months | 35 | 0.00 |
| Cox, 2014(12) | RCT | 1 | Medical-surgical | Mindfulness Training Intervention | Evaluation | 6 weeks | None | 2 | N/A |
| Cox, 2018(13) | RCT | 5 | Medical-surgical | Coping Skills Training | Evaluation | 6 weeks | 3 months, 6 months | 86 | 23.26 |
| de Bernardo, 2017(14) | Uncontrolled | 1 | Neonatal | Family Centred Care | Piloting & Feasibility | NICU stay | 60 days | 126 | 12.70 |
| Ettenberger, 2017(15) | RCT | 1 | Neonatal | Music Therapy | Evaluation | NICU stay | None | 36 | N/A |
| Feeley, 2008(16) | Uncontrolled | 1 | Neonatal | Promoting Mothers Ability to Communicate | Piloting & Feasibility | NICU stay | 1.5 months, 6 months | 33 | N/A |
| Fotiou, 2016(17) | RCT | 1 | Neonatal | Relaxation Techniques | Evaluation | NICU stay | 10-15 days, 3 months | 59 | N/A |
| John, 2018(18) | Quasi-experimental | 1 | Neonatal | Activity Based Group Therapy | Evaluation | 4 weeks | None | 39 | N/A |
| Johnson, 2007(19) | Uncontrolled | 1 | Neonatal | Kangaroo Care | Implementation | 60 minutes | None | 18 | N/A |
| Jones, 2012(20) | RCT | 2 | Mixed | Family Diaries | Piloting & Feasibility | 2 months | 3 months | 36 | 16.67 |
| Jotzo, 2005(21) | RCT | 1 | Neonatal | Trauma-Preventive Psychology | Evaluation | NICU stay | None | 50 | N/A |
| Kadivar, 2015(22) | Quasi-experimental | 2 | Neonatal | Narrative Writing | Evaluation | 10 days | None | 70 | N/A |
| Kaufer, 2008(23) | Uncontrolled | 1 | Medical | Psychosocial Palliative Care | Evaluation | Unclear | 2 to 16 months | 98 | 0.00 |
| Kentish-Barnes, 2017(24) | RCT | 22 | Mixed | Condolence Letter | Evaluation | Within 3 days of death | 30 days, 6 months | 242 | 21.49 |
| Kloos, 2008(25) | RCT | 1 | Surgical | Progress Diary | Evaluation | ICU stay | 3 days, 1 week | 91 | 0.00 |
| Knapp, 2013(26) | Uncontrolled | 1 | Surgical | EPICS Family Bundle | Evaluation | ICU stay | 8 weeks | 84 | N/A |
| Koh, 2007(27) | RCT | 1 | Neonatal | Taped Conversations with Neonatologist | Evaluation | 10 days | 4 months, 12 months | 200 | N/A |
| Kucuk Alemdar, 2018(28) | Uncontrolled | 1 | Neonatal | Spiritual Care | Evaluation | 30-60 minutes | None | 62 | N/A |
| Lautrette, 2007(29) | RCT | 22 | Mixed | Communication Strategy and Brochure | Evaluation | Undefined single conference | 90 day | 126 | 0.00 |
| Lee, 2010(30) | RCT | 3 | Neonatal | Bright Light Therapy | Piloting & Feasibility | 3 weeks | 3 weeks | 30 | 0.00 |
| Lee, 2013(31) | Uncontrolled | 1 | Neonatal | Booklet & Nursing Guide | Evaluation | 2 weeks | 2 weeks | 69 | 0.00 |
| Micik, 2002(32) | Quasi-experimental | 1 | Surgical | Nurse Information Sessions | Implementation | ICU stay | 5 days, 5 months | 40 | 2.50 |
| Miles, 2006(33) | RCT | 2 | Neonatal | Skin-To-Skin Contact | Evaluation | 4 weeks | 4 months, 12 months | 78 | 30.77 |
| Morelius, 2015(34) | RCT | 2 | Neonatal | Skin-To-Skin Contact | Evaluation | 12 days | 1 month, 4 months | 37 | 13.51 |
| Mouradian, 2013(35) | Uncontrolled | 1 | Neonatal | Art-Based Occupation Group | Evaluation | 2 hours | None | 40 | N/A |
| Nielsen, 2019(36) | RCT | 4 | Medical-surgical | Family Diaries | Evaluation | ICU stay | 3 months | 106 | 14.15 |
| Noergaard, 2018(37) | Quasi-experimental | 1 | Neonatal | "More Father-Friendly NICU" | Evaluation | NICU stay | None | 109 | N/A |
| Pagnementa, 2016(38) | Uncontrolled | 4 | Mixed | Family Communication | Evaluation | ICU stay | Discharge | 163 | 27.61 |
| Pineda, 2012(39) | Quasi-experimental | 1 | Neonatal | Single-Patient Room | Implementation | NICU stay | 5 weeks/term equivalence | 81 | 0.00 |
| Preyde, 2003(40) | Quasi-experimental | 2 | Neonatal | Parent Buddy Program | Evaluation | NICU stay | 16 weeks | 60 | 18.33 |
| Prichard, 2015(41) | Quasi-experimental | 1 | Mixed | Hand Massaging | Piloting & Feasibility | 3 days | None | 30 | N/A |
| Rennick, 2011(42) | RCT | 3 | Pediatric | Touch and Talk | Piloting & Feasibility | Unclear | None | 65 | N/A |
| Ribeiro, 2018(43) | RCT | 1 | Neonatal | Music Therapy | Evaluation | NICU stay | None | 21 | N/A |
| Roa, 2018(44) | Uncontrolled | 1 | Neonatal | Music Therapy | Implementation | NICU stay | None | 122 | N/A |
| Roberts, 2000(45) | RCT | 2 | Neonatal | Kangaroo Care | Evaluation | NICU stay | None | 30 | N/A |
| Rosa, 2018(46) | RCT | 36 | Mixed | Flexible Family Visitation | Evaluation | ICU stay | 30 days | 1685 | 86.05 |
| Rosenbaum, 2015(47) | RCT | 1 | Neonatal | Neonatal Bereavement Support | Evaluation | At caregiver discretion | 3 months, 12 months | 75 | 30.67 |
| Saenz, 2009(48) | RCT | 1 | Neonatal | Early Discharge | Evaluation | At discharge | 3 months | 171 | 18.13 |
| Samra, 2015(49) | RCT | 2 | Neonatal | Skin-To-Skin Contact | Implementation | 3 hours | 24 hours before discharge | 40 | 15.00 |
| Segre, 2013(50) | Uncontrolled | 1 | Neonatal | Listening Visits | Piloting & Feasibility | 1 month | None | 23 | N/A |
| Shaw, 2013(51) | RCT | 4 | Neonatal | Parental Trauma Prevention | Evaluation | 3 weeks or 4 weeks | 5 weeks | 103 | 4.85 |
| Shaw, 2014(52) | RCT | 4 | Neonatal | Parental Trauma Prevention | Evaluation | 3 weeks or 4 weeks | 6 months | 103 | 7.77 |
| Villamizar-Carvajal, 2018(53) | RCT | 3 | Neonatal | Creating Opportunities for Parent Engagement (COPE) | Evaluation | 2 weeks | None | 60 | N/A |
| Weis, 2013(54) | RCT | 1 | Neonatal | Guided Family-Centred Care | Evaluation | NICU stay | None | 134 | N/A |
| Welch, 2016(55) | RCT | 1 | Neonatal | Family Support | Evaluation | NICU stay | 4 months | 80 | 0.00 |
| White, 2018(56) | RCT | 5 | Mixed | Family Support | Evaluation | ICU stay | 6 months | 1006 | 19.58 |
| Wong, 2019(57) | Uncontrolled | 1 | Mixed | Social Support Network | Evaluation | ICU stay | None | 25 | N/A |
| Yun, 2017(58) | Uncontrolled | 1 | Neurological | Transition Nursing Program | Development | Pre-transfer | None | 94 | N/A |
| **Caregiver Role** | | | | | | | | | |
| **Source** | **Design1** | **Sites** | **Setting** | **Intervention** | **Stage** | **Duration2** | **Follow-Up** | **Caregivers3** | **Attrition4** |
| Als, 2003(59) | RCT | 3 | Neonatal | Newborn Individualized Developmental Care and Assessment Program | Evaluation | NICU stay | 2 weeks | 92 | 0.00 |
| Azoulay, 2018(60) | RCT | 7 | Mixed | Family-Staff Communication Questions | Evaluation | 5 days | None | 302 | 52.65 |
| Browne, 2005(61) | RCT | 1 | Neonatal | Family-Based Infant Intervention | Evaluation | 30-45 minutes | 1 month | 84 | 5.95 |
| Cox, 2019(62) | RCT | 5 | Medical-surgical | Personalized Web-Based Decision Aid | Evaluation | 3 days | 3 months, 6 months | 416 | 21.63 |
| Torke, 2016(63) | RCT | 1 | Mixed | Family Navigator | Piloting & Feasibility | 90% ICU stay | 8 weeks | 26 | 0.00 |
| van der Pal, 2007(64) | RCT | 2 | Neonatal | Newborn Individualized Developmental Care and Assessment Program | Evaluation | NICU stay | 2 weeks | 360 | 0.00 |
| **Caregiver Support** | | | | | | | | | |
| **Source** | **Design1** | **Sites** | **Setting** | **Intervention** | **Stage** | **Duration2** | **Follow-Up** | **Caregivers3** | **Attrition4** |
| Abdel-Latif, 2015(65) | RCT | 1 | Neonatal | Caregiver Bedside Presence | Evaluation | NICU stay | None | 72 | 25.40 |
| Affleck, 1989(66) | RCT | 1 | Neonatal | Transitional Consultation Program | Evaluation | 15 weeks | 6 months | 94 | 0.00 |
| Agren, 2019(67) | RCT | 2 | Mixed | Health Promoting Conversations | Piloting & Feasibility | 2 weeks | 3 months, 12 months | 17 | 41.18 |
| Als, 2015(68) | RCT | 1 | Pediatric | Psychoeducational Tool | Piloting & Feasibility | 2 weeks | 6 months | 31 | 19.35 |
| Breisinger, 2018(69) | Quasi-experimental | 1 | Cardiothoracic | Postcardiac Surgery Family Tool Kit | Implementation | At admission | None | 83 | N/A |
| Carson, 2016(70) | RCT | 4 | Medical | Family Emotional Support Meetings | Evaluation | 10 days | 3 months | 365 | 14.52 |
| Chaboyer, 2007(71) | RCT | 1 | Medical-surgical | Liaison Nurse | Evaluation | 4 weeks "on call" | None | 100 | N/A |
| Chien, 2005(72) | Uncontrolled | 1 | Medical | Needs-Based Education Program | Evaluation | 3 days | None | 66 | N/A |
| Chourasia, 2013(73) | Uncontrolled | 1 | Neonatal | Counselling | Evaluation | 45 minutes | 48 hours | 100 | 0.00 |
| Cobiella, 1990(74) | RCT | 1 | Neonatal | Prenatal Adaptation | Evaluation | 13 minutes | 1 week, 2 weeks | 30 | 30.00 |
| Curtis, 2016(75) | RCT | 2 | Mixed | Communication Facilitator | Evaluation | 2 days | 3 months, 6 months | 268 | 54.48 |
| Daly, 1994(76) | RCT | 1 | Surgical | Family Information Pack | Evaluation | ICU stay | None | 60 | N/A |
| de Alencar, 2009(77) | Uncontrolled | 1 | Neonatal | Kangaroo Care | Evaluation | NICU stay | 50 days | 177 | 2.26 |
| Douglas, 2005(78) | RCT | 1 | Mixed | Family Diaries | Evaluation | At discharge | 2 months | 290 | 26.90 |
| Egerod, 2011(79) | Uncontrolled | 2 | Medical-surgical | Family Diaries | Evaluation | Reading diary at leisure | 3 months, 12 months | 13 | 0.00 |
| Franck, 2011(80) | RCT | 4 | Neonatal | Pain Management | Evaluation | NICU stay | 3 months | 213 | 20.66 |
| Glazebrook, 2007(81) | RCT | 6 | Neonatal | Parenting Baby Interaction | Evaluation | 6 weeks | 3 months | 233 | 14.59 |
| Hane, 2015(82) | RCT | 1 | Neonatal | Family Nurture Intervention | Evaluation | NICU stay | None | 65 | N/A |
| Holditch-Davis, 2013(83) | Quasi-experimental | 4 | Neonatal | Preterm Infant Interventions | Evaluation | NICU stay | 2 months | 208 | 0.00 |
| Ingram, 2017(84) | Quasi-experimental | Multiple | Neonatal | Train-to-Home | Implementation | At discharge | Unclear | 245 | N/A |
| Jang, 2005(85) | Uncontrolled | 1 | Neonatal | Workbook | Evaluation | 3 days | 1 week | 32 | 0.00 |
| Jones, 2004(86) | RCT | 2 | Mixed | Self-Help Manual | Evaluation | 6 weeks | 2 months, 6 months | 104 | 16.35 |
| Matricardi, 2013(87) | RCT | 1 | Neonatal | Parental Specific NICU Intervention | Evaluation | 5 weeks | None | 42 | N/A |
| Melnyk, 1997(88) | Quasi-experimental | 1 | Pediatric | Creating Opportunities for Parent Engagement (COPE) | Evaluation | 2-16 hours after admission to 24-36 hours after transfer | 4 weeks | 30 | 13.33 |
| Melnyk, 2001(89) | Quasi-experimental | 1 | Neonatal | Creating Opportunities for Parent Engagement (COPE) | Piloting & Feasibility | 2-4 days after admission until 1 week after discharge | 3 months, 6 months | 42 | 0.00 |
| Melnyk, 2004(90) | RCT | 2 | Neonatal | Creating Opportunities for Parent Engagement (COPE) | Evaluation | 2-4 days after admission until 1 week after discharge | 3 months | 143 | 0.00 |
| Melnyk, 2006(91) | RCT | 2 | Neonatal | Creating Opportunities for Parent Engagement (COPE) | Evaluation | 2-4 days after admission until 1 week after discharge | 1 week, 2 months | 260 | 5.00 |
| Meyer, 1994(92) | RCT | 1 | Neonatal | Family-Based | Evaluation | At discharge | None | 34 dyads | N/A |
| Mitchell, 2004(93) | Uncontrolled | 1 | Mixed | Structured Individualize Transfer Method | Evaluation | 2 weeks | None | 162 | N/A |
| O'Brien, 2013(94) | Quasi-experimental | 1 | Neonatal | Family Integrated Care | Piloting & Feasibility | NICU stay | None | 93 | N/A |
| Ong, 2019(95) | Uncontrolled | 1 | Neonatal | Structured Nursing | Evaluation | 10 days | 2 weeks | 216 | 0.00 |
| Preyde, 2007(96) | Quasi-experimental | 2 | Neonatal | Peer Support | Evaluation | Unclear | 4 months | 59 | 16.95 |
| Rodriguez Martinez, 2003(97) | RCT | 1 | Mixed | Family Participation | Evaluation | 3 days | 12 months | 60 | 18.33 |
| Roman, 1995(98) | Quasi-experimental | 1 | Neonatal | Parent-to-Parent Support | Piloting & Feasibility | 4 months | 4 months, 12 months | 58 | 18.97 |
| Samuel, 2015(99) | RCT | 1 | Pediatric | Follow-Up Clinic | Piloting & Feasibility | 2 months | 6 months | 209 | 24.89 |
| Shaw, 2014(100) | Uncontrolled | 3 | Medical-surgical | Family Communication | Evaluation | Unclear | 8 weeks | 67 | 19.40 |
| Turan, 2008(101) | RCT | 1 | Neonatal | Stress Reduction | Evaluation | 10 days | None | 76 | N/A |
| Turner, 2009(102) | Uncontrolled | 1 | Neonatal | Neonatal Discharge Support Group | Evaluation | Open attendance without limit | 6 months | 9 | 0.00 |

1RCT, randomized controlled trial; Quasi-experimental, non-randomized controlled trial; Uncontrolled, non-randomized uncontrolled trial

2Total duration of intervention

3Number of caregivers enrolled

4Percent of enrolled caregivers lost at last time point of study (i.e., last day of intervention duration or last point of follow-up)

Supplemental Table 5. Included studies with notable subgroups determined from study eligibility criteria

|  |  |  |
| --- | --- | --- |
| **Source** | **Setting** | **Notable Subgroup** |
| Browne, 2005 | Neonatal | Actual LOS >2 weeks |
| Matricardi, 2013 | Neonatal | Actual LOS >3 weeks |
| Lee, 2010 | Neonatal | Anticipated LOS >2 weeks |
| Lee, 2013 | Neonatal | Anticipated LOS >3 weeks |
| Cano Gimenez, 2015 | Neonatal | Anticipated LOS >4 weeks |
| Ribeiro, 2018 | Neonatal | Anticipated LOS >4 weeks |
| John, 2018 | Neonatal | Anticipated LOS >4 weeks |
| Clarke-Pounder, 2015 | Neonatal | Anticipated LOS >2 weeks |
| Segre, 2013 | Neonatal | Clinically depressed mothers only |
| Barnato, 2017 | Mixed | End of Life |
| Carson, 2016 | Medical | End of Life |
| Kaufer, 2008 | Medical | End of Life |
| Kentish-Barnes, 2017 | Mixed | End of Life |
| Lautrette, 2007 | Mixed | End of Life |
| Rosenbaum, 2015 | Neonatal | End of Life |
| White, 2018 | Mixed | End of Life |
| Combe, 2005 | Not reported | End of Life |
| Curtis, 2016 | Mixed | End of Life |
| Affleck, 1989 | Neonatal | ICU Transition |
| Chaboyer, 2007 | Medical-surgical | ICU Transition |
| Fotiou, 2016 | Neonatal | ICU Transition |
| Ingram, 2017 | Neonatal | ICU Transition |
| Jang, 2005 | Neonatal | ICU Transition |
| Melnyk, 1997 | Pediatric | ICU Transition |
| Melnyk, 2001 | Neonatal | ICU Transition |
| Melnyk, 2004 | Pediatric | ICU Transition |
| Melnyk, 2006 | Neonatal | ICU Transition |
| Mitchell, 2004 | Mixed | ICU Transition |
| Roman, 1995 | Neonatal | ICU Transition |
| Saenz, 2009 | Neonatal | ICU Transition |
| Turner, 2009 | Neonatal | ICU Transition |
| Yun, 2017 | Neurological | ICU Transition |

Sorted first by subgroup then by source alphabetically

Supplemental Table 6. Summary of findings from long-term follow-up of interventions

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Follow-Up of One Month or Less** | | | | |
| **Source** | **Intervention** | **Last Point of Follow-Up** | **Psychological Outcomes** | **Significant Effect of**  **Intervention1** |
| Als, 2003 | Newborn Individualized Developmental Care and Assessment Program | 6 months | Distress | Decreased distress |
| Bernard, 2011 | Brief Cognitive-Behavioral Therapy | 1 month | Depression, PTSD | None |
| Browne, 2005 | Family-Based Infant Intervention | 1 month | Distress, Wisdom & Knowledge | Decreased distress, Increased wisdom & knowledge |
| Chiang, 2017 | Family Education | 5 days | Anxiety, Depression, Distress, Courage, Humanity, Justice, Transcendence, Wisdom & Knowledge | None |
| Chourasia, 2013 | Counselling | 48 hours | Distress | Decreased distress |
| Clarke-Pounder, 2015 | Decision-Making Tool | 2 weeks | Anxiety, Transcendence | None |
| Cobiella, 1990 | Prenatal Adaptation | 2 weeks | Anxiety, Depression, PTSD | Decreased anxiety |
| Jang, 2005 | Workbook | 1 week | Distress, Courage | None |
| Kloos, 2008 | Progress Diary | 1 week | Anxiety | None |
| Lee, 2010 | Bright Light Therapy | 3 weeks | Depression | None |
| Lee, 2013 | Booklet & Nursing Guide | 2 weeks | Distress, Burden | Decreased distress |
| Melnyk, 1997 | Creating Opportunities for Parent Engagement (COPE) | 4 weeks | Anxiety, Depression, PTSD, Distress | Decreased PTSD |
| Ong, 2019 | Structured Nursing | 2 weeks | Distress | Decreased distress |
| Rosa, 2018 | Flexible Family Visitation | 30 days | Anxiety, Depression, Temperance | Decreased anxiety, Decreased depression, Increased Temperance |
| van der Pal, 2007 | Newborn Individualized Developmental Care and Assessment Program | 2 weeks | Distress, Courage | Decreased distress |
| **Follow-Up Longer Than One Month to Three Months** | | | | |
| **Source** | **Intervention** | **Last Point of Follow-Up** | **Psychological Outcomes** | **Significant Effect of Intervention1** |
| Carson, 2016 | Family Emotional Support Meetings | 3 months | Anxiety, Depression, PTSD | Increased PTSD |
| de Alencar, 2009 | Kangaroo Care | 50 days | Depression | Decreased depression |
| de Bernardo, 2017 | Family Centred Care | 60 days | Distress, Courage, Humanity, Wisdom & Knowledge |  |
| Douglas, 2005 | Family Diaries | 2 months | Depression, Burden, Courage | None |
| Fotiou, 2016 | Relaxation Techniques | 3 months | Anxiety, PTSD | None |
| Franck, 2011 | Pain Management | 3 months | Anxiety, Depression, Distress, Burden | None |
| Glazebrook, 2007 | Parenting Baby Interaction | 3 months | Distress, Humanity | None |
| Holditch-Davis, 2013 | Preterm Infant Interventions | 2 months | Anxiety, Depression, PTSD, Distress | None |
| Jones, 2012 | Family Diaries | 3 months | PTSD | Decreased PTSD |
| Knapp, 2013 | EPICS Family Bundle | 8 weeks | Courage, Humanity, Justice | None |
| Lautrette, 2007 | Communication Strategy and Brochure | 90 day | Anxiety, Depression, PTSD | Decreased anxiety, Decreased depression, Decreased PTSD |
| Melnyk, 2004 | Creating Opportunities for Parent Engagement (COPE) | 3 months | Anxiety, Depression | None |
| Melnyk, 2006 | Creating Opportunities for Parent Engagement (COPE) | 2 months | Anxiety, Depression, Distress, Burden, Transcendence | Decreased anxiety, Decreased depression, Decreased distress, Increased transcendence |
| Nielsen, 2019 | Family Diaries | 3 months | Anxiety, Depression, Distress | None |
| Pineda, 2012 | Single-Patient Room | 5 weeks | Anxiety, Depression, Distress, Courage | Increased distress |
| Saenz, 2009 | Early Discharge | 3 months | Anxiety, Depression, Courage | Decreased depression |
| Shaw, 2013 | Family Communication | 8 weeks | Temperance, Transcendence | Increased temperance |
| Shaw, 2013 | Parental Trauma Prevention | 5 weeks | Anxiety, Depression, PTSD | Decreased depression, Decreased PTSD |
| Torke, 2016 | Family Navigator | 8 weeks | Anxiety, Depression, Distress, Burden | None |
| **Follow-Up Longer Than Three Months to Six Months** | | | | |
| **Source** | **Intervention** | **Last Point of Follow-Up** | **Psychological Outcomes** | **Significant Effect of Intervention1** |
| Affleck, 1989 | Transitional Consultation Program | 6 months | Anxiety, Depression, Burden, Courage | Increased courage |
| Als, 2015 | Psychoeducational Tool | 6 months | Anxiety, Depression, PTSD | None |
| Barnato, 2017 | Storytelling | 6 months | Anxiety, Depression, PTSD, Distress, Burden | None |
| Colville, 2010 | Pediatric Follow-Up Clinic | 5 months | Anxiety, Depression, PTSD | None |
| Cox, 2018 | Coping Skills Training | 6 months | Anxiety, Depression, PTSD, Distress, Courage, Temperance, Transcendence | None |
| Cox, 2019 | Personalized Web-Based Decision Aid | 6 months | Anxiety, Depression, PTSD, Distress, Transcendence, Wisdom & Knowledge | None |
| Curtis, 2016 | Communication Facilitator | 6 months | Anxiety, Depression, PTSD | Decreased depression |
| Feeley, 2008 | Promoting Mothers Ability to Communicate | 6 months | Anxiety, PTSD, Distress | None |
| Jones, 2004 | Self-Help Manual | 6 months | Anxiety, Depression, PTSD | None |
| Kentish-Barnes, 2017 | Condolence Letter | 6 months | PTSD, Distress | None |
| Melnyk, 2001 | Creating Opportunities for Parent Engagement (COPE) | 6 months | Anxiety, Depression, Distress, Burden | None |
| Micik, 2002 | Nurse Information Sessions | 5 months | Distress | Decreased distress |
| Morelius, 2015 | Skin-To-Skin Contact | 4 months | Depression, Distress | None |
| Preyde, 2003 | Parent Buddy Program | 16 weeks | Anxiety, Depression, Distress | Decreased anxiety, Decreased depression, Decreased distress |
| Preyde, 2007 | Peer Support | 4 months | Courage, Transcendence, Wisdom & Knowledge | Increased courage, Increased transcendence, Increased wisdom & knowledge |
| Samuel, 2015 | Follow-Up Clinic | 6 months | Anxiety, Depression, PTSD | Decreased anxiety, Decreased depression, Decreased PTSD |
| Shaw, 2014 | Parental Trauma Prevention | 6 months | Anxiety, Depression, PTSD | Decreased anxiety, Decreased depression, Decreased PTSD |
| Welch, 2016 | Family Support | 4 months | Anxiety, Depression | Decreased anxiety, Decreased depression |
| White, 2018 | Family Support | 6 months | Depression, Distress, Transcendence | Increased transcendence |
| **Follow-Up Longer Than Six Months** | | | | |
| **Source** | **Intervention** | **Last Point of Follow-Up** | **Psychological Outcomes** | **Significant Effect of Intervention1** |
| Agren, 2015 | Patient-Partner Psychoeducational Support | 12 months | Depression | None |
| Agren, 2019 | Health Promoting Conversations | 12 months | PTSD, Distress, Burden, Transcendence | Decreased PTSD, Decreased distress, Decreased burden |
| Bohart, 2019 | Recovery Programme | 12 months | Anxiety, Depression, PTSD, Courage | None |
| Kaufer, 2008 | Psychosocial Palliative Care | 16 months | Anxiety, Transcendence, Wisdom & Knowledge | Decreased anxiety, Increased Transcendence, Increased Wisdom & Knowledge |
| Koh, 2007 | Taped Conversations with Neonatologist | 12 months | Anxiety, Depression, PTSD, Transcendence | Increased transcendence |
| Miles, 2006 | Skin-To-Skin Contact | 12 months | Anxiety, Depression, Distress, Burden, Transcendence | None |
| Robinson, 1998 | Witnessed Resuscitation | 9 months | Anxiety, Depression, Distress | None |
| Rodriguez Martinez, 2003 | Family Participation | 12 months | Anxiety | Decreased anxiety |
| Roman, 1995 | Parent-to-Parent Support | 12 months | Anxiety, Depression, Burden | Decreased anxiety |
| Rosenbaum, 2015 | Neonatal Bereavement Support | 12 months | Depression, Burden, Transcendence | Increased depression, Increased burden, Decreased transcendence |
| Agren, 2015 | Patient-Partner Psychoeducational Support | 12 months | Depression | None |

1Effect deemed significant when at least p<0.05

Supplemental Table 7. Estimates for ratio of means for each type of psychological outcome

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Psychological Outcome** | **Corresponding Figure** | **Subgroup** | **No. Included Estimates** | **Estimate (95% CI)** | **Interpretation of Estimate** |
| Anxiety |  | After Intervention | 7 | 0.92 (0.84-1.01) | No statistical difference |
|  |  | At 1 Month or Less | 4 | 0.89 (0.80-1.00) | No statistical difference |
|  |  | Longer Than 1 Month Up to 3 Months | 8 | 0.92 (0.85-1.01) | No statistical difference |
|  |  | Longer Than 3 Months Up to 6 Months | 10 | 0.94 (0.89-0.99) | ***Favours intervention*** |
|  |  | Longer Than 6 Months | 4 | 1.00 (0.87-1.15) | No statistical difference |
|  |  | After Intervention Up to 3 Months | 19 | 0.92 (0.87-0.97) | ***Favours intervention*** |
|  |  | Longer Than 3 Months | 14 | 0.96 (0.91-1.02) | No statistical difference |
|  |  | Adult ICU | 16 | 0.92 (0.86-0.99) | ***Favours intervention*** |
|  |  | Neonatal or Pediatric ICU | 17 | 0.94 (0.90-0.98) | ***Favours intervention*** |
|  |  | Caregiver Experience | 18 | 0.92 (0.87-0.99) | ***Favours intervention*** |
|  |  | Caregiver Role | 2 | 0.99 (0.96-1.01) | No statistical difference |
|  |  | Caregiver Support | 13 | 0.94 (0.90-0.99) | **Favours intervention** |
| Depression |  | After Intervention | 6 | 0.75 (0.48-1.19) | No statistical difference |
|  |  | At 1 Month or Less | 5 | 0.85 (0.65-1.10) | No statistical difference |
|  |  | Longer Than 1 Month Up to 3 Months | 8 | 0.88 (0.75-1.03) | No statistical difference |
|  |  | Longer Than 3 Months Up to 6 Months | 10 | 0.91 (0.75-1.10) | No statistical difference |
|  |  | Longer Than 6 Months | 3 | 1.37 (1.05-1.79) | ***Favours control*** |
|  |  | After Intervention Up to 3 Months | 19 | 0.83 (0.69-0.99) | ***Favours intervention*** |
|  |  | Longer Than 3 Months | 13 | 0.99 (0.83-1.20) | No statistical difference |
|  |  | Adult ICU | 15 | 0.97 (0.98-1.07) | No statistical difference |
|  |  | Neonatal or Pediatric ICU | 17 | 0.84 (0.67-1.05) | No statistical difference |
|  |  | Caregiver Experience | 18 | 0.95 (0.82-1.11) | No statistical difference |
|  |  | Caregiver Role | 2 | 1.05 (0.74-1.50) | No statistical difference |
|  |  | Caregiver Support | 12 | 0.80 (0.62-1.02) | No statistical difference |
| PTSD |  | After Intervention | 3 | 0.82 (0.67-1.01) | No statistical difference |
|  |  | At 1 Month or Less | 2 | 1.10 (0.87-1.39) | No statistical difference |
|  |  | Longer Than 1 Month Up to 3 Months | 5 | 0.89 (0.72-1.10) | No statistical difference |
|  |  | Longer Than 3 Months Up to 6 Months | 9 | 0.93 (0.80-1.10) | No statistical difference |
|  |  | Longer Than 6 Months | 2 | 1.04 (1.03-1.05) | ***Favours control*** |
|  |  | After Intervention Up to 3 Months | 10 | 0.91 (0.80-1.04) | No statistical difference |
|  |  | Longer Than 3 Months | 11 | 0.96 (0.84-1.09) | No statistical difference |
|  |  | Adult ICU | 14 | 0.95 (0.84-1.06) | No statistical difference |
|  |  | Neonatal or Pediatric ICU | 7 | 0.91 (0.79-1.06) | No statistical difference |
|  |  | Caregiver Experience | 12 | 0.95 (0.83-1.10) | No statistical difference |
|  |  | Caregiver Role | 1 | 0.96 (0.94-0.99) | ***Favours intervention*** |
|  |  | Caregiver Support | 8 | 0.90 (0.79-1.03) | ***Favours intervention*** |
| Distress |  | After Intervention | 7 | 1.03 (0.97-1.09) | No statistical difference |
|  |  | At 1 Month or Less | 4 | 0.97 (0.82-1.15) | No statistical difference |
|  |  | Longer Than 1 Month Up to 3 Months | 4 | 0.99 (0.90-1.10) | No statistical difference |
|  |  | Longer Than 3 Months Up to 6 Months | 5 | 1.02 (1.00-1.04) | ***Favours control*** |
|  |  | Longer Than 6 Months | 2 | 1.00 (0.90-1.11) | No statistical difference |
|  |  | After Intervention Up to 3 Months | 15 | 1.02 (0.95-1.07) | No statistical difference |
|  |  | Longer Than 3 Months | 7 | 1.02 (1.00-1.04) | No statistical difference |
|  |  | Adult ICU | 7 | 1.02 (1.00-1.04) | ***Favours control*** |
|  |  | Neonatal or Pediatric ICU | 15 | 1.01 (0.95-1.07) | No statistical difference |
|  |  | Caregiver Experience | 12 | 1.01 (0.94-1.08) | No statistical difference |
|  |  | Caregiver Role | 3 | 1.04 (0.90-1.20) | No statistical difference |
|  |  | Caregiver Support | 7 | 1.01 (0.97-1.07) | No statistical difference |
| Burden |  | After Intervention | 0 | N/A | N/A |
|  |  | At 1 Month or Less | 1 | 1.35 (0.98-1.87) | No statistical difference |
|  |  | Longer Than 1 Month Up to 3 Months | 4 | 1.07 (1.03-1.13) | ***Favours control*** |
|  |  | Longer Than 3 Months Up to 6 Months | 2 | 0.91 (0.74-1.13) | No statistical difference |
|  |  | Longer Than 6 Months | 2 | 0.94 (0.79-1.12) | ***Favours control*** |
|  |  | After Intervention Up to 3 Months | 5 | 1.08 (1.05-1.12) | ***Favours control*** |
|  |  | Longer Than 3 Months | 4 | 0.93 (0.81-1.06) | No statistical difference |
|  |  | Adult ICU | 3 | 1.02 (0.81-1.27) | No statistical difference |
|  |  | Neonatal or Pediatric ICU | 5 | 1.05 (0.99-1.12) | No statistical difference |
|  |  | Caregiver Experience | 3 | 1.14 (0.90-1.45) | No statistical difference |
|  |  | Caregiver Role | 0 | N/A | N/A |
|  |  | Caregiver Support | 6 | 1.04 (0.97-1.11) | No statistical difference |
| Courage |  | After Intervention | 0 | N/A | N/A |
|  |  | At 1 Month or Less | 1 | 1.23 (1.12-1.35) | ***Favours intervention*** |
|  |  | Longer Than 1 Month Up to 3 Months | 1 | 1.00 (0.97-1.03) | No statistical difference |
|  |  | Longer Than 3 Months Up to 6 Months | 2 | 1.06 (0.92-1.23) | No statistical difference |
|  |  | Longer Than 6 Months | 2 | 0.96 (0.96-0.97) | ***Favours control*** |
|  |  | After Intervention Up to 3 Months | 2 | 1.10 (0.90-1.35) | No statistical difference |
|  |  | Longer Than 3 Months | 4 | 1.02 (0.94-1.10) | No statistical difference |
|  |  | Adult ICU | 3 | 0.98 (0.96-1.00) | ***Favours control*** |
|  |  | Neonatal or Pediatric ICU | 3 | 1.11 (0.98-1.26) | ***Favours intervention*** |
|  |  | Caregiver Experience | 3 | 0.97 (0.96-0.99) | ***Favours control*** |
|  |  | Caregiver Role | 1 | 1.23 (1.12-1.35) | ***Favours intervention*** |
|  |  | Caregiver Support | 2 | 1.07 (0.94-1.22) | No statistical difference |
| Humanity |  | After Intervention | 2 | 1.07 (0.91-1.25) | No statistical difference |
|  |  | At 1 Month or Less | 0 | N/A | N/A |
|  |  | Longer Than 1 Month Up to 3 Months | 1 | 1.10 (0.9801.24) | No statistical difference |
|  |  | Longer Than 3 Months Up to 6 Months | 0 | N/A | N/A |
|  |  | Longer Than 6 Months | 0 | N/A | N/A |
|  |  | After Intervention Up to 3 Months | 3 | 1.11 (1.07-1.15) | ***Favours intervention*** |
|  |  | Longer Than 3 Months | 0 | N/A | N/A |
|  |  | Adult ICU | 0 | N/A | N/A |
|  |  | Neonatal or Pediatric ICU | 3 | 1.11 (1.07-1.15) | ***Favours intervention*** |
|  |  | Caregiver Experience | 1 | 0.91 (0.67-1.23) | No statistical difference |
|  |  | Caregiver Role | 0 | N/A | N/A |
|  |  | Caregiver Support | 2 | 1.11 (1.07-1.15) | ***Favours intervention*** |
| Transcendence |  | After Intervention | 2 | 1.06 (1.04-1.08) | ***Favours intervention*** |
|  |  | At 1 Month or Less | 2 | 0.98 (0.78-1.23) | No statistical difference |
|  |  | Longer Than 1 Month Up to 3 Months | 3 | 1.03 (1.03-1.04) | ***Favours intervention*** |
|  |  | Longer Than 3 Months Up to 6 Months | 4 | 1.04 (1.00-1.08) | ***Favours intervention*** |
|  |  | Longer Than 6 Months | 3 | 1.00 (0.86-1.17) | No statistical difference |
|  |  | After Intervention Up to 3 Months | 7 | 1.04 (1.02-1.06) | ***Favours intervention*** |
|  |  | Longer Than 3 Months | 7 | 1.03 (0.97-1.09) | No statistical difference |
|  |  | Adult ICU | 7 | 1.04 (1.02-1.07) | ***Favours intervention*** |
|  |  | Neonatal or Pediatric ICU | 7 | 1.00 (0.93-1.08) | No statistical difference |
|  |  | Caregiver Experience | 7 | 1.02 (0.95-1.10) | No statistical difference |
|  |  | Caregiver Role | 2 | 1.04 (1.00-1.08) | ***Favours intervention*** |
|  |  | Caregiver Support | 5 | 1.04 (1.02-1.05) | ***Favours intervention*** |

Supplemental Table 8. Summary of findings from interventions on caregiver psychological outcomes included in quantitative meta-analysis

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Negative Psychological Outcomes** | | | | | |
| **Outcome** | **Assessed By1,2** | **Follow-Up Range** | **No. Studies3** | **No. RCTs3** | **GRADE of Evidence4** |
| Anxiety | Beck Anxiety Inventory; Depression Anxiety Stress Scale; Hospital Anxiety and Depression Scale; Inventory of Situations and Responses of Anxiety; Profile of Mood States; State Trait Anxiety Inventory | 5 Days to 16 Months | 24 Adult; 26 Neonatal or Pediatric | 16 Adult; 15 Neonatal or Pediatric | Moderate |
| Depression | Beck Depression Inventory; Center for Epidemiologic Studies Depression Scale; Depression Adjective Checklist; Depression Anxiety Stress Scale; Edinburgh Postnatal Depression Scale; Hospital Anxiety and Depression Scale; Profile of Mood States | 5 Days to 12 Months | 17 Adult; 24 Neonatal or Pediatric | 15 Adult; 19 Neonatal or Pediatric | Moderate |
| PTSD | Davidson Trauma Scale; Harvard Trauma Questionnaire; Impact of Events Scale; Post Hospital Stress Index for Parents; Post-Traumatic Stress Symptoms; Post-Traumatic Symptom Scale; Short Form Health Survey | 2 Weeks to 12 Months | 14 Adult; 8 Neonatal or Pediatric | 14 Adult; 8 Neonatal or Pediatric | Moderate |
| Distress | Center for Epidemiological Studies Depression Scale; Decisional Conflict Scale; Depression Anxiety Stress Scale; Family Sense of Coherence; Global Short Form Mental Health; Inventory of Complicated Grief; Parenting Stress Index; Pediatric Stressor Scale; Prenatal Stressor Scale NICU; Symptoms of Stress Inventory; Swedish Parenthood Stress Questionnaire | 48 Hours to 12 Months | 11 Adult; 27 Neonatal or Pediatric | 8 Adult; 17 Neonatal or Pediatric | Low |
| Burden | Caregiver Reaction Assessment; Decision Regret Scale; Family Assessment Device; Index of Parent Behavior; Lee's Fatigue Scale; Measure of Social Support Scale; Montgomery-Borgatta Caregiver Burden; Profile of Mood States; The Worry Index | 2 Weeks to 12 Months | 6 Adult; 9 Neonatal or Pediatric | 4 Adult; 8 Neonatal or Pediatric | Low |
| **Positive Psychological Outcomes** | | | | | |
| **Outcome** | **Assessed By1,2** | **Follow-Up Range** | **No. Studies3** | **No. RCTs3** | **GRADE of Evidence4** |
| Courage | Brief Coping Inventory for Stressful Situations; Caregiver Reaction Assessment; Coping Inventory for Stressful Situations; Critical Care Family Needs Inventory; Critical Care Family Assistance Program Family Satisfaction Survey; Family Satisfaction with Care Questionnaire; ICU Family Satisfaction Survey; Parent to Infant Attachment; Self-Confidence Scale; Ways of Coping Checklist; Well Being Scale | 5 Days to 12 Months | 5 Adult; 8 Neonatal or Pediatric | 3 Adult; 4 Neonatal or Pediatric | Very Low |
| Humanity | Caring Dimensions Inventory; Critical Care Family Assistance Program Family Satisfaction Survey; Critical Care Family Needs Inventory; Maternal Caregiving Behavior; Neurobehavioral Assessment of Preterm Infant | 5 Days to 3 Months | 3 Adult; 4 Neonatal or Pediatric | 0 Adult; 3 Neonatal or Pediatric | Very Low |
| Justice | Caring Dimensions Inventory; Critical Care Family Assistance Program Family Satisfaction Survey; Critical Care Family Needs Inventory; ICU Family Satisfaction Survey; Parental Stress Scale; Self-Efficacy in Infant Care Scale | 5 Days to 8 Weeks | 2 Adult; 1 Neonatal or Pediatric | 0 Adult; 1 Neonatal or Pediatric | Very Low |
| Temperance | Caring Dimensions Inventory; Self-Efficacy Scale | 30 Days to 12 Months | 2 Adult; 0 Neonatal or Pediatric | 2 Adult; 0 Neonatal or Pediatric | Very Low |
| Transcendence | Caring Dimensions Inventory; Critical Care Family Assistance Program Family Satisfaction Survey; Critical Care Family Needs Inventory; EuroQoL Five Dimensions; Family Inventory of Needs Pediatric; Family Satisfaction with Care Questionnaire; Hearth Hope Index; ICU Family Satisfaction Survey; Maternal Self Report Inventory; Parental Behavior in the ICU; Parental Beliefs Scale NICU; Royal Free Interview for Spiritual and Religious Beliefs; Quality of Communications Scale; Quality of Life Enjoyment Satisfaction Questionnaire; Self-Efficacy in Infant Care Scale | 5 Days to 16 Months | 13 Adult; 9 Neonatal or Pediatric | 8 Adult; 6 Neonatal or Pediatric | Low |
| Wisdom & Knowledge | Critical Care Family Assistance Program Family Satisfaction Survey; Critical Care Family Needs Inventory; Family Satisfaction with Care Questionnaire; Knowledge of Preterm Infant Behavior; Medical Comprehension Scale | 1 Month to 16 Months | 3 Adult; 1 Neonatal or Pediatric | 1 Adult; 1 Neonatal or Pediatric | Very Low |

RCT, randomized controlled trial

1Clinical scales or assessment tools with published psychometric properties

2Portions of single questions of assessment tools were considered

3Quantitative studies that reported no outcome measures or that reported only correlations between outcomes were not counted

4Determined for RCTs that used clinical scales or assessment tools with published psychometric properties

Supplemental Table 9. Summary of findings from qualitative studies1

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Caregiver Experience** | | | | | |
| **Source** | **Setting** | **Intervention** | **Analysis** | **Themes or Theory** | **Authors’ Conclusions** |
| Rennick, 2011 | Pediatric | Pain management nursing intervention; Touch and Talk | Thematic | Importance of comforting the child- importance of parental presence; making a difference in the child's pain experience; feeling comfortable and confident about participating in care | Giving parents the choice of being involved in their child’s care using touch and distraction techniques during painful procedures can provide an invaluable opportunity to foster parenting and support the child during a difficult PICU experience. |
| Johnson, 2007 | Neonatal | Maternal kangaroo care | Thematic | Maternal-infant benefits of kangaroo holding; Need for support for holding; Satisfaction with interactions | Results led to increased understanding of the multifaceted advantages of kangaroo holding on maternal attachment behaviors. |
| Wong, 2019 | Adult | Social support network | Grounded theory | The core category was regaining control which represents the families' journey toward resilience within the ICU. The major categories represent facilitators and barriers to regaining control. One of the main facilitators was drawing strength, which explains the manner with which families receive social support from their own and other family members to help them cope. | Social support networks facilitate the families' ability to regain control. Further research is needed to determine whether families suffer a secondary stress reaction from individual interactions with other patients' families in the ICU. |
| **Caregiver Role** | | | | | |
| **Source** | **Setting** | **Intervention** | **Analysis** | **Themes or Theory** | **Authors’ Conclusions** |
| Ingram, 2017 | Neonatal | Planned family-centred discharge process; Train-to-Home | Thematic | Practical preparation; Emotional preparation; Role of feeding | Using a parent-centred approach to communication and informing parents about the needs and progress of their preterm infant is welcomed by parents and staff. |
| **Caregiver Support** | | | | | |
| **Source** | **Setting** | **Intervention** | **Analysis** | **Themes or Theory** | **Authors’ Conclusions** |
| Mouradian, 2013 | Neonatal | Art-based occupation group using scrapbooking | Thematic | Distraction; Calming & relaxing; Fun & enjoyable; Looking to the future; Time to share with others and reducing isolation | An art-based occupation group using scrapbooking is an effective brief intervention to reduce parent anxiety in the NICU, and parent interviews suggested that participation has broad clinical implications for parent well-being. |
| Turner, 2009 | Neonatal | Parent support group | Thematic | Recalling time in the nursery is distressing; Parents are anxious about taking their baby home; Anxiety about possible re-hospitalization of baby; Coping with ongoing medical needs after discharge is difficult; Learning to parent their premature baby; Regaining control; Thankful to see babies developing normally; Good positive relationship with baby after leaving hospital; Positive views with regards to nursing staff and peer support; Negative views with regard to the lack of balance of information and support in parent support group sessions | Peer support groups are effective and helpful to NICU parents. |
| Combe, 2005 | Not reported | Prospective patient diaries | Thematic | Better understanding of the events of the critical illness; Helping with more realistic goal setting during the recovery period; Improving communication within families through discussion of the diary; Providing a source of comfort for the bereaved; Feeling upset after seeing photographs of their loved ones after they had died. | More formal audit of these diaries is required. |
| Egerod, 2011 | Adult | Intensive care diaries | Grounded theory | The core category was constructing the illness narrative, which was a process of narration embedded in the emerging theory of psychosocial recovery after critical illness. The main categories within the patient perspective were information acquisition and gaining insight, and the main categories within the relative perspective were supporting the patient, supporting oneself, and negotiating access. | Intensive care diaries are a low-technology, low-cost rehabilitative intervention for patients and relatives to help bridge the span from intensive care to recovery. |

1Adapted from the Summary of Qualitative Findings Table structure proposed by Lewin et al., 2018

Supplemental Table 10. Estimates for ratio of means for each type of psychological outcome by intervention type and patient setting

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Psychological Outcome** | **Sensitivity analysis** | **Subgroup** | **No. Included Estimates** | **Estimate (95% CI)** | **Interpretation of Estimate** | **I2 Value (%)1** |
| Anxiety | Intervention type | Caregiver experience | 18 | 0.92 (0.87-0.99) | ***Favours intervention*** | **94.14** |
|  | Intervention type | Caregiver role | 2 | 0.99 (0.96-1.01) | No statistical difference | 0.00 |
|  | Intervention type | Caregiver support | 13 | 0.94 (0.90-0.97) | ***Favours intervention*** | **92.69** |
|  | Patient setting | Adult | 17 | 0.92 (0.86-0.99) | ***Favours intervention*** | **96.33** |
|  | Patient setting | Neonatal or pediatric | 16 | 0.94 (0.90-0.98) | ***Favours intervention*** | **87.78** |
| Depression | Intervention type | Caregiver experience | 18 | 0.95 (0.82-1.11) | No statistical difference | **95.27** |
|  | Intervention type | Caregiver role | 2 | 1.05 (0.74-1.50) | No statistical difference | 25.27 |
|  | Intervention type | Caregiver support | 12 | 0.89 (0.78-1.02) | No statistical difference | **98.83** |
|  | Patient setting | Adult | 15 | 0.96 (0.86-1.08) | No statistical difference | **94.69** |
|  | Patient setting | Neonatal or pediatric | 17 | 0.84 (0.67-1.05) | No statistical difference | **96.53** |
| PTSD | Intervention type | Caregiver experience | 12 | 0.95 (0.83-1.10) | No statistical difference | **95.23** |
|  | Intervention type | Caregiver role | 1 | 0.96 (0.94-0.99) | ***Favours intervention*** | N/A |
|  | Intervention type | Caregiver support | 8 | 0.94 (0.85-1.02) | No statistical difference | **95.75** |
|  | Patient setting | Adult | 14 | 0.95 (0.84-1.06) | No statistical difference | **98.33** |
|  | Patient setting | Neonatal or pediatric | 7 | 0.91 (0.79-1.06) | No statistical difference | **95.89** |
| Distress | Intervention type | Caregiver experience | 12 | 1.01 (0.94-1.08) | No statistical difference | **75.07** |
|  | Intervention type | Caregiver role | 3 | 1.04 (0.90-1.20) | No statistical difference | **92.12** |
|  | Intervention type | Caregiver support | 6 | 1.01 (0.97-1.07) | No statistical difference | 45.61 |
|  | Patient setting | Adult | 7 | 1.02 (1.00-1.04) | ***Favours intervention*** | **24.66** |
|  | Patient setting | Neonatal or pediatric | 14 | 1.01 (0.95-1.07) | No statistical difference | **82.85** |
| Burden | Intervention type | Caregiver experience | 3 | 1.14 (0.90-1.45) | No statistical difference | 33.32 |
|  | Intervention type | Caregiver role | 0 | N/A | N/A | N/A |
|  | Intervention type | Caregiver support | 5 | 1.04 (0.97-1.11) | No statistical difference | 49.71 |
|  | Patient setting | Adult | 3 | 1.02 (0.81-1.27) | No statistical difference | 41.84 |
|  | Patient setting | Neonatal or pediatric | 5 | 1.05 (0.99-1.12) | No statistical difference | 37.57 |
| Courage | Intervention type | Caregiver experience | 3 | 0.97 (0.96-0.99) | ***Favours control*** | 62.17 |
|  | Intervention type | Caregiver role | 1 | 1.23 (1.12-1.35) | ***Favours intervention*** | N/A |
|  | Intervention type | Caregiver support | 2 | 1.07 (0.94-1.22) | No statistical difference | 98.70 |
|  | Patient setting | Adult | 3 | 0.98 (0.96-1.00) | ***Favours control*** | **76.53** |
|  | Patient setting | Neonatal or pediatric | 3 | 1.11 (0.98-1.26) | No statistical difference | **94.08** |
| Humanity | Intervention type | Caregiver experience | 1 | 0.91 (0.67-1.23) | No statistical difference | N/A |
|  | Intervention type | Caregiver role | 0 | N/A | N/A | N/A |
|  | Intervention type | Caregiver support | 2 | 1.11 (1.07-1.15) | ***Favours intervention*** | 0.01 |
|  | Patient setting | Adult | 0 | N/A | N/A | N/A |
|  | Patient setting | Neonatal or pediatric | 3 | 1.11 (1.07-1.15) | ***Favours intervention*** | 0.01 |
| Transcendence | Intervention type | Caregiver experience | 7 | 1.02 (0.95-1.1) | No statistical difference | **98.05** |
|  | Intervention type | Caregiver role | 2 | 1.04 (1.00-1.08) | ***Favours intervention*** | **95.24** |
|  | Intervention type | Caregiver support | 5 | 1.04 (1.02-1.05) | ***Favours intervention*** | 28.60 |
|  | Patient setting | Adult | 7 | 1.04 (1.02-1.07) | ***Favours intervention*** | **88.63** |
|  | Patient setting | Neonatal or pediatric | 7 | 1.00 (0.93-1.08) | No statistical difference | **98.98** |

1The *I*2 was viewed as a proportion of variability due to *τ*2 and interpreted as low (25-49%), moderate (50-74%), or **high (≥75%)**

Supplemental Table 11. Risk of bias assessments for all included studies

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Random sequence generation1** | **Allocation concealment1** | **Blinding of participants and researchers1** | **Blinding of outcome assessment** | **Incomplete outcome data2,3** | **Selective reporting** |
| Abdel-Latif, 2015 | Low | Low | High | High | High | Low |
| Affleck, 1989 | Low | Low | High | Low | Low | Low |
| Agren, 2015 | Low | Low | High | High | High | Low |
| Agren, 2019 | Low | Low | High | Low | High | Low |
| Als, 2003 | Low | Low | High | Low | Low | Low |
| Als, 2015 | Low | Low | High | Low | Low | Low |
| Azoulay, 2018 | Low | Low | Low | Low | High | Low |
| Barnato, 2017 | High | High | High | High | Low | Low |
| Bernard, 2011 | High | High | High | High | Low | Low |
| Bohart, 2019 | Low | Low | High | Unclear | High | Low |
| Breisinger, 2018 | High | High | High | High | Low | Low |
| Browne, 2005 | High | High | High | Low | Low | Low |
| Cano Gimenez, 2015 | High | High | High | High | Low | Low |
| Carson, 2016 | Low | Low | Low | Low | Low | Low |
| Carvalho, 2009 | High | High | High | High | Low | Low |
| Chaboyer, 2007 | Low | Low | High | Low | Low | Low |
| Chiang, 2016 | Low | Low | Low | Low | Low | Low |
| Chiang, 2017 | Low | Low | High | Low | Low | Low |
| Chien, 2005 | High | High | High | High | Low | Low |
| Chourasia, 2013 | High | High | High | High | Low | Low |
| Clarke-Pounder, 2015 | Low | Low | High | Low | Low | Low |
| Cobiella, 1990 | Unclear | Unclear | Unclear | Unclear | High | High |
| Colville, 2010 | Low | Low | High | High | High | Low |
| Combe, 2005 | N/A | N/A | N/A | High | Low | Low |
| Cox, 2014 | High | High | High | High | Low | Low |
| Cox, 2018 | Low | Low | Low | Low | High | Low |
| Cox, 2019 | Low | Low | High | Low | High | Low |
| Curtis, 2016 | Unclear | Low | High | Unclear | High | Low |
| Daly, 1994 | High | High | High | Low | Low | Low |
| de Alencar, 2009 | N/A | N/A | N/A | High | Low | Low |
| de Bernardo, 2017 | High | High | High | High | Low | Low |
| Douglas, 2005 | Low | Unclear | Unclear | Unclear | High | Low |
| Egerod, 2011 | N/A | N/A | N/A | High | Low | Low |
| Ettenberger, 2017 | High | High | High | High | Low | Low |
| Feeley, 2008 | N/A | N/A | N/A | High | Low | Low |
| Fotiou, 2016 | Low | Low | Unclear | Unclear | Low | Low |
| Franck, 2011 | Low | Low | Unclear | Unclear | High | Low |
| Glazebrook, 2007 | Low | Low | Low | Low | Low | Low |
| Hane, 2015 | Low | Low | Unclear | Unclear | Low | Low |
| Holditch-Davis, 2013 | Low | Low | High | Low | Low | Low |
| Ingram, 2017 | High | High | High | High | Low | Low |
| Jang, 2005 | N/A | N/A | N/A | High | Low | Low |
| John, 2018 | Low | Low | Low | Unclear | Low | Low |
| Johnson, 2007 | N/A | N/A | N/A | High | Low | Low |
| Jones, 2004 | Low | Low | High | Low | Low | Low |
| Jones, 2012 | Low | Low | Unclear | Unclear | Low | Low |
| Jotzo, 2005 | High | High | High | High | Low | Low |
| Kadivar, 2015 | High | High | High | High | Low | Low |
| Kaufer, 2008 | Low | Low | Unclear | Unclear | Low | Low |
| Kentish-Barnes, 2017 | Low | Low | Low | Low | High | Low |
| Kloos, 2008 | Low | Unclear | Unclear | Low | Low | Low |
| Knapp, 2013 | High | High | Unclear | Unclear | Low | Low |
| Koh, 2007 | Low | Low | High | Low | Low | Low |
| Kucuk Alemdar, 2018 | Low | Unclear | Unclear | Unclear | Low | Low |
| Lautrette, 2007 | Low | Low | High | Low | Low | Low |
| Lee, 2010 | Low | Low | Low | Low | Low | Low |
| Lee, 2013 | High | High | High | High | Low | Low |
| Matricardi, 2013 | Low | Unclear | High | High | Low | Low |
| Melnyk, 1997 | Low | Low | High | Low | Low | Low |
| Melnyk, 2001 | Low | Low | High | Low | Low | Low |
| Melnyk, 2004 | Low | Low | High | Low | Low | Low |
| Melnyk, 2006 | Low | Low | High | Low | Low | Low |
| Meyer, 1994 | Low | Unclear | High | Low | Low | Low |
| Micik, 2002 | High | High | High | Low | Low | Low |
| Miles, 2006 | High | Low | High | High | High | High |
| Mitchell, 2004 | High | Unclear | Unclear | Unclear | Low | Low |
| Morelius, 2015 | Low | Low | High | Low | Low | Low |
| Mouradian, 2013 | High | High | High | High | Low | Low |
| Nielsen, 2019 | Low | Low | High | High | Low | Low |
| Noergaard, 2018 | High | High | High | High | Low | Low |
| O'Brien, 2013 | N/A | N/A | N/A | High | Low | Low |
| Ong, 2019 | N/A | N/A | N/A | High | Low | Low |
| Pagnementa, 2016 | N/A | N/A | N/A | Unclear | High | Low |
| Pineda, 2012 | Low | Low | Low | High | Low | Low |
| Preyde, 2003 | High | High | High | High | High | Low |
| Preyde, 2007 | High | High | High | High | High | Low |
| Prichard, 2015 | High | High | High | High | Low | Low |
| Rennick, 2011 | Low | Low | Unclear | Unclear | Low | Low |
| Ribeiro, 2018 | Low | Low | High | High | Low | Low |
| Roa, 2018 | N/A | N/A | N/A | Low | Low | Low |
| Roberts, 2000 | Low | Low | High | High | Low | Low |
| Rodriguez Martinez, 2003 | Low | Low | Low | Low | High | Low |
| Roman, 1995 | High | High | High | High | High | High |
| Rosa, 2018 | Low | Low | Low | Low | High | Low |
| Rosenbaum, 2015 | Unclear | Low | High | High | High | Low |
| Saenz, 2009 | Low | Unclear | High | Low | Low | Low |
| Samra, 2015 | Low | Low | Low | Low | Low | Low |
| Samuel, 2015 | Low | Low | High | Unclear | Low | Low |
| Segre, 2013 | N/A | N/A | N/A | High | Low | Low |
| Shaw, 2013 | Low | Low | High | High | Low | Low |
| Shaw, 2014 | N/A | N/A | N/A | Low | High | Low |
| Shaw, 2014 | Low | Low | High | High | Low | Low |
| Torke, 2016 | Low | Low | High | Unclear | Low | Low |
| Turan, 2008 | Low | Unclear | High | High | Low | Low |
| Turner, 2009 | N/A | N/A | N/A | High | Low | Low |
| van der Pal, 2007 | Low | Low | High | High | Low | Low |
| Villamizar-Carvajal, 2018 | Low | Low | High | Low | Low | Low |
| Weis, 2013 | Low | Low | High | High | Low | Low |
| Welch, 2016 | Low | Low | High | High | Low | Low |
| White, 2018 | Low | Unclear | High | High | High | Low |
| Wong, 2019 | N/A | N/A | N/A | High | Low | Low |
| Yun, 2017 | High | Unclear | Unclear | High | Low | Low |

Determined by the Cochrane Risk of Bias Assessment Tool

NB: Nearly all trials were unblinded to patients, informal caregivers, physicians, and researchers.

1Study did not receive a score if no control group was included

2Overall attrition above 20% represents high risk of attrition bias; in controlled studies, attrition below 20% and unequal between intervention and control group represents high risk of attrition bias; ratings of unclear represent that either overall attrition or attrition between groups was not reported

3Adapted from Babic et al., 2019

Supplemental Table 12. Quality assessments for quantitative studies

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Study** | **Design limitations1** | **Indirect evidence** | **Inconsistent or heterogeneous results** | **Imprecise results2** | **Publication or reporting bias** |
| Abdel-Latif, 2015 | Low | Moderate | Very low | Low | Low |
| Affleck, 1989 | Low | Moderate | Moderate | Low | Low |
| Agren, 2015 | Low | Moderate | Low | Very low | Low |
| Agren, 2019 | Low | Moderate | High | Very low | Moderate |
| Als, 2003 | Low | Moderate | High | Low | Moderate |
| Als, 2015 | Moderate | High | Moderate | Very low | Low |
| Azoulay, 2018 | Moderate | High | Low | High | High |
| Barnato, 2017 | Low | Low | Moderate | Very low | Moderate |
| Bernard, 2011 | Low | Moderate | Low | Low | Low |
| Bohart, 2019 | Low | Moderate | Moderate | Moderate | High |
| Breisinger, 2018 | Low | Low | Very low | Low | Low |
| Browne, 2005 | Low | Moderate | Low | Low | Low |
| Cano Gimenez, 2015 | Low | Moderate | Moderate | Moderate | Low |
| Carson, 2016 | High | High | High | High | Moderate |
| Carvalho, 2009 | Low | Moderate | Very low | Low | Low |
| Chaboyer, 2007 | Low | Moderate | Low | Moderate | Low |
| Chiang, 2016 | High | High | Moderate | Very low | Low |
| Chiang, 2017 | Moderate | High | High | Low | Low |
| Chien, 2005 | Low | Moderate | Moderate | Low | Low |
| Chourasia, 2013 | Low | Moderate | Moderate | Low | Low |
| Clarke-Pounder, 2015 | Low | Moderate | Moderate | Low | Low |
| Cobiella, 1990 | Low | Low | Very Low | Low | Low |
| Colville, 2010 | Low | Moderate | Low | Moderate | Low |
| Cox, 2014 | Low | Moderate | Moderate | Very low | Low |
| Cox, 2018 | High | High | High | Low | High |
| Cox, 2019 | Moderate | High | High | High | High |
| Curtis, 2016 | Moderate | High | High | Moderate | Moderate |
| Daly, 1994 | Low | Moderate | Moderate | Low | Low |
| de Alencar, 2009 | Very low | Very low | Low | Moderate | Low |
| de Bernardo, 2017 | Very low | Low | Low | Moderate | Low |
| Douglas, 2005 | Very low | Low | Low | Moderate | Low |
| Ettenberger, 2017 | Low | Low | Low | Low | Low |
| Feeley, 2008 | Very low | Very Low | Low | Very low | Low |
| Fotiou, 2016 | Low | Moderate | High | Low | Low |
| Franck, 2011 | Low | Moderate | High | Moderate | High |
| Glazebrook, 2007 | High | High | High | High | High |
| Hane, 2015 | Low | Moderate | Moderate | Low | Low |
| Holditch-Davis, 2013 | Moderate | High | Low | High | High |
| Jang, 2005 | Very low | Very low | Low | Very low | Low |
| John, 2018 | High | Moderate | Low | Very low | Low |
| Jones, 2004 | Moderate | High | Moderate | Moderate | Moderate |
| Jones, 2012 | Low | Moderate | Moderate | Very low | Moderate |
| Jotzo, 2005 | Low | Moderate | Moderate | Low | Low |
| Kadivar, 2015 | Low | Low | Low | Low | Moderate |
| Kaufer, 2008 | Moderate | High | Moderate | Low | Low |
| Kentish-Barnes, 2017 | High | High | Moderate | High | High |
| Kloos, 2008 | Low | Moderate | Moderate | Low | Low |
| Knapp, 2013 | Low | Low | Moderate | Low | Low |
| Koh, 2007 | Moderate | High | High | High | Low |
| Kucuk Alemdar, 2018 | Very low | Very low | Low | Low | Low |
| Lautrette, 2007 | Low | Moderate | High | Moderate | High |
| Lee, 2010 | High | High | Moderate | Very low | Moderate |
| Lee, 2013 | Low | Moderate | Moderate | Low | Low |
| Matricardi, 2013 | Low | Moderate | Moderate | Very low | Low |
| Melnyk, 1997 | Moderate | High | Moderate | Very low | Low |
| Melnyk, 2001 | Moderate | High | Moderate | Very low | Low |
| Melnyk, 2004 | Low | Moderate | Low | Moderate | Moderate |
| Melnyk, 2006 | Moderate | High | Moderate | High | Moderate |
| Meyer, 1994 | Low | Moderate | Low | Low | Low |
| Micik, 2002 | Low | Low | Moderate | Very low | Low |
| Miles, 2006 | Moderate | High | Moderate | Low | Moderate |
| Mitchell, 2004 | Very low | Moderate | Moderate | Moderate | Low |
| Morelius, 2015 | Moderate | High | High | Very low | Moderate |
| Nielsen, 2019 | Moderate | High | High | Moderate | High |
| Noergaard, 2018 | Low | Low | Low | Moderate | Low |
| O'Brien, 2013 | Very low | Very low | Low | Low | Low |
| Ong, 2019 | Very low | Very low | Moderate | High | Low |
| Pagnementa, 2016 | Very low | Very low | Moderate | Moderate | High |
| Pineda, 2012 | Moderate | Low | Moderate | Low | Low |
| Preyde, 2003 | Low | Very low | Moderate | Low | Moderate |
| Preyde, 2007 | Low | Low | Very low | Low | Moderate |
| Prichard, 2015 | Low | Very low | Very low | Very low | Low |
| Ribeiro, 2018 | Low | Moderate | Low | Very low | Low |
| Roa, 2018 | Very low | Low | High | Moderate | Low |
| Roberts, 2000 | Low | Moderate | Moderate | Very low | Moderate |
| Rodriguez Martinez, 2003 | High | High | Moderate | Low | Low |
| Roman, 1995 | Low | Low | Low | Very low | Low |
| Rosa, 2018 | High | High | High | High | High |
| Rosenbaum, 2015 | Moderate | High | Very low | Low | Low |
| Saenz, 2009 | Low | Moderate | Moderate | Moderate | Low |
| Samra, 2015 | High | High | Moderate | Very low | Moderate |
| Samuel, 2015 | Low | Moderate | Moderate | High | Moderate |
| Segre, 2013 | Very low | Very low | Low | Very low | Low |
| Shaw, 2013 | Moderate | High | High | Moderate | High |
| Shaw, 2014 | Very low | Low | Low | Low | Moderate |
| Shaw, 2014 | Moderate | High | High | Moderate | High |
| Torke, 2016 | Moderate | High | High | Moderate | Low |
| Turan, 2008 | Low | Moderate | Moderate | Low | Low |
| van der Pal, 2007 | Low | Moderate | Very low | High | Moderate |
| Villamizar-Carvajal, 2018 | Moderate | Moderate | Moderate | Low | Moderate |
| Weis, 2013 | Low | Moderate | Low | Moderate | Low |
| Welch, 2016 | Low | Moderate | High | Low | Low |
| White, 2018 | Low | Moderate | High | High | High |
| Yun, 2017 | Very low | Low | Moderate | Low | Low |

Determined by the BMJ Best Practice GRADE of Evidence Assessment Tool

1Majority of studies did not have blinding of participants or allocation concealment

2Low quality evidence is in general due to very few events that affected imprecision

Supplemental Table 13. Quality assessment for qualitative studies

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Study** | **Assessment of methodological limitations1** | **Assessment of relevance2** | **Assessment of coherence3** | **Assessment of adequacy4** | **Publication bias5** | **Overall assessment of confidence6,7** |
| Combe, 2005 | Moderate concerns | No or minor concerns | Serious concerns | Moderate concerns | Moderate concerns | Moderate confidence |
| Egerod, 2011 | Moderate concerns | No or minor concerns | Moderate concerns | Moderate concerns | Minor concerns | Moderate confidence |
| Ingram, 2017 | No or minor concerns | No or minor concerns | Moderate concerns | No or minor concerns | Minor concerns | High confidence |
| Johnson, 2007 | Serious concerns | No or minor concerns | Minor concerns | Moderate concerns | Moderate concerns | Low confidence |
| Mouradian, 2013 | Moderate concerns | No or minor concerns | Minor concerns | Moderate concerns | Moderate concerns | Moderate confidence |
| Rennick, 2011 | Minor concerns | Minor concerns | Moderate concerns | Moderate concerns | Minor concerns | High confidence |
| Turner, 2009 | Moderate concerns | No or minor concerns | Moderate concerns | Moderate concerns | Minor concerns | Moderate confidence |
| Wong, 2019 | Serious concerns | No or minor concerns | Minor concerns | Moderate concerns | Moderate concerns | Low confidence |

Determined by the GRADE-CERQual (Confidence in the Evidence from Reviews of Qualitative research); Lewin et al., 2018

For each individual component the following levels of concern were possible with regard to reducing the overall confidence in the review findings: No or very minor concerns; Minor concerns; Moderate concerns; Serious concerns.

1The extent to which there are concerns about the design or conduct of the study

2The extent to which the body of evidence from the included study is applicable to the context specified in the review question

3An assessment of how clear and well-supported the fit is between the data from the included study and the overall synthesis of qualitative studies in the review

4An overall determination of the degree of richness and quantity of data supporting a review finding

5Whether the researcher critically examined their own role, potential bias, and influence during analysis and selection of data for publication

6All included studies started off by default at high confidence and then were rated down by one or more levels if there were concerns regarding any of the components

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