



***Evaluation of evidence on the effectiveness of interventions for caregiving practices and behaviours for optimal social and emotional development of infants: an overview of systematic reviews***

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**Evidence Evaluation Report**

## CONTENTS

|   |    |
|---|----|
| List of abbreviations.....  | 5  |
| Preamble.....   | 7  |
| Abstract.....   | 8  |
| Plain language summary.....   | 12 |
| Summary of evidence statements.....   | 14 |
| Background.....   | 25 |
| Infant and child social and emotional development and wellbeing.....  | 25 |
| Early interventions to improve infants’ social and emotional health and caregiving relationships, skills and bonding..... | 28 |
| How early intervention might improve caregiving and infants’ social and emotional development and wellbeing.....          | 29 |
| Why it is important to describe and understand the factors influencing engagement with caregiving interventions.....      | 30 |
| Why caregiving interventions in the first 90 weeks are important.....   | 30 |
| Objectives.....   | 31 |
| Methods for the overview (Question One).....  | 32 |
| Criteria for considering reviews for inclusion.....   | 32 |
| Search method for identification of reviews.....  | 35 |
| Data collection and analysis.....   | 36 |
| Selection of reviews.....   | 36 |
| Data extraction and management.....   | 36 |
| Assessment of methodological quality of included reviews.....   | 37 |
| Quality of included reviews.....  | 37 |
| Quality of included studies within reviews.....   | 38 |
| Quality of evidence in included reviews.....  | 38 |
| Data synthesis.....   | 39 |
| Methods for the qualitative analysis (Question Two).....  | 39 |
| Criteria for considering intervention/population categories for inclusion.....  | 39 |
| Data collection and analysis.....   | 40 |
| Data extraction and management.....   | 40 |
| Data synthesis.....   | 40 |
| Results.....  | 41 |
| Description of included reviews in the overview (Question One).....   | 41 |

|   |     |
|---|-----|
| Table 1: Summary of citations retrieved in searches for overview of systematic reviews.....               | 41  |
| Table 2: Intervention categories of included reviews.....   | 43  |
| Methodological quality of included reviews.....   | 43  |
| Quality of included reviews .....   | 43  |
| Table 3: Review quality assessed by ROBIS and AMSTAR.....   | 45  |
| Quality of the evidence in included reviews.....  | 45  |
| Table 4: Outcome domains by intervention/population categories, with quality of the evidence (GRADE)..... | 46  |
| Description of included reviews in the qualitative analysis (Question Two).....                           | 47  |
| Effects of interventions.....   | 48  |
| Home visiting interventions.....  | 48  |
| Table 5: Home visiting interventions evidence profile .....   | 52  |
| Antenatal and postnatal education and/or support interventions .....                                      | 63  |
| Table 6: Antenatal and postnatal education and/or support interventions evidence profile.....             | 66  |
| Kangaroo care interventions.....  | 80  |
| Table 7: Kangaroo care interventions evidence profile .....   | 83  |
| Massage interventions.....  | 89  |
| Table 8: Massage interventions evidence profile .....   | 91  |
| Interventions for preventing postnatal depression .....   | 100 |
| Table 9: Interventions for preventing postnatal depression evidence profile .....                         | 102 |
| Interventions for treating maternal depression in the perinatal period .....                              | 110 |
| Table 10: Interventions for treating maternal depression in the perinatal period evidence profile .....   | 112 |
| NBAS-based interventions .....  | 120 |
| Table 11: NBAS-based interventions evidence profile.....  | 121 |
| Interventions for enhancing sensitivity and/or attachment security .....                                  | 125 |
| Table 12: Interventions for enhancing sensitivity and/or attachment security evidence profile ..          | 128 |
| Interventions for preventing later antisocial behaviour and delinquency .....                             | 134 |
| Table 13: Interventions for preventing later antisocial behaviour and delinquency evidence profile .....  | 137 |
| Day care interventions .....  | 144 |
| Table 14: Day care interventions evidence profile .....   | 146 |
| Skin-to-skin care interventions .....   | 149 |
| Table 15: Skin-to-skin care interventions evidence profile .....  | 150 |
| Behavioural sleep interventions .....   | 152 |

|   |     |
|---|-----|
| Table 16: Behavioural sleep interventions evidence profile.....                                   | 153 |
| Anticipatory guidance interventions.....  | 154 |
| Table 17: Anticipatory guidance interventions evidence profile.....                               | 155 |
| Interventions for promoting effective parenting.....  | 156 |
| Table 18: Interventions for promoting effective parenting evidence profile.....                   | 158 |
| Interventions for parents of infants at risk of developmental delays.....                         | 160 |
| Table 19: Interventions for parents of infants at risk of developmental delays evidence profile.. | 162 |
| Interventions for parents of preterm and low birthweight infants.....                             | 167 |
| Table 20: Interventions for parents of preterm and low birthweight infants evidence profile.....  | 171 |
| Interventions for teenage parents.....  | 180 |
| Table 21: Interventions for teenage parents evidence profile.....                                 | 182 |
| Interventions for parents from low and middle income countries.....                               | 187 |
| Table 22: Interventions for parents from low and middle income countries evidence profile.....    | 189 |
| Interventions for low income/socially disadvantaged parents.....                                  | 194 |
| Table 23: Interventions for low-income/socially disadvantaged parents evidence profile.....       | 197 |
| Interventions for parents with alcohol or drug problems.....                                      | 203 |
| Table 24: Interventions for parents with alcohol or drug problems evidence profile.....           | 206 |
| Interventions for fathers.....  | 209 |
| Table 25: Interventions for fathers evidence profile.....   | 209 |
| Discussion.....   | 211 |
| Summary of main results.....  | 211 |
| Overall completeness and applicability of evidence.....   | 218 |
| Quality of the evidence.....  | 219 |
| Potential biases in the overview process.....   | 220 |
| Agreements and disagreements with other studies or reviews.....                                   | 221 |
| Authors' conclusions.....   | 221 |
| Implications for practice.....  | 221 |
| Implications for research.....  | 222 |
| Differences between protocol and review.....  | 224 |
| References.....   | 226 |
| References to reviews included in this overview.....  | 226 |
| Other references.....   | 230 |

## List of abbreviations

|          |  |
|----------|--|
| AAPI     | Adult Adolescent Parenting Inventory   |
| AMSTAR   | A measurement tool for the 'assessment of multiple systematic reviews'                                 |
| APIB     | Assessment of Preterm Infant Behavior  |
| BAS      | British Abilities Scales   |
| BDI      | Beck Depression Inventory  |
| BITSEA   | Brief Infant Toddler Social and Emotional Assessment   |
| BSID     | Bayley Scales of Infant Development  |
| BSID-MDI | Bayley Scales of Infant Development – Mental Development Index   |
| BSID-PDI | Bayley Scales of Infant Development – Psychomotor Development Index                                    |
| CAPI     | Child Abuse Potential Inventory  |
| CBCL     | Child Behavior Checklist   |
| CBT      | Cognitive Behavioural Therapy  |
| CCT      | Controlled clinical trial  |
| CCTI     | Colorado Child Temperament Inventory   |
| CES-D    | Center for Epidemiological Studies Depression Scale  |
| CITS     | Carey Infant Temperament Scale   |
| CI       | Confidence Interval  |
| cm       | Centimetre   |
| cRCT     | Cluster-randomised controlled trial  |
| CTS      | Conflict Tactics Scale   |
| DAS      | Dyadic Adjustment Scale  |
| DASII    | Developmental Assessment Scales for Indian Infants   |
| EA Scale | Emotional Availability Scale   |
| ECBI     | Eyberg Child Behavior Inventory  |
| EPDS     | Edinburgh Postnatal Depression Scale   |
| ES       | Effect Size  |
| ES (d)   | Cohen's d (effect size calculated as difference between intervention and control divided by pooled SD) |
| (F)      | Fixed Effect   |
| FSSQ     | Functional Social Support Questionnaire  |
| g        | Grams  |
| GA       | Gestational Age  |
| GDS      | Gessell Developmental Schedules  |
| GMDS     | Griffiths Mental Development Scales  |
| GRADE    | Grading of Recommendations Assessment, Development and Evaluation                                      |
| GRS      | Global Rating Scale  |
| HADS     | Hospital Anxiety and Depression Scale  |
| HOME     | Home Observation for Measurement of the Environment  |
| HDRS     | Hamilton Depression Rating Scale (also Hamilton Rating Scale for Depression)                           |
| I        | Inconsistent results   |
| $I^2$    | Measure of Statistical Heterogeneity   |
| IPT      | Interpersonal Therapy  |
| IQ       | Intelligence Quotient  |
| IBQ      | Infant Behavior Questionnaire  |
| KBIT     | Kaufman Brief Intelligence Test  |
| K10      | Kessler Psychological Distress Scale   |
| MAI      | Maternal Attachment Inventory  |
| MAS      | Maternal Attitude Scale  |
| MBRS     | Maternal Behavior Rating Scale   |

|        |  |
|--------|--|
| MD     | Mean Difference  |
| MDI    | Mental Development Index   |
| MHPWC  | Mental Health and Parenting Working Committee                              |
| MSCA   | McCarthy Scales of Children's Abilities                                    |
| N      | Number   |
| NBAS   | Neonatal Behavioral Assessment Scale                                       |
| NCAFS  | Nursing Child Assessment of Feeding Scale                                  |
| NCATS  | Nursing Child Assessment Teaching Scale                                    |
| NHMRC  | National Health and Medical Research Council                               |
| NIDCAP | Newborn Individualized Developmental Care and Assessment Program           |
| NR     | Not reported   |
| nRCT   | Non-randomised controlled trial  |
| NS     | Not significant  |
| OR     | Odds Ratio   |
| P      | P value  |
| PAA    | Preschool Assessment of Attachment System                                  |
| PCERA  | Parent-Child Early Relational Assessment                                   |
| PD     | Personality Disorder   |
| PDI    | Psychomotor Development Index  |
| PEDI   | Paediatric Evaluation of Disability Inventory                              |
| PICO   | Patient/Participant/Population; Intervention; Comparison/Control; Outcomes |
| PSI    | Parenting Stress Index   |
| Q      | Cochran Q test of heterogeneity of the effect size                         |
| qRCT   | Quasi-randomised controlled trial  |
| (R)    | Random Effects   |
| RCT    | Randomised controlled trial  |
| RITQ   | Revised Infant Temperament Questionnaire                                   |
| ROBIS  | Risk Of Bias in Systematic reviews tool                                    |
| RR     | Risk Ratio   |
| SB     | Stanford-Binet (Intelligence Scale)  |
| SCAN   | Schedule for Assessment in Neuropsychiatry                                 |
| SCID   | Structured Clinical Interview for DSM Disorders                            |
| SD     | Standard deviation   |
| SES    | Socioeconomic Status   |
| SF-36  | 36-Item Short Form Health Survey   |
| SMD    | Standardised Mean Difference   |
| SRQ-20 | 20-item Self-Reporting Questionnaire                                       |
| SRS    | Social Relationship Scale  |
| SSP    | Strange Situation Procedure  |
| SSQ6   | Social Support Questionnaire 6   |
| ST     | Supportive Therapy   |
| STAI   | State-Trait Anxiety Inventory  |
| VAS    | Visual Analogue Scale  |
| WHO    | World Health Organization  |
| WISC   | Wechsler Intelligence Scale for Children                                   |
| WPPSI  | Wechsler Preschool and Primary Scale of Intelligence                       |

## Preamble

The National Health and Medical Research Council (NHMRC) is Australia's leading expert body promoting the development and maintenance of public and individual health standards, with a mission statement of *'Working to build a healthy Australia'*. In its 2012 to 2015 triennium, NHMRC's Prevention and Community Health Committee identified mental health as a key project area, and committed to considering an evidence based approach to promote optimal social and emotional wellbeing and development of infants, children and adults, through early caregiving practices and behaviours. NHMRC subsequently funded this evaluation of the evidence and established the Mental Health and Parenting Working Committee (MHPWC) to advise on its scope and consider its findings to inform the development of NHMRC Guidance aimed at supporting parents, and health professionals who work with parents on the effectiveness of interventions and messages for parenting practices and behaviours, delivered at a population level to infants up to 12 months of age, for optimal social and emotional development, including the development of recommendations.

# Abstract

## Background

Early interventions to improve parenting practices and behaviours (and the parent or caregiver-infant relationship) can increase infant social and emotional wellbeing and development through counteracting both biological and social disadvantage.

## Objectives

To assess the effectiveness of interventions, programs or messages for caregiving practices and behaviours for the optimal social and emotional development of infants in their first year of life, as children and as adolescents (in an overview of systematic reviews); and also to identify characteristics of interventions, programs or messages that are most likely to lead to optimal social and emotional development (in a qualitative analysis of the included systematic reviews).

## Search methods

We searched five systematic review databases and 13 other databases from January 1994 to October or December 2014, using broad search strategies.

## Selection criteria

In the overview of systematic reviews, we included systematic reviews of randomised controlled trials (RCTs), cluster-randomised trials (cRCT), quasi-randomised trials (qRCT), non-randomised controlled trials (nRCT), controlled before and after studies, interrupted time series, cohort studies, case-control studies, and historically controlled studies of expecting parents (mothers, fathers, partners) of infants prior to birth, or parents (or any teenagers or adults defined as primary caregivers such as mothers, fathers, foster parents, grandparents or relatives) of infants from birth to one year of age (at enrolment or study commencement). We included parenting or parent-child interventions, programs or services aimed at parents or caregivers or parents/caregivers and children where the intervention commenced prior to, or after birth, and up to one year of age for the infant and addressed one or more of: prevention or management of infant regulatory problems; parenting/caregiving practices; parenting/caregiving education/programs pre- and post-pregnancy; programs aimed at improving infant social and emotional wellbeing.

In the qualitative analysis, to complement the information revealed from the overview, we included the systematic reviews identified as addressing 'effective' interventions which contributed pooled results.

## Data collection and analysis

For the overview, two reviewers independently extracted data from the included systematic reviews and assessed review quality using *a measurement tool for the 'assessment of multiple systematic reviews'* (AMSTAR) and a tool to assess the *risk of bias in systematic reviews* (ROBIS). The quality of the evidence in the included systematic reviews was assessed using the *Grading of Recommendations Assessment, Development and Evaluation* (GRADE) system [<http://www.gradeworkinggroup.org/>] for pooled results, and the findings were presented using Evidence Summaries, Evidence Profiles and Evidence Statements.



For the qualitative analysis, data such as results of subgroup analyses and reported moderator effects were extracted from the systematic reviews assessing 'effective' interventions. For the purposes of this overview, 'effective' interventions were defined as those shown to lead to an improvement in at least one of the pre-specified primary and/or secondary outcome domains and, for at least one of the outcomes, the quality of evidence was able to be assessed using the GRADE system; excluding those categories where a benefit was observed for only one outcome and judged to be very low quality evidence using the GRADE system. These criteria were applied by one reviewer and checked by another reviewer. The main findings were summarised and presented after the Evidence Profiles for the 'effective' interventions.

## Main results

We included 51 systematic reviews which were grouped into 21 intervention/population categories. Less than one third of reviews were assessed to be of high quality and at low risk of bias (27%: 14/51) on the AMSTAR and ROBIS tools respectively.

Of the 21 intervention/population categories identified, 14 were judged to be 'effective', based on intervention types (N=9): home visiting interventions; antenatal and postnatal education and/or support interventions; kangaroo care interventions; massage interventions; interventions for preventing postnatal depression; interventions for treating maternal depression in the perinatal period; NBAS-based interventions; interventions for enhancing sensitivity and/or attachment security; interventions for preventing later antisocial behaviour and delinquency; or based on population groups (N=5): interventions for parents of infants at risk of developmental delays; interventions for parents of preterm and low birthweight infants; interventions for teenage parents; interventions for parents from low and middle income countries; and interventions for low income/socially disadvantaged parents.

For seven intervention/population categories there was insufficient evidence available to determine effectiveness, with benefits seen for only one outcome where we were able to use the GRADE system to assess the quality of evidence and this evidence was judged to be of very low quality (N=2: day care interventions; skin-to-skin care interventions); or due to no clear differences seen for pooled outcomes (N=1: interventions for parents with alcohol or drug problems); or no pooled numerical results were available in the included reviews and therefore the quality of the evidence (using the GRADE system) was not able to be assessed for any outcome (N=4: behavioural sleep interventions; anticipatory guidance interventions; interventions for promoting effective parenting; and interventions for fathers).

Only three intervention categories reported outcomes relating to the primary outcome domain: infant social and emotional wellbeing or development up to one year of age. No clear difference in infant temperament was observed with home visiting interventions (one systematic review, moderate to low quality evidence), or massage interventions (one systematic review, low to very low quality evidence), and similarly, no clear difference in infant emotional wellbeing, behaviour or social function was seen with interventions for treating maternal depression in the perinatal period (one systematic review, low quality evidence).

Outcome measures within the below secondary outcome domains were shown to be improved with the following:

- Development for the infant, as a child, and up to 18 years: some benefits seen with home visiting interventions; antenatal and postnatal education and/or support interventions; kangaroo care interventions; massage interventions; interventions for parents of infants at

risk of developmental delays; interventions for parents of preterm and low birthweight infants; and interventions for parents from low and middle income countries.

- Behaviour for the infant, as a child, and up to 18 years: some benefits seen with home visiting interventions; antenatal and postnatal education and/or support interventions; massage interventions; and interventions for preventing later antisocial behaviour and delinquency.
- Physical wellbeing and safety for the infant, as a child, and up to 18 years: some benefits seen with home visiting interventions; and kangaroo care interventions.
- Parent-infant relationship: some benefits seen with home visiting interventions; antenatal and postnatal education and/or support interventions; interventions for treating maternal depression in the perinatal period; NBAS-based interventions; interventions for enhancing sensitivity and/or attachment security; interventions for parents of preterm and low birthweight infants; interventions for teenage parents; interventions for parents from low and middle income countries; and interventions for low-income/socially disadvantaged parents.
- Parent/caregiver psychosocial wellbeing: some benefits seen with antenatal and postnatal education and/or support interventions; interventions for preventing postnatal depression; interventions for treating maternal depression in the perinatal period; and interventions for parents from low and middle income countries.
- Parent/caregiver knowledge, practices and behaviours: some benefits seen with home visiting interventions; antenatal and postnatal education and/or support interventions; and kangaroo care interventions.
- Family relationships: some benefits seen with antenatal and postnatal education and/or support interventions.
- Systems outcomes: some benefits seen with home visiting interventions; antenatal and postnatal education and/or support interventions.

No harms were identified within any pooled primary or secondary outcome domain for the 21 intervention/population categories. In this context, harm refers to a significantly poorer outcome in the intervention group relative to the control group. None of the included systematic reviews provided pooled results regarding harms. Where single study results found significantly poorer outcomes, these findings have been noted in the results section for each relevant intervention/population category.

From the qualitative analysis, very few clear findings relating to the specific characteristics contributing to the effectiveness of the above mentioned interventions for optimal social and emotional development of infants were identified. There was some indication that some interventions delivered by professionals may be more effective than those delivered by others (paraprofessionals/lay persons), that targeting children's risk factors (e.g. prematurity) may be more effective than targeting parental risk factors (e.g. maternal depression or single parenthood), that antenatal commencement may not be necessary (or beneficial) for some interventions, and that interventions that are more direct or with a restricted focus may be more beneficial than those which are more comprehensive, or with multiple foci.

### **Authors' conclusions**

Fourteen intervention categories (or interventions for particular populations) were identified as effective in this overview, with effectiveness regarded when improvements were observed in one or more of the outcomes associated with improved social and emotional development of the infant, child and later on as the adolescent. These interventions/population categories included: home visiting interventions; antenatal and postnatal education and/or support interventions; kangaroo

care interventions; massage interventions; interventions for preventing postnatal depression; interventions for treating maternal depression in the perinatal period; NBAS-based interventions; interventions for enhancing sensitivity and/or attachment security; interventions for preventing later antisocial behaviour and delinquency; interventions for parents of infants at risk of developmental delays; interventions for parents of preterm and low birthweight infants; interventions for teenage parents; interventions for parents from low and middle income countries; and interventions for low income/socially disadvantaged parents.

Further research and improved conduct and reporting of such research, is required to determine the characteristics that contribute to the effectiveness of these interventions for optimal social and emotional development of infants.

## Plain language summary

### What is the issue?

The practices and behaviours of parents and other caregivers are crucial for children's early social and emotional development.

### Why is this important?

The first year of a child's life is an important period for their social and emotional development. Early interventions (during pregnancy or in the first year of a child's life) can improve parents' or caregivers' practices and behaviours and the relationship between the parent or caregiver and the child, and can therefore lead to improvements in the child's social and emotional wellbeing and development, when they are infants, children, and later on as adolescents. It is not currently known which early interventions, programs or messages for parents or caregivers in the first year of children's life are the most effective (leading to improved social and emotional wellbeing and development) and least effective (leading to poorer social and emotional wellbeing and development).

### What evidence did we find?

This review includes 51 systematic literature reviews, assessing 21 different categories (14 of early interventions, as well as early interventions for seven different groups of people). The quality of the reviews was moderate, with less than one third of the reviews considered to be 'high' quality.

Only three intervention categories reported outcomes relating to the primary outcome domain: infant social and emotional wellbeing or development up to one year of age. We found that home visiting interventions (visiting parents or caregivers and infants at their home) and massage interventions (parents giving their infants massages) did not have a clear impact on infant temperament. Similarly, treating mothers who have depression did not have a clear impact on infants' emotional wellbeing, behaviour or social function.

We found that 14 of the 21 different categories of early interventions/ interventions for different groups of people were effective, in that they improved outcome(s) associated with infants' social and emotional wellbeing or development (such as outcomes related to: development, behaviour or physical wellbeing and safety; the parent-infant relationship; parent/caregiver psychosocial wellbeing; parent/caregiver knowledge, practices and behaviours; family relationships; and/or systems outcomes). These effective interventions were: home visiting interventions; antenatal and postnatal education and/or support interventions; kangaroo care interventions; massage interventions; interventions for preventing postnatal depression; interventions for treating maternal depression in the perinatal period; NBAS-based interventions; interventions for enhancing sensitivity and/or attachment security; interventions for preventing later antisocial behaviour and delinquency; interventions for parents of infants at risk of developmental delays; interventions for parents of preterm and low birthweight infants; interventions for teenage parents; interventions for parents from low and middle income countries; and interventions for low income/socially disadvantaged parents.

There was not enough evidence to determine whether seven of the 21 different categories of early interventions/interventions for different groups of people were effective for improving infant social and emotional wellbeing or development, including: day care interventions; skin-to-skin care interventions; interventions for parents with alcohol or drug problems; behavioural sleep

interventions; anticipatory guidance interventions; interventions for promoting effective parenting; and interventions for fathers.

None of the categories of early interventions in this review reported harms (meaning there were no instances where a significantly poorer pooled outcome was found in the intervention group relative to the control group within the pre-specified outcome domains).

This evaluation only included outcomes relevant to infant social and emotional wellbeing and development. It did not evaluate the overall effectiveness of parent/caregiving interventions/practices across all possible outcomes and therefore the intervention/population categories considered may have demonstrated benefits for other areas of infant/child development or may achieve other intended outcomes.

Further research is needed to determine which characteristics of the effective interventions for optimal social and emotional development of infants are most important.

## Summary of evidence statements

| HOME VISITING INTERVENTIONS   |  |
|---|--|
| <b>Infant social and emotional wellbeing or development up to one year of age</b>   | <u>Temperament</u> : Moderate to low quality evidence from one systematic review shows no clear difference in infant temperament (measured using the CITS) at four to 16 months with home visiting interventions (five RCTs, N=814).   |
| <b>Development for the infant, as a child, and up to 18 years</b>                   | <p><u>Cognitive development</u>: Low quality evidence from one systematic review shows improved cognitive development (measured using the BSID-MDI) at nine to 24 months with home visiting interventions (eight RCTs, N=1,670).</p> <p><u>Motor development</u>: Low quality evidence from one systematic review shows no clear differences in motor development (measured using the BSID-PDI) at nine to 18 months with home visiting interventions (four RCTs, N=390).</p> <p><u>Intelligence</u>: Low quality evidence from one systematic review shows higher IQ (measured using the SB Intelligence Test) at 12 to 48 months for children with home visiting interventions (five RCTs, N=870).</p> <p><u>Weight</u>: Low quality evidence from one systematic review shows no clear differences in children's weight up to 48 months with home visiting interventions (three RCTs, N=463).</p> <p><u>Height</u>: Low quality evidence from one systematic review shows no clear differences in children's height up to 48 months with home visiting interventions (three RCTs, N=463).</p>   |
| <b>Behaviour for the infant, as a child, and up to 18 years</b>                     | <u>Sleeping difficulties</u> : Moderate quality evidence from one systematic review shows fewer sleeping difficulties (reported by mothers) at six to 12 months in infants with home visiting interventions (four RCTs, N=763).  |
| <b>Physical wellbeing and safety for the infant, as a child, and up to 18 years</b> | <p><u>Unintentional injuries</u>: Moderate quality evidence from one systematic review shows reduced rates of unintentional child injuries up to 48 months with home visiting interventions (six RCTs, N=1,836).</p> <p><u>Uptake of immunisation</u>: Low quality evidence from one systematic review shows higher uptake of child immunisation (six months to five years) with home visiting interventions (eight RCTs, one nRCT, N=2,518).</p> <p><u>Uptake of preventive health services (other than immunisation)</u>: Very low quality evidence from one systematic review shows no clear differences in uptake of other preventive health services (six months to five years) with home visiting interventions (three RCTs, N=425).</p> <p><u>Uptake of acute care health services: hospital admission (excluding intentional or unintentional injury)</u>: Low quality evidence from one systematic review shows fewer children's hospital admissions (excluding injury) at nine to 46 months with home visiting interventions (four RCTs, three nRCTs, N=2,897).</p> <p><u>Uptake of acute care health services: use of emergency medical services</u>: Moderate quality evidence from one systematic review shows no clear differences in use of emergency services up to 46 months with home visiting interventions (four RCTs, one nRCT, N=1,193).</p> |
| <b>Parent-infant relationship</b>   | <u>Quality of the home environment</u> : Moderate to low quality evidence from one systematic review shows improvement in parenting interaction and quality (measured using the HOME Inventory) at six weeks to 36 months with home visiting interventions (10 RCTs, two nRCTs, N=1,708).  |

|   |  |
|---|--|
| <b>Parent/caregiver knowledge, practices and behaviours</b> | <p><u>Family size</u>: Moderate to low quality evidence from one systematic review suggests no clear differences in family size (repeat pregnancy; births two years post-intervention; family size 10 years post-intervention) one to 10 years post-intervention with home visiting interventions (three RCTs, one nRCT, N=1,282).</p> <p><u>Use of public assistance</u>: Low quality evidence from one systematic review shows no clear differences in mothers' use/receipt of public assistance at 12 to 48 months with home visiting interventions (three RCTs, N=1,413).</p> <p><u>Maternal employment</u>: Moderate to low quality evidence from one systematic review shows no clear differences in maternal employment at 12 to 46 months with home visiting interventions (three RCTs, N=1,413).</p> <p><u>Breastfeeding</u>: Moderate quality evidence from one systematic reviews shows that home visiting interventions can increase breastfeeding at three months post birth (three RCTs, one nRCT, N=938).</p> |
| <b>Systems outcomes</b>                                     | <p><u>Child maltreatment</u>: Very low quality evidence from one systematic review shows that child and/or parent-focused primary prevention interventions can reduce child maltreatment (measured using reports of substantiated child abuse or neglect) at one to 17 years (nine RCTs, one quasi-experimental study, two matched cohorts, N=5,661).</p>  |

| <b>ANTENATAL AND POSTNATAL EDUCATION AND/OR SUPPORT INTERVENTIONS</b> |   |
|---|---|
| <b>Development for the infant, as a child, and up to 18 years</b>     | <p><u>Cognitive development</u>: High to moderate quality evidence from one systematic review shows that parenting education with expectant and new parents can improve cognitive development (measured using the BSID MDI, SB Intelligence Test, and other validated measures) post-intervention (15 months) (38 RCTs, N~3,800)<sup>1</sup> and at follow up (28.6 months later) (31 RCTs, N~3,100)<sup>1</sup>.</p> <p><u>Motor development</u>: High quality evidence from one systematic review shows that parenting education with expectant and new parents can improve motor development (measured using the BSID PDI and related measures) post-intervention (15 months) (22 RCTs, N~2,200)<sup>1</sup> and at follow up (28.6 months later) (13 RCTs, N~1,300)<sup>1</sup>.</p> <p><u>Social development</u>: Moderate quality evidence from one systematic review shows that parenting education with expectant and new parents can improve social development (assessed with measures of social competence and behaviour regulation, e.g. competence subscales of the BITSEA, tests for secure attachment, and measures of communication and peer relations) post-intervention (15 months) (34 RCTs, N~3,400)<sup>1</sup> and at follow up (28.6 months later) (21 RCTs, N~2,100)<sup>1</sup>.</p> <p><u>Mental health</u>: Moderate quality evidence from one systematic review shows that parenting education with expectant and new parents can improve mental health (measured using the CBCL, assessments of child mood states, and other validated scales) post-intervention (15 months) (40 RCTs, N~4,000)<sup>1</sup> and at follow up (28.6 months later) (21 RCTs, N~2,100)<sup>1</sup>.</p> |

<sup>1</sup>Estimated sample sizes based on average sample of N=100 for each of the 133 RCTs

~Follow up effects – average time interval between end of intervention and follow up was 28.6 months

|   |   |
|---|---|
| <b>Behaviour for the infant, as a child, and up to 18 years</b> | <p><u>Sleep</u>: Moderate to very low quality evidence from one systematic review shows that sleep education interventions can increase infant night-time sleep at six and 12 weeks and day-time sleep at six, but not 12, weeks. These interventions do not have a clear impact on increasing length of uninterrupted sleep during the day or the night at six or 12 weeks (two RCTs per outcome, N=NR per outcome).</p> <p><u>Crying</u>: Low quality evidence from one systematic review suggests that sleep education interventions do not have a clear impact on crying time in infants at six to 12 weeks (two RCTs, N=NR).</p>   |
| <b>Parent-infant relationship</b>                               | <p><u>Parenting quality</u>: Moderate quality evidence from one systematic review shows that parenting education with expectant and new parents can improve parenting quality (measured using the Infant-Toddler HOME Inventory, NCATS, and other related validated scales) post-intervention (15 months) (103 RCTs, N~10,300)<sup>2</sup> and at follow up (28.6 months later) (39 RCTs, N~3,900)<sup>2</sup>.</p>   |
| <b>Parent/caregiver psychosocial wellbeing</b>                  | <p><u>Parental stress</u>: Moderate quality evidence from one systematic review shows that parenting education with expectant and new parents can decrease parental stress (measured using the Parental Distress scale of PSI, and related measures) post-intervention (15.0 months) (26 RCTs, N~2,600)<sup>2</sup> with no clear effect at follow up (28.6 months later) (six RCTs, N~600)<sup>2</sup>.</p> <p><u>Parental mental health</u>: High and moderate quality evidence from one systematic review shows that parenting education with expectant and new parents can improve parental mental health (measured using the CES-D, STAI, EPDS and other validated measures) post-intervention (15 months) (33 RCTs, N~3,300)<sup>2</sup> and at follow up (28.6 months later) (12 RCTs, N~1,200)<sup>2</sup>.</p> |
| <b>Parent/caregiver knowledge, practices and behaviours</b>     | <p><u>Maternal knowledge</u>: Low quality evidence from one systematic review shows that interventions for education about infant behaviour can increase maternal knowledge (measured using 12 to 15 item questionnaires) up to four weeks postpartum (two RCTs, N=56).</p> <p><u>Health promoting parental behaviour</u>: Moderate quality evidence from one systematic review shows that parenting education with expectant and new parents can improve health promoting behaviour (measured using the percentage of children who received full immunisation, or number of paediatric well child visits) post-intervention (15 months) (30 RCTs, N~3,000)<sup>2</sup>.</p>  |
| <b>Family relationships</b>                                     | <p><u>Couple adjustment</u>: High quality evidence from one systematic review shows that parenting education with expectant and new parents can improve couple adjustment (measured using the DAS, revised CTS and related scales) post-intervention (15 months) (13 RCTs, N~1,300)<sup>2</sup> and at follow up (28.6 months later) (four RCTs, N~400)<sup>2</sup>.</p>  |
| <b>Systems outcomes</b>   | <p><u>Child maltreatment</u>: High and moderate quality evidence from one systematic review shows that parenting education with expectant and new parents can reduce child maltreatment (measured using identified cases of child abuse (e.g. from protective service agencies), or the CAPI) post-intervention (15 months) (29 RCTs, N~2,900)<sup>2</sup> with no clear effect at follow up (28.6 months later) (seven RCTs, N~700)<sup>2</sup>.</p>   |

<sup>2</sup> Estimated sample sizes based on average sample of N=100 for each of the 133 RCTs

~Follow up effects – average time interval between end of intervention and follow up was 28.6 months



| <b>KANGAROO CARE INTERVENTIONS</b>  |   |
|---|---|
| <b>Development for the infant, as a child, and up to 18 years</b>                   | <p><u>Weight</u>: Low quality evidence from one systematic review shows that weight gain at latest follow up (at discharge or 40 weeks' postmenstrual age up to six months of age or six month follow up) is increased with kangaroo care for low birthweight infants (10 RCTs, N=1,072).</p> <p><u>Length</u>: High quality evidence from one systematic review shows that length gain at latest follow up (40 weeks' postmenstrual age to three months of age) is increased with kangaroo care for low birthweight infants (two RCTs, N=251).</p> <p><u>Head circumference</u>: Moderate quality evidence from one systematic review shows that head circumference gain at latest follow up (at discharge or 40 weeks' postmenstrual age to three months of age) is increased with kangaroo care for low birthweight infants (three RCTs, N=369).</p>   |
| <b>Physical wellbeing and safety for the infant, as a child, and up to 18 years</b> | <p><u>Mortality</u>: High quality evidence from one systematic review shows that infant mortality is reduced at discharge or 40 to 41 weeks' postmenstrual age with kangaroo care for low birthweight infants (eight RCTs, N=1,736) and moderate quality evidence at latest follow up (discharge or 40 to 41 weeks' postmenstrual age up to 12 months corrected age) (11 RCTs, N=2,167), though the effect of kangaroo care on mortality at six months of age or six months follow up is unclear (moderate quality evidence: two RCTs, N=354).</p> <p><u>Infection</u>: High quality evidence from one systematic review shows that severe infection/sepsis at latest follow up (discharge or 40 to 41 weeks' postmenstrual age to six months' corrected age) (seven RCTs, N=1,343) and nosocomial infection/sepsis at discharge or 40 to 41 weeks' postmenstrual age (three RCTs, N=913) are reduced with kangaroo care for low birthweight infants, though low quality evidence from the same systematic review indicates no clear effect of kangaroo care on mild/moderate infection or illness at latest follow up (40 to 41 weeks' postmenstrual age to six months of age) (four RCTs, N=1,266).</p> |
| <b>Parent/caregiver knowledge, practices and behaviours</b>                         | <p><u>Breastfeeding</u>: Low quality evidence from one systematic review shows that breastfeeding at discharge or 40 to 41 weeks' postmenstrual age is increased with kangaroo care for low birthweight infants (nine RCTs, N=1,576), and moderate quality evidence shows a probable increase at one to two month follow up (six RCTs, N=538) and at three month follow up (five RCTs, N=924), though high quality evidence shows that the effect at six month follow up is unclear (six RCTs, N=952).</p>  |

| <b>MESSAGE INTERVENTIONS</b>  |   |
|---|---|
| <b>Infant social and emotional wellbeing or development up to one year of age</b> | <p><u>Temperament</u>: Low to very low quality evidence from one systematic review suggests no clear impact of massage interventions on infant temperament post-intervention (measured using the CCTI, IBQ and RITQ) (activity: four weeks to three months (one RCT, two qRCTs, N=121); persistence: six weeks to three months (one RCT, one qRCT, N=81); or soothability: four to six weeks (two qRCTs, N=80).</p> |

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| <p><b>Development for the infant, as a child, and up to 18 years</b></p> | <p><u>Weight, length and head circumference:</u> Very low quality evidence from one systematic review shows post-intervention increases in weight (four weeks to six months) (15 RCTs, three qRCTs, N=2,271); length (four weeks to three months) (nine RCTs, two qRCTs, N=1,683) and head circumference (four to six weeks) (seven RCTs, two qRCTs, N=1,423) with massage interventions.</p> <p><u>Psychomotor development:</u> Low quality evidence from one systematic review shows improved psychomotor development with massage interventions (measured using the BSID or Levin PDI) post-intervention (three to six months) (three RCTs, one qRCT, N=466).</p> <p><u>Cognitive development:</u> Very low quality evidence from one systematic review shows no clear difference in cognitive development with massage interventions (measured using the BSID or Levin MDI) post-intervention (three to six months) (three RCTs, one qRCT, N=466).</p> <p><u>Motor and language development:</u> Low to very low quality evidence from one systematic review shows improved gross motor and fine motor development with massage interventions but no clear difference in language development (measured using the GDS and Capital Institute Mental Checklist) post-intervention (at one to two months) (two RCTs, N=237).</p> |
| <p><b>Behaviour for the infant, as a child, and up to 18 years</b></p>   | <p><u>Personal-social behaviour:</u> Very low quality evidence from one systematic review shows improved personal-social behaviour with massage interventions (measured using the GDS and Capital Institute Mental Checklist) post-intervention (at one to two months) (two RCTs, N=237).</p> <p><u>Crying:</u> Low quality evidence from one systematic review shows a reduction in crying or fussing time with massage interventions post-intervention (one to 16 weeks) (four RCTs, N=341).</p> <p><u>Sleep:</u> Very low quality evidence from one systematic review shows increased infant sleep duration over 24 hours with massage interventions post-intervention (four weeks to three months) (four RCTs, N=634), but no mean increase in 24 hour sleep (two RCTs, N=225) or duration of night sleep post-intervention (four weeks) (two RCTs, N=225).</p>   |
| <p><b>Parent-infant relationship</b></p>                                 | <p><u>Mother-infant interactions:</u> Low to very low quality evidence from one systematic review shows no clear differences in mother and child interactions (measured using the NCATS and Murray GRS) with massage interventions post-intervention (at five to 16 weeks) (two RCTs, one qRCT, N=131) or follow up (12 to 24 months) (one RCT, one qRCT, N=65).</p> <p><u>Maternal sensitivity:</u> Very low quality evidence from one systematic review shows no clear differences in maternal sensitivity (warm/cold and non-intrusive/intrusive maternal behaviours: measured using the Murray GRS) with massage interventions post-intervention (at five to six weeks) (one RCT, one qRCT, N=84).</p> <p><u>Infant interactions with mother (infant contribution):</u> Very low quality evidence from one systematic review shows no clear differences in infants' interactions with their mothers (attentive/non-attentive; lively/inert and happy/distressed infant responses: measured using the Murray GRS) with massage interventions post-intervention (five to six weeks) (one RCT, one qRCT, N=84).</p>  |
| <p><b>Parent/caregiver psychosocial wellbeing</b></p>                    | <p><u>Parenting stress:</u> Very low quality evidence from one systematic review shows no clear differences in parenting stress (measured using the PSI) with massage interventions post-intervention (at four weeks to two months) (one RCT, one qRCT, N=55).</p>  |

| <b>INTERVENTIONS FOR PREVENTING POSTNATAL DEPRESSION</b> |  |
|--|--|
| <b>Parent-infant relationship</b>                        | <u>Maternal-infant attachment</u> : Moderate quality evidence from one systematic review shows that psychological and psychosocial interventions do not have a clear effect on maternal-infant attachment (measured using the Dysfunction Interaction Scale of the PSI) at 24 to 52 weeks postpartum (two RCTs, N=268).  |
| <b>Parent/caregiver psychosocial wellbeing</b>           | <u>Depression and anxiety</u> : High quality evidence from one systematic review shows that psychological and psychosocial interventions can prevent postnatal depression (diagnosed using the SCID or SCAN) at 12 to 24 weeks postpartum (five RCTs, N=939) and anxiety (measured using the HADS or STAI) at 24 to 52 weeks postpartum (four RCTs, N=815); and moderate quality evidence indicates these interventions can reduce depressive symptoms (measured using the BDI, EPDS, HADS or K10) at three to 52 weeks postpartum (20 RCTs, 14,727), however low quality evidence also shows no clear effect on depression scores (measured using the BDI, CES-D, EPDS, HADS, SF-36) at six to 52 weeks postpartum (19 RCTs, 12,376).<br><u>Parental stress</u> : Moderate quality evidence from one systematic review indicates that psychological and psychosocial interventions do not have a clear effect on reducing stress (measured using the PSI) at 52 weeks postpartum (three RCTs, N=465). |
| <b>Parent/caregiver views of the intervention</b>        | <u>Maternal dissatisfaction with care</u> : Very low quality evidence from one systematic review indicates that psychological and psychosocial interventions have no clear effect on reducing maternal dissatisfaction with care provided (tool(s) for measurement NR) at zero to eight weeks postpartum (two RCTs, N=825), but may decrease dissatisfaction at eight to 24 weeks postpartum (four RCTs, N=3,014).   |
| <b>Family relationships</b>                              | <u>Marital discord</u> : Moderate quality evidence from one systematic review indicates that psychological and psychosocial interventions do not have a clear effect on reducing marital discord (measured using one question, or a VAS developed by a researcher) at 24 to 52 weeks postpartum (three RCTs, N=291).<br><u>Social support</u> : Moderate quality evidence from one systematic review indicates that psychological and psychosocial interventions do not have a clear effect on perceived social support at 12 to 24 weeks postpartum (two RCTs, N=718; measured using the Duke FSSQ and maternal health service contact) and at 24 to 52 weeks postpartum (seven RCTs, N=8,290; measured using maternal views, the SRS, Duke FSSQ, SSQ6, and a subscale of Satisfaction with Motherhood Scale).  |

| <b>INTERVENTIONS FOR TREATING MATERNAL DEPRESSION IN THE PERINATAL PERIOD</b>     |  |
|---|--|
| <b>Infant social and emotional wellbeing or development up to one year of age</b> | <u>Emotional well-being</u> : Low quality evidence from one systematic review indicates no clear effect on children's emotional wellbeing (measured using observer ratings of infant affect: PCERA) up to six months when maternal depression in the perinatal period is treated (one RCT, two qRCTs, N=152).<br><u>Behaviour and social function</u> : Low quality evidence from one systematic review indicates no clear effect on children's behaviour or social function (measured using observer rating of infant behaviour: PCERA) up to six months when maternal depression in the perinatal period is treated (one RCT, two qRCTs, N=151). |

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|--|---|
| <b>Parent-infant relationship</b>              | <u>Quality of parenting behaviours</u> : Low quality evidence from one systematic review shows an improvement in the quality of parenting behaviours (measured using the PCERA or MAI) up to six months when maternal depression in the perinatal period is treated (three RCTs, two qRCTs, N=359).   |
| <b>Parent/caregiver psychosocial wellbeing</b> | <u>Parental mental health</u> : Low to very low quality evidence from one systematic review shows an improvement in parental mental health (parents' depressive symptoms measured using the BDI, EPDS or HDRS) up to six months when maternal depression in the perinatal period is treated (11 RCTs, three qRCTs, N=1698), but no clear effect at six to 12 months (two RCTs, N=975), or > 12 months (one RCT, one qRCT, N=273). |

#### **NBAS-BASED INTERVENTIONS**

|                                   |  |
|-----------------------------------|--|
| <b>Parent-infant relationship</b> | <u>Parenting quality</u> : Low quality evidence indicates that parenting quality (measured using outcomes including observations of parent-child interactions, self-report measures of parenting, and four scales from the Cohler MAS) is enhanced with NBAS-based training at eight days post-intervention to nine months postpartum (11 RCTs, two qRCTs, N=668). |
|-----------------------------------|--|

#### **INTERVENTIONS FOR ENHANCING SENSITIVITY AND/OR ATTACHMENT SECURITY**

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|-----------------------------------|---|
| <b>Parent-infant relationship</b> | <u>Sensitivity and attachment</u> : Moderate quality evidence from two systematic reviews shows maternal sensitivity (measured using the Ainsworth/Erickson sensitivity rating scales, HOME Inventory, NCATS, or other tools) and attachment (measured using the SSP, or other tools) are improved with sensitivity interventions (51 interventions assessed in RCTs, N=6,282 and 23 interventions assessed in RCTs, N=1,255 respectively), and high quality evidence shows no clear impact on disorganised attachment (measured using the Main and Solomon coding system, or Crittenden's PAA) (time of outcome measures not reported) (10 studies (11/15 interventions assessed in RCTs), N=842). |
|-----------------------------------|---|

#### **INTERVENTIONS FOR PREVENTING LATER ANTISOCIAL BEHAVIOUR AND DELINQUENCY**

|   |   |
|---|---|
| <b>Behaviour for the infant, as a child, and up to 18 years</b> | <u>Child disruptive behaviour</u> : Moderate quality evidence from one systematic review shows that home visiting interventions to prevent later antisocial behaviour and delinquency can reduce child disruptive behaviour (measured using the CBCL, ECBI, or by the number of children 'hitting others') (time of outcome measure not reported) (eight RCTs, N=NR). |
|---|---|

#### **DAY CARE INTERVENTIONS**

|   |   |
|---|---|
| <b>Development for the infant, as a child, and up to 18 years</b> | <u>Intelligence</u> : Very low quality evidence from one systematic review shows that early education or day care interventions can improve IQ (measuring tools/tests NR) at 36 months (three RCTs, one qRCT, N=1,109). |
|---|---|

| <b>SKIN-TO-SKIN CARE INTERVENTIONS</b>                            |   |
|---|---|
| <b>Development for the infant, as a child, and up to 18 years</b> | <u>Weight</u> : Moderate quality evidence from one systematic review suggests no clear impact of skin-to-skin care for healthy newborns on infant body weight at 14 days of age (two RCTs, N=43).   |
| <b>Parent/caregiver knowledge, practices and behaviours</b>       | <u>Breastfeeding</u> : Very low quality evidence from one systematic review shows that skin-to-skin care for healthy newborns can increase breastfeeding at one to four months post birth (13 RCTs, N=702), though low and very low quality evidence suggests no clear impact at one month post birth (two RCTs, N=62) or on duration of breastfeeding (seven RCTs, N=304). |

| <b>INTERVENTIONS FOR PARENTS OF INFANTS AT RISK OF DEVELOPMENTAL DELAYS</b> |  |
|---|--|
| <b>Development for the infant, as a child, and up to 18 years</b>           | <u>Overall developmental ability</u> : Low and low to very low quality evidence from one systematic review shows improved overall developmental ability (using standardised measures such as BSID, BAS, GMDS, MSCA, SB, and WPPSI) with interventions for infants with developmental delays at 15 months to 18 years (five nRCTs, N=194), infants at risk of intellectual disability at 18 to 54 months (three RCTs, N=234) and preterm infants at three to 60 months (11 RCTs, two qRCTs, N=2,508). |

| <b>INTERVENTIONS FOR PARENTS OF PRETERM AND LOW BIRTHWEIGHT INFANTS</b> |  |
|---|--|
| <b>Development for the infant, as a child, and up to 18 years</b>       | <p><u>Cognitive development in infancy</u>: Mostly low quality evidence from three systematic reviews shows that home visiting, parenting skills and developmental interventions each improve cognitive development (measured using the BSID or GMDS) from six months, up to two years of age in infants born preterm (41 RCTs, five qRCTs, one cohort study, N=7,315).</p> <p><u>Cognitive development at preschool age</u>: Moderate quality evidence from two systematic reviews shows that parenting skills and developmental interventions each improve cognitive development (measured using the SB Intelligence Scales, MSCA, WPPSI or BAS) at three to five years of age in children born preterm (eight RCTs, N=2,237).</p> <p><u>Cognitive development at school age</u>: Low to very low quality evidence from two systematic reviews suggests no clear effect of parenting skills and developmental interventions on cognitive development (measured using the WISC or KBIT) from five to 17 years of age in children born preterm (seven RCTs, N=2,259).</p> <p><u>Motor development in infancy</u>: Moderate to low quality evidence from two systematic reviews shows that parenting skills and developmental interventions each improve motor development (measured using the BSID-PDI or GMDS locomotor subscale) from six months, up to two years of age in infants born preterm (25 RCTs, two qRCTs, N=4,265).</p> <p><u>Motor development at preschool age</u>: Low quality evidence from one systematic review suggests no clear effect of developmental interventions on motor development (measured using the GMDS locomotor subscale or PEDI) at three to five years of age in children born preterm (two RCTs, N=168).</p> <p><u>Cerebral palsy</u>: Low quality evidence from one systematic review suggests no clear effect of developmental interventions on the rate of cerebral palsy up to six years of age in children born preterm (four RCTs and one qRCT, N=737).</p> |

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|-----------------------------------|---|
| <b>Parent-infant relationship</b> | <p><u>Mother-infant interaction</u>: Very low quality evidence from one systematic review suggests no clear effect of relationship interventions on mother-infant interaction (measured using the NCAFS or NCATS) up to three months corrected age for infants born preterm (three qRCTs, N=508).</p> <p><u>Parenting quality and interaction</u>: Very low quality evidence from one systematic review shows an improvement in parenting quality and interaction (measured using the HOME Inventory) with home visiting interventions at eight to 12 months of age for infants born preterm (four RCTs, one cohort and one quasi-experimental study, N=336).</p> |
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| <b>INTERVENTIONS FOR TEENAGE PARENTS</b>                    |  |
|---|--|
| <b>Parent-infant relationship</b>                           | <p><u>Parent-child interactions</u>: Low quality evidence from one systematic review shows that teenage parenting interventions can improve combined parent-child interactions post-intervention (up to six weeks) and at three month follow up, as well as children's interactions with parents at three month follow up, and parents' interactions with children post-intervention (up to six weeks); very low quality evidence shows no clear effect on parent's interactions with children three month follow up (all measured using the NCATS total score, parent or baby subscale) (two RCTs, N=47).</p> |
| <b>Parent/caregiver knowledge, practices and behaviours</b> | <p><u>Sense of competence in parenting role</u>: Low to very low quality evidence from one systematic review indicates no clear impact of teenage parenting interventions on sense of parenting competence (measured using the AAPI) at four to seven weeks (two RCTs, N=70).</p>  |

| <b>INTERVENTIONS FOR PARENTS FROM LOW AND MIDDLE INCOME COUNTRIES</b> |  |
|---|--|
| <b>Development for the infant, as a child and up to 18 years</b>      | <p><u>Infant growth</u>: Unclear quality evidence from one systematic review shows that interventions in low to middle income settings to address maternal mental health improve infant growth (time of outcome measure not reported) (two RCTs, 1 historical matched control study, N=1,125).</p> <p><u>Infant development</u>: Unclear quality evidence from one systematic review shows that interventions in low to middle income settings to address maternal mental health improve infant development (measured using the GMDS or DAS-II) (time of outcome measure unclear) (two RCTs, N=473).</p>   |
| <b>Parent-infant relationship</b>                                     | <p><u>Mother-infant relationship</u>: Unclear quality evidence from one systematic review shows that interventions in low to middle income settings to address maternal mental health improve mother-infant relationships (measured using rated observations of parent-child interactions and the Acholi adaptation of the HOME Inventory) at six to 12 months (three RCTs, one historical matched control study, N=1,123).</p>  |
| <b>Parent/caregiver psychosocial wellbeing</b>                        | <p><u>Maternal depression</u>: Moderate to low quality evidence from one systematic review shows that interventions in low to middle income settings to address maternal mental health improve maternal depression at four weeks to 12 months postpartum (measured using the, SCID-1, CES-D, EPDS, SRQ-20, HDRS, K10 or Kitgum Maternal Mood Scale) (11 RCTs, one qRCT, one historical group control study, N=15,429), and unclear quality evidence shows these interventions improve maternal depression at three to four months (four RCTs, one qRCT, N=943), six months (six RCTs, one historical matched control study, N=1,945), and 12 months postpartum (two RCTs, N=12,541).</p> |

| <b>INTERVENTIONS FOR LOW-INCOME/SOCIALLY DISADVANTAGED PARENTS</b> |   |
|--|---|
| <b>Parent-infant relationship</b>                                  | <u>Supportive parent-child interactions</u> : Low quality evidence from one systematic review shows that relationship-based interventions for low income/socially disadvantaged parents can improve parent-child interactions (using observational measures, e.g. EA Scale, HOME, MBRS, NCATS) at 1.5 to 30 months (19 interventions (mostly RCTs), N=6,807). |

| <b>INTERVENTIONS FOR PARENTS WITH ALCOHOL OR DRUG PROBLEMS</b>                      |  |
|---|--|
| <b>Development for the infant, as a child, and up to 18 years</b>                   | <u>Cognitive development</u> : Low quality evidence from one systematic review shows no clear differences in cognitive development (measured using the BSID MDI) at 18 to 36 months with home visiting interventions for parents with alcohol or drug problems (three RCTs, N=199).<br><u>Psychomotor delay</u> : Low quality evidence from one systematic review shows no clear differences in psychomotor development (measured using the BSID PDI) at 18 to 36 months with home visiting interventions for parents with alcohol or drug problems (three RCTs, N=199).   |
| <b>Physical wellbeing and safety for the infant, as a child, and up to 18 years</b> | <u>Incomplete vaccination schedule</u> : Low quality evidence from one systematic review shows no clear difference in completing vaccinations at six months with home visiting interventions for parents with alcohol or drug problems (two RCTs, N=260).<br><u>Infant death</u> : Low quality evidence from one systematic review shows no clear difference in infant death up to six months with home visiting interventions for parents with alcohol or drug problems (two RCTs, N=228).  |
| <b>Parent/caregiver knowledge, practices and behaviours</b>                         | <u>Continued illicit drug use</u> : Very low quality evidence from one systematic review shows no clear difference in continuing to use illicit drugs at six to 36 months with home visiting interventions for parents with alcohol or drug problems (three RCTs, N=348).<br><u>Continued alcohol use</u> : Low quality evidence from one systematic review shows no clear difference in continuing to use alcohol at six to 36 months with home visiting interventions for parents with alcohol or drug problems (three RCTs, N=348).<br><u>Failure to enrol in drug treatment program</u> : Very low quality evidence from one systematic review shows no clear difference in failing to enrol in drug treatment programs (time of outcome measure not reported) with home visiting interventions for parents with alcohol or drug problems (two RCTs, N=211).<br><u>Failure to remain in drug treatment program</u> : Very low quality evidence from one systematic review shows no clear differences in failing to remain in drug treatment programs at three to 18 months with home visiting interventions for parents with alcohol or drug problems (three RCTs, N=315).<br><u>Breastfeeding</u> : Low quality evidence from one systematic review shows no clear differences in breastfeeding at six months with home visiting interventions for parents with alcohol or drug problems (two RCTs, N=260). |
| <b>Systems outcomes</b>   | <u>Infant not in care of biological mother</u> : Very low quality evidence from one systematic review shows no clear differences in numbers not in the care of their biological mother (including non-voluntary foster care) at 12 to 36 months with home visiting interventions for parents with alcohol or drug problems (two RCTs, N=253).  |

**Abbreviations:** AAPI: Adult Adolescent Parenting Inventory; BAS: British Abilities Scales; BDI: Beck Depression Inventory; BITSEA: Brief Infant Toddler Social and Emotional Assessment; BSID: Bayley Scales of Infant Development; CAPI: Child Abuse Potential Inventory; CBCL: Child Behavior Checklist; CCTI: Colorado Child Temperament Inventory; CES-D: Center for

Epidemiological Studies Depression Scale; CTS: Conflict Tactics Scale; CITS: Carey Infant Temperament Scale; DAS: Dyadic Adjustment Scale; EA Scale: Emotional Availability Scale; ECBI: Eyberg Child Behavior Inventory; EPDS: Edinburgh Postnatal Depression Scale; FSSQ: Functional Social Support Questionnaire; GDS: Gessell Developmental Schedules; GMDS: Griffiths Mental Development Scales; GRS: Global Rating Scale; HADS: Hospital Anxiety and Depression Scale; HOME: Home Observation for Measurement of the Environment; HDRS: Hamilton Depression Rating Scale; IQ: Intelligence Quotient; IBQ: Infant Behavior Questionnaire; KBIT: Kaufman Brief Intelligence Test; K10: Kessler Psychological Distress Scale; MAI: Maternal Attachment Inventory; MAS: Maternal Attitude Scale; MBRS: Maternal Behavior Rating Scale; MDI: Mental Development Index; MSCA: McCarthy Scales of Children's Abilities; N: number; NBAS: Neonatal Behavioral Assessment Scale; NCAFS: Nursing Child Assessment of Feeding Scale; NCATS: Nursing Child Assessment Teaching Scale; nRCT: non-randomised controlled trial; P: P value; PAA: Preschool Assessment of Attachment System; PCERA: Parent-Child Early Relational Assessment; PDI: Psychomotor Development Index; PEDI: Paediatric Evaluation of Disability Inventory; PSI: Parenting Stress Index; qRCT: quasi-randomised controlled trial; RCT: randomised controlled trial; RITQ: Revised Infant Temperament Questionnaire; SB: Stanford-Binet (Intelligence Scale); SCAN: Schedule for Assessment in Neuropsychiatry; SCID: Structured Clinical Interview for DSM Disorders; SF-36: 36-Item Short Form Health Survey; SRQ-20: 20-item Self-Reporting Questionnaire; SRS: Social Relationship Scale; SSP: Strange Situation Procedure; SSQ6: Social Support Questionnaire 6; STAI: State-Trait Anxiety Inventory; VAS: Visual Analogue Scale; WISC: Wechsler Intelligence Scale for Children; WPPSI: Wechsler Preschool and Primary Scale of Intelligence



## Background

### Infant and child social and emotional development and wellbeing

Infant mental health has been defined as *“the developing capacity of the child from birth... to experience, regulate, and express emotions; form close and secure interpersonal relationships; and explore the environment and learn – all in the context of family, community and cultural expectations for young children. Infant mental health is synonymous with healthy social and emotional development”* (Parlakian and Siebel 2002). The construct of infant mental health originated just over half a century ago as an interdisciplinary and international field with a focus on the many dynamic social, emotional and cultural forces that shape an infant’s development (Fitzgerald et al 2011; Lawless et al 2014).

In the first year of life, about one in five infants may have one or more regulatory problems, defined as excessive crying, sleeping or feeding difficulties (Hemmi et al 2011). Other indications of emotional disturbance in infancy are dislike of being touched or cuddled by a parent and an abnormal parent or caregiver-infant relationship (Rask et al 2013). In the Copenhagen Child Cohort Study, the population prevalence of mental health disorders among children aged 18 months was estimated to be 16% to 18% (according to the Classification of Diseases ICD-10 and the Diagnostic Zero to Three DC 0-3); with disorders of emotion, behaviour and eating being most common, along with the diagnosis of regulatory disorder (Skovgaard et al 2007). Using data from a ‘National Survey of Child and Adolescent Well-being’ of infants referred to child welfare agencies in the United States, almost 35% of infants aged 12 to 18 months scored high on the Problem Scale of the BITSEA, over 20% scored high on the Competence Scale of the BITSEA, and 10% scored over the CBCL clinical cut-off (Horwitz et al 2013). These rates may be underestimates due to the limitations of currently available diagnostic systems. Looking across the span of childhood and adolescence, nearly one third of children aged one to 15 years in Western Australia were reported by their parents or caregivers to have psychosocial or mental health problems such as trouble with emotions, concentration, behaviour or getting on with people (Patterson et al 2012).

The World Association for Infant Mental Health has proposed that the field of infant mental health, or infant social and emotional development, combines three main assumptions – that infant behaviour cannot be viewed separately from relationships with others; that infants’ most important relationships are with their primary caregivers; and that infant caregivers have relationships with others, in their social contexts (McDonough and Fitzgerald 2003). Thus while genetic predisposition and biological/physical characteristics can partially determine how an infant’s environment shapes their early development and wellbeing, as recognised by the ‘transactional model’, children are ‘actors’ who shape, and are shaped by their environment, with a driving force of development being their relationships. The family, and family environment, is widely regarded as the primary influence on a child’s development (Siddiqi et al 2007), with the most salient features of the environment being its highly intertwined social resources (such as parenting skills and education, cultural practices/approaches, the health status of family members, and intra-family relations) and economic resources (such as wealth, occupational status, and housing conditions) (Siddiqi et al 2007). Some of the most important determinants of early child development identified in recent literature include adequate maternal nutrition, parental mental and physical health, parental stress and depression, parenting styles, unemployment, limited/no income, housing conditions, and neighbourhood quality (Maggi et al 2010).

Parent, caregiver or family characteristics and their social contexts can positively and negatively impact on infants’ social and emotional development. Neighbourhood and family disadvantage; caregiver mental health (Heberle et al 2014); caregiver strain of various types (Borre and Kliever

2014) and parental experience of childhood maltreatment (Dixon et al 2005; Gartland et al 2014; Miranda et al 2013) are some of the many factors that can influence caregiving practices and behaviours, and can in turn negatively impact infant, child and adult mental health outcomes. Family environments where caregivers are experiencing chronic mental or physical illness can, for example, lead to disrupted parent or caregiver-infant interaction, a fundamental process in a child's social and emotional development. Further, a mother's emotional state may have a direct effect on fetal brain development and consequently on child behaviour – and these effects may differ between boys and girls (de Bruijn et al 2009). This transmission can also occur in early infant life, with type of care able to produce changes in neural development and systems regulating social behaviour in the child (Meaney 2001). In a recent study of first-time mothers, maternal-infant bonding was negatively correlated with maternal stress, pain, and postpartum depression, and positively correlated with partner support with the infant, and social support. However in this study, women who were older, more educated, not living in poverty, and married reported lower bonding scores (Kinsey et al 2014).

For parents and caregivers, the arrival of a new infant is often characterised by disrupted participation in activities particularly outside the home, and thus in social support and networks. For parents and particularly new mothers, the work of infant care and household management can be large and exhausting; this may be further compounded by an undervaluing, recognition or trivialisation of this workload by partners and society. Expectations to maintain 'gendered' lines of housework and infant care can impact on wellbeing, particularly for women who often carry a greater burden to assume 'family labour'. A partner therefore, who is understanding, empathic, and recognises infant care as a shared endeavour, can increase a woman's confidence and wellbeing (Rowe and Fisher 2010). High-quality, supportive partner relationships have been shown to impact on both maternal and infant health and wellbeing (Stapleton et al 2012), with both mothers and fathers benefiting from fathers' involvement in relational and task-focused child rearing (Riina and Feinberg 2012).

Increasing evidence highlights the potential public health implications for mothers, fathers and their infants of access to paid parental leave – paid leave may permit mothers sufficient time to sustain breastfeeding and can assist in the development of optimal maternal-infant attachment (reflected, for example, in a mother's confidence about separation from her infant) (Cooklin et al 2012). Paid entitlement to paternity leave (or parental leave to which fathers have access) can additionally increase the participation of fathers in child rearing, leading to positive impacts on child development (Broomhill and Sharp 2012). Mothers returning to income-generating work (particularly full-time paid employment) within the first three months of giving birth can have negative health and developmental outcomes for infants; early returns to paid work have been associated with increased externalising behaviour problems for children, reductions in breastfeeding and immunisation rates (Berger et al 2005). Children up to two years of age have been shown to be at an increasing risk of impaired motor and social development with reducing maternity leave (Sherlock et al 2008). While the potential detrimental effects of returning to income-generating work are recognised, some studies have suggested these are partially 'offset' by positive effects of increased family income (Baum 2003). Income generation is a main reason cited by Australian women for employment resumption following childbirth; while access to paid leave has been highly variable across Australian workplaces, there is evidence that it has been inequitably provided to those who are already socioeconomically advantaged (Cooklin et al 2012). Though improvements in access to paid parental leave in Australia have been observed in recent times, provisions could be improved particularly to encourage further shifts towards gender equality within households and in society, such as through increasing the provision of fathers' or partners' only leave to encourage a greater level of responsibility for parenting, increasing the level of leave payment to more closely match normal earnings, and through measures to ensure job protection for parents who take leave from paid work (Broomhill and Sharp 2012).

While young parental age (teenage mother- and fatherhood) has been associated with poor infant and child development, debate exists as to whether this is mediated through other factors (including financial difficulties, low educational attainment, and parental health), which are all associated with infant and child development (Chittleborough et al 2011; Mollborn and Lovegrove 2011). Children born to women who used substances during pregnancy are also at greater risk of impaired physical growth and development, and physical and mental health problems. The postnatal environment of children born to parents with substance abuse issues additionally puts them at high risk for poor outcomes, with substance use greatly impacting on parent-child relationships, and child behaviour (Barnard and McKeganey 2004).

Adverse birth outcomes such as being born too soon or too small, periventricular leukomalacia, intraventricular haemorrhage, respiratory distress syndrome, and necrotising enterocolitis can have later mental health sequelae such as disrupted behaviour in children, due to immature organ development or organ damage. This can be further compounded by the increased likelihood that preterm and low birthweight babies will be cared for in an environment of disadvantage and deprivation (Spittle et al 2012; Treyvaud et al 2010).

On the other hand, warm, sensitive and responsive caregiving can foster infant attachment, prosocial behaviour and normal social and emotional development (Baggett et al 2010). Increased maternal responsiveness has been shown, for example, to facilitate growth in infants' social, emotional, communication and cognitive competence (in infants born at term, and also particularly in infants born at very low birthweight) (Landry et al 2006). Early parenting behaviours, such as greater mother-reported cognitive stimulation of infants in their first year of life, have been shown to protect infants from future conduct problems (Lahey et al 2008). For children considered highly vulnerable to developmental impairments, such as those born very preterm, positive parenting behaviour can influence early neurobehavioural development; for example, greater parent-child 'synchrony,' and parenting that is positive, warm and sensitive has been associated with greater social-emotional competence for preterm born children at two years of age (Treyvaud et al 2009).

Though historically less discussed, fathers have important impacts on their infants' social and emotional development. Positive father involvement has been shown to have protective effects on infant social, educational, behavioural and psychological outcomes, into childhood and adulthood (Panter-Brick et al 2014). Disengaged or remote father-child interactions from as early as three months however, have been shown to predict externalising behaviours in children longitudinally (Ramchandani et al 2013). Paternal mental ill health and psychopathology, including depression has been associated with fewer positive parent-infant interactions, and later infant/child behavioural problems (Paulson et al 2006). Fathers with high levels of antisocial behaviour have been shown to increase their child's risk of conduct problems the more time they live with them; conversely, the less time fathers with low levels of antisocial behaviour live with their children, the more likely the children are to have conduct problems (Jaffee et al 2003). While active, regular engagement of fathers has been shown to be predictive of positive outcomes (such as reductions in behavioural or psychological problems, enhanced cognitive development, decreased delinquency and economic advantage) (Sarkadi et al 2008), institutional policies and societal attitudes have historically not supported high paternal involvement. Poor support of paid parental leave for fathers, low support from employers for men staying home with infants, and a lack of fathers' groups, are examples of external factors that can adversely impact on fathers' involvement and thus infant quality of development (O'Brien 2009).

In addition to direct parenting or caregiver styles and behaviours, epigenetic effects can play a role in a child's social and emotional development. Transmission of behavioural traits from one generation to the next has been assumed to be largely genetic, but we now understand that

epigenetic mechanisms also play a role and, for example, that parental care patterns can be transmitted across generations (Champagne 2008). An unfavourable intrauterine environment (such as maternal nutritional deprivation or stress) can have potent physiological influences on children such as increased risk of cardiovascular disease, obesity or diabetes as an adult.

Social and emotional development problems in infancy are significant predictors of longer-term difficulties into childhood and adulthood. In infancy, insecure (avoidant and disorganised) attachment has been shown to be predictive of a range of poorer outcomes in later childhood, including, for example, child conduct problems (Vando et al 2008). Secure children have been shown to be better adjusted at school, showing better emotional, social and behavioural adjustment and peer-rated social status (Granot and Mayseless 2001). While behavioural problems in early childhood strongly predict academic and behaviour problems at school age (Halonen et al 2006), this is not necessarily deterministic. Early regulatory problems are often transient, but these problems may persist, particularly when families are experiencing multiple problems (Hemmi et al 2011).

### **Early interventions to improve infants' social and emotional health and caregiving relationships, skills and bonding**

The importance of the first years of life in terms of the quality of parenting practices and behaviours (and the parent or caregiver-infant relationship) for infant and later development and wellbeing is now widely recognised. Worldwide, there is an increasing acknowledgement by governments and policy makers of the need to identify and implement early interventions – such as during pregnancy and the first year of life. These are aimed at promoting 'good parenting', at a universal level, and also in 'high risk' families where parenting skills may be poor, or social and emotional risk factors may be high (Barlow et al 2008; Bowes and Grace 2014).

A diverse range of interventions could support early parenting and influence the quality of the parent or caregiver-infant relationship. It is likely that no single approach will be effective for everyone, and that a comprehensive approach towards interventions, programs, services and policies is needed to work with parents or caregivers, their infants and the families to promote infant and later social and emotional wellbeing and development (Barlow et al 2008; Wise 2013).

In the antenatal period, interventions may be aimed at preparing for pregnancy and childbirth generally (e.g. antenatal classes; breastfeeding programs; smoking cessation interventions), or aimed more specifically at preparing for parenthood (e.g. antenatal group-based parenting programs focused on promoting the transition into parenthood) (Gagnon and Sandall 2007), or supporting expecting parents considered 'at risk' (e.g. those with a history of childhood maltreatment, of violence or substance abuse/use; or those 'demographically at risk', including those occupying a low socioeconomic position) (Barlow et al 2008). Antenatal (and postnatal) educational interventions directed towards individuals or groups, provided face-to-face, or through electronic media can cover a range of 'topics' – including for example, newborn care, feeding and preventative care (e.g. positioning, vaccination, car seat use); normal infant behaviour and development (e.g. crying and sleeping) (Hiscock et al 2014); and maternal/paternal and infant interaction.

Following birth, there are similarly a range of interventions and combinations of interventions that may have the potential to impact quality of the parent or caregiver-infant relationship. Interventions can be specific, aimed at promoting bonding and attachment – such as skin-to-skin contact and kangaroo care (Moore et al 2012), or infant massage (Bennett et al 2013). More comprehensive programs include a range of interventions aimed at improving the capacity of parents to support their infant's social and emotional development (Barlow et al 2008). Programs are offered on a one-to-one basis or in groups across a range of settings (Barlow et al 2010), are delivered using a range of

media (i.e. leaflets, videos), and a range of theoretical approaches may be used to develop and implement such interventions (for example, behavioural (negative impact of focussing on problem behaviour and ignoring positive behaviour) and relational (improving interactions between parent and child) (Mytton et al 2014)). Parenting programs can involve the use of 'manualised' curriculum, aimed at increasing knowledge, skills and understanding of parents or caregivers. Parenting programs can be implemented widely, or directed towards specific 'high risk' groups, including, for example teenage parents or caregivers (Barlow et al 2011), or those with an intellectual disability (Coren et al 2010).

Producing the most cost-effective outcomes is likely to be of high priority to governments and policy makers. In some cases, interventions aimed at preparing for parenthood or supporting parenting may be able to be provided as part of routine care during the antenatal or postnatal period, thus potentially reducing costs. Media-based interventions may offer a potentially 'low cost', efficient approach towards reaching a wide audience (compared with some 'traditional approaches' which may require delivery by a practitioner, for example). While some 'intensive' interventions, including home visiting programs are likely to be associated with comparatively high costs, they may be particularly appropriate (and associated with higher cost savings at the societal level), for example, if they are targeted appropriately, such as to 'high risk' groups (Barlow et al 2008).

Message delivery: Adolescent mothers in the United States frequently use the internet for health information by mobile phone (but do not usually have access to a smart phone) (Logsdon et al 2014). Conversely an Australian study found that over a third of first time mothers did not use the internet for health information, particularly if they had low educational attainment and/or low incomes (Wen et al 2011). Nonetheless digital parenting programs are likely to be more attractive to many parents or caregivers. A review of programs delivered by a variety of digital means found that an average of 78% of parents or caregivers completed programs, compared with less than 50% of parents or caregivers completing programs requiring their attendance (Breitenstein et al 2014).

Message framing: Message content and framing may have profound effects on the acceptability and uptake of parenting and caregiving programs and interventions. For example, directive 'preachy', confrontational and standardised, instead of individualised messages may be negatively perceived to be redundant, annoying and lead to caregivers not revealing their parenting concerns. On the other hand, parents and caregivers can be highly receptive to information about the effects of their lifestyle on fetal health (Edvardsson et al 2011).

## **How early intervention might improve caregiving and infants' social and emotional development and wellbeing**

The first years of a child's life represents a critical period during which trajectories of vulnerability can be determined through a complex interplay between biological, genetic and environmental (social and economic) conditions. Early intervention can lead to improvements in several ways. Parenting programs may emphasise bonding and attachment of mothers/fathers/caregivers since securely attached infants tend to have more favourable long-term outcomes. Interventions, programs or messages implemented at a 'universal' level may increase knowledge, skills and understanding, and thus improve the capacity of parents and caregivers to support infant and later social and emotional development. Targeting to specific ('high risk') groups such as young parents or caregivers may additionally aim to address factors such as pre-existing social disadvantage, and could seek to improve financial, social and material resources in the household; programs targeted at parents of preterm babies, for example, could also involve intensive training on interaction, considered particularly important for this vulnerable subgroup of infants.

## **Why it is important to describe and understand the factors influencing engagement with caregiving interventions**

An invitation to participate in a parenting or caregiving intervention or program may be perceived as a sign of inadequate parenting and this can be a significant barrier to engagement. Those parents likely to benefit may be the least likely to engage (Barrett 2010). As well as stigma, other barriers may include competing demands on time, group dynamics, accessibility of programs, skills of program deliverers and sociocultural contexts (Mytton et al 2014). Key barriers to specifically engaging fathers in parenting or caregiving interventions have been described as operating throughout design, delivery and evaluation; without consideration of potential gender biases, fathers are likely to be marginalised from the outset of these programs (Panter-Brick et al 2014).

## **Why caregiving interventions in the first 90 weeks are important**

When parents or caregivers lack the necessary skills, social supports and knowledge of infant and child development, risks of maltreatment are increased (Tomison 1998). With growing evidence that early intervention can counteract both biological and social disadvantage (Brooks-Gunn et al 2000), the 90 week period from conception to when an infant turns one is considered a critical time for intervention.

## Objectives

The objective of this evaluation was to assess the effectiveness of current interventions, programs or messages for caregiving practices and behaviours for the optimal social and emotional development of infants in their first year of life, and as children and adults; and also to identify characteristics of interventions, programs or messages that are most likely to lead to optimal social and emotional development.

The evaluation comprises:

- a) An **overview** of systematic reviews;
- b) A **qualitative analysis** of the systematic reviews identified in the overview and the relevant primary studies of which they are comprised, to complement the information revealed from the above overview.

## Research questions

The overview addresses Question One (and sub-questions). The overview and qualitative analysis together address Question Two (and sub-questions).

### ***Question One: What is the effectiveness of interventions for caregiving practices or behaviours for optimal social and emotional development of infants?***

- What interventions, programs or messages for practices and behaviours of parents/caregivers prior to birth (during pregnancy) and in the first year of an infant's life have been shown to lead to improved social and emotional development of the infant, the child and later on as the adolescent (up to 18 years of age)?
- What interventions, programs or messages for practices and behaviours of parents/caregivers prior to birth (during pregnancy) and in the first year of an infant's life have been shown to lead to poorer social and emotional development for the infant, the child and later on as the adolescent (up to 18 years of age)?

### ***Question Two: What are the characteristics of interventions/programs/messages for caregiving practices or behaviours that optimise infant social and emotional development? (The 'who', 'when', 'where', 'how', and why)***

- **Who** could<sup>3</sup> deliver the intervention, program or messages to optimise infant social and emotional wellbeing and development? (e.g. 'experts', midwives, general practitioners)
- **Where** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development? (e.g. hospitals, homes)
- **To whom** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development? (e.g. pregnant women, mothers/fathers/primary caregivers, families, grandparents)
- **When** could be the best time for the intervention, program, or message delivery to occur?
  - The 'best time' in regards to caregiver preferences and accessibility.
  - The 'best time' in regards to improved outcomes for the infant, child and later on as the adolescent, and for the caregiver.
- **How** could the intervention, program or messages regarding infant social and emotional wellbeing and development be delivered? (e.g. face-to-face, online, one-on-one, in groups)

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<sup>3</sup>We used could here and in the sentences that follow to acknowledge that studies conducted outside of Australia were not precluded. The MHPWC will therefore need to interpret what was found in the literature to the operational realities of the Australian context.

- **How** could the intervention, program or messages regarding infant social and emotional wellbeing and development be framed?
- What could **impede** or interfere with engagement with interventions or programs or caregivers enacting upon messages? (e.g. barriers to maximising reach and uptake)
- What could **facilitate** or drive engagement with interventions or programs or caregivers enacting upon messages? (e.g. enablers to maximising reach and uptake).

## Methods for the overview (Question One)

The methodologies for the overview were approved by the Office of the NHMRC on 24 October 2014.

### Criteria for considering reviews for inclusion

#### Types of reviews

We included systematic reviews of RCTs, cRCTs, qRCTs, nRCTs, controlled before and after studies, interrupted time series, cohort studies, case-control studies, and historically controlled studies. We excluded systematic reviews of cross-sectional studies, case series and case studies.

For the purpose of the overview, NHMRC defined a systematic review as per the Cochrane Collaboration's definition: "A review of a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyse data from the studies that are included in the review. Statistical methods (meta-analysis) may or may not be used to analyse and summarise the results of the included studies" (Cochrane Collaboration 2005). We included a small number of systematic reviews that did not satisfy all components of this definition (for example did not formally critically appraise studies (assess risk of bias), but were identified to be (or identified as) systematic reviews, and we reported on this as part of the quality assessment (see 'Quality of included reviews' below, and 'Differences between protocol and review').

We excluded reviews published in non-English language (where a publically available translation was not available), and excluded reviews published in abstract form only.

#### Types of participants

Participants in eligible studies for the overview were expecting parents (mothers, fathers, partners) of infants prior to birth, or parents (or any teenagers or adults defined as primary caregivers such as mothers, fathers, foster parents, grandparents or relatives) of infants from birth to one year of age (at enrolment/study commencement) (including studies in which the maximum mean age of the infants at enrolment is one year, reflecting the fact that while this evaluation focuses on interventions for optimal social and emotional development of infants up to one year of age, it was anticipated that a number of studies evaluating relevant interventions may well have included children who are slightly older than this; in addition to younger infants). We also planned to include girls and young women (and boys and young men) participating in pre-conception parenting knowledge and awareness programs providing that the studies reported on infant social and emotional wellbeing and development.

Eligible participants were from the general population as well as from high-risk groups.



## **Types of interventions and comparisons**

Interventions in eligible studies for the overview were parenting or parent-child programs, defined as parent or parenting or parent-child interventions, programs or services aimed at parents or caregivers or parents/caregivers and children that address one or more of:

- Prevention or management of infant regulatory (feed, sleep, cry) problems;
- Parenting/caregiving practices (such as bonding, infant cues, encouraging infant self-regulation);
- Parenting/caregiving education/programs pre and post pregnancy;
- Programs aimed at improving infant social and emotional wellbeing.

Studies were eligible for inclusion irrespective of the theoretical framework underpinning the parenting intervention/program (i.e. behavioural, cognitive behavioural, humanistic etc.).

We included studies where the intervention commenced prior to, or after birth, and up to one year of age for the infant. We excluded studies where the intervention commenced once the infant was older than one year of age; however we included studies in which the intervention continued after the infant turned one.

We excluded studies focused solely on the effects of pharmacological interventions, and interventions delivered solely to infants, with no focus on parenting/caregiving education, practices and/or behaviours.

We included parenting/caregiving/parent-child interventions or programs compared with standard care, usual practice or no intervention, or to an alternative parenting/caregiving/parent-child intervention or program (including where the comparator was a program or intervention focused on an alternative 'topic' (i.e. preventative care and safety versus normal infant behaviour and development)).

## **Types of outcomes measures**

We pre-specified short, medium and long-term outcomes for the child, with short term outcomes being those measured in infancy, medium term outcomes being those measured in childhood, and long-term outcomes being those measured in adolescence and up to adulthood. We also pre-specified short-term outcomes for the parent/caregiver, given these outcomes may lead to, or be an indicator of, improved social and emotional wellbeing of the child. Pre-specified outcomes focused on positive as well as negative measures of infant social and emotional wellbeing and development, and measures of parental/caregiver knowledge, behaviours/practices and wellbeing.

Outcomes in the following categories were to be considered: infant development; infant behaviour; infant physical wellbeing and safety; parent/caregiver psychosocial wellbeing; parent/caregiver knowledge, practices and behaviours; parent/caregiver views of intervention; parent/caregiver-child relationships; family relationships; systems outcomes (e.g. notification to agencies, and placement with family/in the community).

Within each category of outcomes, we included sub-outcomes; for example, infant development covers a wide range of outcomes such as early regulatory problems (which may include sleeping, crying and feeding difficulties). Where possible and appropriate, outcomes were to be measured using standardised and validated parent-report and objective assessment instruments.

## Primary outcome

- **Infant social and emotional wellbeing and development up to one year of age.**  
*This may have included individual or composite measures of social and emotional wellbeing and development, as reported by the included systematic reviews (and the individual studies within these reviews), and may have included for example, individual outcomes related to relevant screening or measurement tools.*

## Secondary outcomes

- **Development for the infant, as a child, and up to 18 years**, e.g. normative standards for growth and development; language and cognitive development (e.g. successful in reading, writing, literacy and numeracy; problem solving and decision making skills; pre-school transition; academic achievement; school engagement, attachment and retention); social and emotional wellbeing (e.g. mental health, identity, social competence, self-esteem, self-efficacy, coping, emotional intelligence).
- **Behaviour for the infant, as a child, and up to 18 years** e.g. early infant regulatory problems (sleeping, crying, feeding difficulties); internalising and externalising behaviour difficulties; problem behaviours (e.g. conduct disorder); positive behaviour and prosocial behaviour; law-abiding behaviour and convictions; risk avoidance and risky behaviour (e.g. youth pregnancy, suicide, smoking, substance abuse).
- **Physical wellbeing and safety for the infant, as a child, and up to 18 years** e.g. optimal physical health and healthy lifestyle (e.g. adequate nutrition; adequate exercise and physical activity; free from preventable disease); safety (e.g. safe from unintended injury).
- **Parent-infant relationship**, e.g. infant interaction with parent/caregiver; parent/caregiver interaction with infant; combined parent/caregiver-infant interactions (e.g. positive interactions; emotional warmth and responsiveness; absence of hostility); attachment.
- **Parent/caregiver psychosocial wellbeing**, e.g. depression, anxiety, stress; quality of life.
- **Parent/caregiver knowledge, practices and behaviours**, e.g. knowledge (e.g. basic infant care); behaviours and practices/skills; sense of confidence and competence in the parenting/caregiving role; parent harmful use of substances (e.g. alcohol) or its avoidance/reduction.
- **Parent/caregiver views of intervention**, e.g. views of and attitudes towards intervention, including satisfaction.
- **Family relationships**, e.g. relationship between parents/caregivers, and relationships between other family members.
- **Systems outcomes**, e.g. notification/re-notification to agencies; maltreatment/abuse or neglect; placement with relatives/in the community.

## Prioritising reviews for inclusion

A process for prioritising reviews for inclusion in the overview was developed (see 'Differences between protocol and review'). In addition to meeting the 'Criteria for considering reviews for inclusion' specified above, we included reviews that:

- Clearly had included studies in populations of infants from birth to one year of age (at enrolment/study commencement);
- Did not substantially/entirely overlap in content with another included review (in cases where reviews overlapped in content, we included the most comprehensive, or recent, of the reviews).

We did not prioritise reviews that:

- Reported exclusively on outcome measures related to the secondary outcome domains without a focus on the infant: parent/caregiver psychosocial wellbeing; parent/caregiver knowledge, practices and behaviours; parent/caregiver views of the intervention; family relationships; and systems outcomes [or had a restricted focus on one specific developmental outcome e.g. language development];
- Had no included studies<sup>4</sup>;
- Had no included studies in populations of infants from birth to one year of age at study enrolment/study commencement;
- Did not clearly report the ages of children in the included studies.

## Search method for identification of reviews

### Electronic searches

We searched the following electronic databases, from January 1994 to October-December 2014.

#### *Systematic review databases*

- The Cochrane Library's Cochrane Database of Systematic Reviews (CDSR);
- The Centre for Reviews and Dissemination Database of Abstracts of Reviews of Effects (DARE);
- The Campbell Collaboration Library of Systematic Reviews;
- The Evidence for Policy and Practice Information and Co-ordinating Centre (EPPI-Centre) Database of Promoting Health Effectiveness Reviews (DoPHER);
- The Joanna Briggs Institute (JBI) Database of Systematic Reviews and Implementation Reports.

#### *Other electronic databases*

- Medical Literature Analysis and Retrieval System Online (MEDLINE) (Ovid);
- Excerpta Medica Database (EMBASE) (Ovid);
- Cumulative Index to Nursing and Allied Health Literature (CINAHL) (EBSCO);
- PsychINFO (Ovid);
- BIOSIS Previews (Web of Science);
- Social Science Citation Index (SSCI) (Web of Science Core Collection)
- Conference Proceedings Citation Index (CPCI-SSH) (Web of Science Core Collection)
- Sociological Abstracts (CSA) (Proquest)
- Education Resources Information Center (ERIC): Proquest
- Population Information Online (POPLINE);
- Australian Indigenous HealthInfoNet;
- Australian Institute of Family Studies (AIFS) Library
- System for Information on Grey Literature in Europe (OpenSIGLE).

A broad search strategy was used to search the CDSR, and was adapted as appropriate for each database, with the addition of search terms relating to the infant, and the use of a systematic review filter where relevant. (See 'Differences between protocol and review')

Search terms and detailed search strategies are included in the Technical Report.

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<sup>4</sup>Such as where a Cochrane systematic review did not identify, and thus did not include, any completed RCTs

## Searching other resources

The reference lists of articles identified through database searches were examined for further relevant studies.

## Data collection and analysis

### Selection of reviews

The inclusion of studies identified through the literature search was based on whether or not the pre-specified elements of the PICO (Participant/Population; Intervention; Comparison/Control; Outcomes) criteria were met. For the overview, all citations identified in the literature searches were assessed independently by two reviewers based on information in the publication title and, where available, the abstract. Relevant publications were retrieved and reviewed in full text before a final decision was made on their inclusion or exclusion. Disagreements were resolved by discussion to reach consensus, or by involving a third reviewer.

Consistent with the PICO criteria, the following a priori exclusion criteria were applied to the citations retrieved through the literature search:

- Duplicate citation;
- Wrong study design or publication type. (For the overview, studies that were not systematic reviews were excluded). Studies were excluded if they were not reported in full (e.g. research or systematic review protocols, conference proceedings, articles published in abstract form);
- Wrong participants;
- Wrong intervention;
- Wrong outcomes. Studies that did not include outcomes relevant to the research question were excluded;
- Study not published in the English language.

### Data extraction and management

We developed and piloted a data extraction form to summarise the key characteristics of the reviews for the overview, including:

- Bibliographic information;
- Review/study characteristics – objective, research method, setting;
- Participant characteristics;
- Intervention and comparison characteristics;
- Outcomes assessed and review/study results/findings;
- Results of the quality appraisal of the review/study.

Two reviewers independently extracted data for the included studies. Differences were resolved by discussion to reach consensus, or by discussion with a third reviewer.

## Assessment of methodological quality of included reviews

### Quality of included reviews

We assessed the quality of the included systematic reviews for the overview, using the AMSTAR instrument (Shea et al 2009) and the new ROBIS tool (Whiting et al 2015). Both tools were used as they take a different approach to assessing review quality, AMSTAR has some limitations when applied to overviews of systematic reviews (as it was developed as a tool to assess the quality of systematic reviews of primary studies), and ROBIS is a newer tool that may overcome some of the limitations of AMSTAR.

AMSTAR assesses the degree to which review methods avoided bias by evaluating the methods against 11 distinct criteria; including:

- Use of an 'a priori' design;
- Duplicate study selection and data extraction;
- Comprehensive searching of the literature;
- Use of publication status as an exclusion criterion;
- Provision of a list of (included and excluded) studies;
- Provision of characteristics of included studies;
- Assessment of methodological quality of included studies;
- Appropriate use of quality of included studies in formulating conclusions;
- Appropriate methods for combining results of studies;
- Assessment of publication bias;
- Conflict of interest (both review and included studies) stated.

Each AMSTAR item was rated as yes (clearly done), no (clearly not done), can't answer, or not applicable, based on the published review (Shea et al 2009). A review that adequately met all of the 11 criteria was considered to be a review of the highest quality. Quality ratings were as follows: 8+: high quality; 4-7: moderate quality; 3 or lower: low quality.

We also piloted Phases 2 and 3 of the ROBIS tool, a new tool to assess the risk of bias in systematic reviews (Whiting et al 2015). This tool was developed to benefit those involved in systematic reviews, in particular, agencies/organisations involved in guideline development and critical appraisal of systematic reviews. ROBIS aims to allow researchers (involved in guideline development) to assess the risk of bias in systematic reviews which can then be taken into consideration when making recommendations. Phase 2 of the tool considers four key domains:

- Study eligibility criteria;
- Identification and selection of studies;
- Data collection and study appraisal;
- Synthesis and findings.

A series of questions within each of the four domains (with answers 'Yes', 'Probably Yes', 'Probably No', 'No', and 'No Information') elicit information about possible limitations of the systematic review, leading to a judgement about the concerns within that domain (Low, High, or Unclear). In Phase 3, the risk of bias of the review as a whole is considered, with signalling questions and information to support overall judgement of risk of bias (Low, High, or Unclear) (Whiting et al 2015).

The key differences between AMSTAR and ROBIS are that ROBIS uses signalling questions across four domains to pinpoint key issues within a systematic review, which facilitates an overall assessment of that review, whereas AMSTAR uses a component approach (of 11 criteria). Thus, ROBIS requires a judgement of low, high or unclear risk of bias (in line with the Cochrane Collaboration's risk of bias

tool for individual RCTs) whereas AMSTAR requires an assessor to give a score out of 11 (with a score of eight and above representing high quality).

Two reviewers independently assessed review quality. Differences were resolved by discussion to reach consensus.

### **Quality of included studies within reviews**

We did not reassess the quality of included studies within reviews but instead reported study quality according to the review authors' assessment and reporting. We collected this information during the data extraction process. We used ratings of study quality in the synthesis and interpretation of results; for example, to downplay the certainty of conclusions and ratings of effectiveness where studies were all of poor methodological quality or had serious methodological shortcomings that may have predisposed the review's results to bias.

### **Quality of evidence in included reviews**

The quality of the evidence in the included systematic reviews was assessed and has been reported using the GRADE system (Guyatt 2008). The GRADE system assesses the following features for the evidence found:

- Study limitations (risk of bias): internal validity of the evidence.
- Inconsistency: heterogeneity or variability in the estimates of effect across studies.
- Indirectness: the degree of differences between population, intervention, comparator, for the intervention and outcome of interest.
- Imprecision (random error): extent to which confidence in the effect estimate is adequate to support a particular decision.
- Publication bias: degree of selective publication of studies.

The GRADE system rates the quality of the evidence as:

- High (further research is very unlikely to change confidence in the estimate of effect).
- Moderate (further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate).
- Low (further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate).
- Very low (any estimate of effect is very uncertain).

The five features above were used to determine the quality of the evidence for pooled results from the included systematic reviews (see 'Differences between protocol and review'). The evidence was downgraded from 'high quality' by one level for serious limitations, or by two levels for very serious limitations, depending on the assessments for risk of bias, indirectness of evidence, inconsistency, imprecision of effect estimates and potential publication bias.

The below system was used to determine the quality of the evidence where one or more of the five features were not able to be assessed due to information not being reported in the systematic reviews (see 'Differences between protocol and review'):

- Where information regarding one feature was not reported, the overall quality of the evidence was presented as a range, including the quality determined with the information available, and one quality level lower (e.g. an outcome with no limitations identified across four features, but no information available to assess the fifth feature was judged to be 'high to moderate quality evidence').

- Where the risk of bias domain was not reported, it was assumed to not require downgrading unless there was some indication of lower study quality, such as inclusion of qRCTs. The overall quality of evidence was determined with the information available, with 'assumed' in brackets;
- Where the inconsistency domain was not reported, it was assumed to not require downgrading unless there was some indication of substantial heterogeneity, such as wide confidence intervals. The overall quality of evidence was determined with the information available, with 'assumed' in brackets;
- Where information regarding two features was not reported, the overall quality of the evidence was judged to be 'unclear'.

We used the GRADE system to assess the quality of evidence for all outcome measures regarded as 'critical' or 'important' for decision making by the MHPWC. The MHPWC made a preliminary assessment of the importance of outcome domains prior to the completion of the overview. At this time, all outcome domains were rated as 'critical', with the exception of two domains: parent/caregiver views of the intervention and systems outcomes, which were rated as 'important' but not critical for decision making. As per the GRADE process, after reviewing all individual outcomes revealed in the overview, the MHPWC reassessed and made a final decision about the relative importance of each individual outcome within the outcome domains as part of the recommendation formulation process.

### **Data synthesis**

The results of the overview are presented in this Evidence Evaluation Report and a separate Technical Report. The Evidence Evaluation Report includes Evidence Summaries, Evidence Profiles (presenting the quality of the evidence using the GRADE system (Guyatt 2008), and the importance of each individual outcome as judged by the MHPWC), and Evidence Statements. The Technical Report includes Evidence Tables containing details of each included systematic review.

## **Methods for the qualitative analysis (Question Two)**

The methodologies for the qualitative analysis were revised once the overview was complete and were approved by the Office of the NHMRC on 9 September 2015.

### **Criteria for considering intervention/population categories for inclusion**

Question Two focused only on exploring the characteristics of interventions/programs/messages for caregiving practices or behaviours found to optimise infant social and emotional development in the overview.

'Effective' intervention/population categories were defined as:

- Those shown to lead to an improvement in at least one of the pre-specified primary and/or secondary outcome domains; and
- Only where a benefit was observed for one or more outcomes where the GRADE system was used to assess the quality of the evidence in the overview; excluding those categories where benefit was observed for only one outcome and this evidence was judged to be very low quality, using the GRADE system.

## Data collection and analysis

### Data extraction and management

For the 'effective' intervention/population categories, as defined above, we extracted information from the included systematic reviews [which contributed pooled results] on:

- **Who** could deliver the intervention, program or messages;
- **Where** the intervention, program or messages could be delivered;
- **When** the intervention, program or messages could be delivered;
- **To whom** the intervention, program or messages could be delivered/directed;
- **How** the intervention, program or messages could be framed;
- **How** the intervention, program or messages could be delivered;
- What could **impede** or interfere with engagement with the intervention or program, or messages being enacted upon (i.e. barriers to maximising reach and uptake);
- What could **facilitate** or drive engagement with the intervention or program, or messages being enacted upon (i.e. enablers to maximising reach and uptake).

Wherever possible, we extracted the results of reported subgroup analyses related to the pooled results from the included reviews (such as from Cochrane systematic reviews), reported moderator effects (such as from linear regression analyses) relating to the pooled results from the included reviews, or the narrative summaries or judgements (regarding the 'who', 'where', 'when', 'to who,' and 'how') made by the authors of the included systematic reviews.

One reviewer extracted data for the included reviews, and this was checked by a second reviewer.

### Data synthesis

The findings related to Question Two have been incorporated into the Evidence Evaluation Report and Technical Report. The data extracted from the included reviews for Question Two has been incorporated into the Evidence Tables (in the Technical Report), and for each 'effective' intervention/population category, the main findings from the qualitative analysis have been summarised and presented beneath each relevant Evidence Profile (in the Evidence Evaluation Report) in a narrative summary 'Characteristics that may have contributed to the effectiveness of [intervention/population category] for optimal social and emotional development of infants.'



## Results

### Description of included reviews in the overview (Question One)

Through the database searching, a total of 8,057 citations were identified using the search strategies described in the Technical Report. An additional 38 citations were identified through reference screening. Assessment of the 8,095 titles and abstracts resulted in 532 potentially relevant articles and the exclusion of 7,563 citations.

Of the 532 citations that were reviewed in full-text, 276 were excluded as they did not fulfil the initial inclusion criteria. When we applied the criteria for review prioritisation, 205 reviews were identified as relevant, but were not included in the overview for reasons outlined in the Technical Report ('Relevant but excluded reviews').

We have included 51 systematic reviews in the overview. See Table 1 for a summary of citations retrieved.

**Table 1: Summary of citations retrieved in searches for overview of systematic reviews**

| STAGE   | N CITATIONS  |
|---|--------------|
| <b>Total number of citations identified</b>                 | <b>8,095</b> |
| Citations excluded after title/abstract review              | 7,563        |
| <b>Number of citations reviewed in full-text</b>            | <b>532</b>   |
| Studies excluded after full-text review                     | 276          |
| Reviews identified as relevant but not included in overview | 205          |
| <b>Final number of included reviews</b>                     | <b>51</b>    |

**Abbreviations:** N: number

Common reasons for not prioritising the 205 'relevant but excluded reviews' were: no included studies in populations of infants from birth to one year of age at study commencement/intervention onset; unclear ages of children in the included studies at intervention onset; results limited to parent/caregiver psychosocial wellbeing or parent/caregiver knowledge, practices and behaviours outcome domains; a more comprehensive review was available. We believe that this approach has preserved the intent and stated aims of the overview and that little of relevance has been omitted.

The 51 included systematic reviews contained a total of 1,067 relevant eligible studies and more than 262,859 participants meeting our inclusion criteria. Most studies (more than 801: approximately 80%) were RCTs<sup>5</sup>, the remainder being a diverse mix of experimental and quasi-experimental studies.

The 51 included reviews either focussed on a type of intervention (14 interventions; 30 reviews) or they targeted a particular population (seven population groups; 22 reviews). One review (Yoshikawa 1995) was included in two intervention groupings (day care interventions and interventions for preventing later antisocial behaviour and delinquency). In the vast majority of included reviews (and studies within those reviews) participants were predominately mothers. Only a minority of reviews/studies included fathers as participants, however one review focused specifically on interventions with fathers of infants (see 'Interventions for fathers' below).

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<sup>5</sup>Definitions of RCT differed between reviews (and studies) e.g. in some instances, qRCTs were treated as RCTs

Measurement of infant social and emotional wellbeing is an emerging field and there is no clear consensus about what constitutes an acceptable measure of this outcome. Furthermore, interventions within the first year of an infant's life have typically focused on survival and physical wellbeing, rather than on development and wellbeing. Infant social and emotional wellbeing outcomes are often from parent reports and rarely from direct measurements or observations of the infant.

The direct measure of the overview's primary outcome, 'infant social and emotional wellbeing or development up to one year of age', was very rarely reported in the included systematic reviews, however the evaluation included other outcomes from the outcome domains pre-specified by the MHPWC. It is the MHPWC's expert opinion that these outcomes are likely to influence and/or to have a flow-on effect to the primary outcome.

In order to be included in the overview, each outcome reported in the included review needed to be considered by the evidence reviewers as an appropriate measure within the primary or secondary outcome domains. Unless this was the case, outcomes from the included reviews were not reported in the overview. In almost all cases, individual outcomes were reported by only one systematic review.

Matching of specific outcomes reported in the included reviews to the pre-specified outcome domains was mostly done through a process of logic, for example, with measures of cognitive and physical development clearly corresponding to the 'development for the infant, as a child, and up to 18 years' outcome domain. In other cases we were guided by the relevant systematic reviews. For example, Elkan 2000 described the HOME Inventory as measuring aspects of stimulation, which was interpreted as assessing parent-infant interaction. Other included reviews extended this to include parenting quality, as well as parent-infant interaction.

**Table 2: Intervention categories of included reviews**

| CATEGORY   | N REVIEWS (POOLED RESULTS) | REVIEWS   |
|--|----------------------------|---|
| <b>INTERVENTION FOCUS</b>  |                            |   |
| 1. Home visiting interventions   | 5 (3)                      | Elkan 2000*; Peacock 2013; Wade 1999; Reynolds 2009*; Segal 2012^     |
| 2. Antenatal and postnatal education and/or support interventions          | 4 (2)                      | Bryanton 2013*; Gagnon 2007; Pinquart 2010*; Shaw 2006                |
| 3. Kangaroo care interventions   | 2 (1)                      | Conde-Agudelo 2014*; Dodd 2005  |
| 4. Massage interventions   | 1 (1)                      | Bennett 2013*   |
| 5. Interventions for preventing postnatal depression                       | 1 (1)                      | Dennis 2013*  |
| 6. Interventions for treating maternal depression in the perinatal period  | 2 (1)                      | Bee 2014*; Poobalan 2007  |
| 7. NBAS-based interventions  | 1 (1)                      | Das Eiden 1996*   |
| 8. Interventions for enhancing sensitivity and/or attachment security      | 3 (2)                      | Bakermans-Kranenburg 2003*; Bakermans-Kranenburg 2005*; Doughty 2007  |
| 9. Interventions for preventing later antisocial behaviour and delinquency | 3 (2)                      | Bernazzani 2001; Piquero 2008*; Yoshikawa 1995^                       |
| 10. Day care interventions   | 2 (2)                      | Yoshikawa 1995^; Zoritch 2000*  |
| 11. Skin-to-skin care intervention   | 1 (1)                      | Moore 2012*   |
| 12. Behavioural sleep interventions  | 1 (0)                      | Douglas 2013  |
| 13. Anticipatory guidance interventions                                    | 2 (0)                      | Piotrowski 2009; Regalado 2001  |
| 14. Interventions for promoting effective parenting                        | 2 (2)                      | Gardner 2006^; Mercer 2006^   |
| <b>POPULATION FOCUS</b>  |                            |   |
| 15. Interventions for parents of infants at risk of developmental delays   | 3 (2)                      | Kemp 2013; Kong 2013^; Wallace 2010*                                  |
| 16. Interventions for parents of preterm and low birthweight infants       | 5 (4)                      | Brett 2011; Evans 2014*; Goyal 2013*; Spittle 2012*; Vanderveen 2009* |
| 17. Interventions for teenage parents                                      | 2 (1)                      | Barlow 2011*; Coren 2003  |
| 18. Interventions for parents from low and middle income countries         | 4 (1)                      | Grantham-McGregor 2014; Knerr 2013; Mejia 2012; Rahman 2013*          |
| 19. Interventions for low-income or socially disadvantaged parents         | 3 (3)                      | Maulik 2009^; Miller 2011^; Mortensen 2014*                           |
| 20. Interventions for parents with alcohol or drug problems                | 4 (3)                      | Bowie 2005^; Niccols 2012; Suchman 2006^; Turnbull 2012*              |
| 21. Interventions for fathers  | 1 (0)                      | Magill-Evans 2006   |

\*Reviews contributing quantitatively pooled results for which the quality of this pooled evidence was assessed using the GRADE system

^Results contributing only narratively pooled results for which the quality of this evidence was not assessed using the GRADE system

**Abbreviations:** N: number; NBAS: Neonatal Behavioral Assessment Scale

## Methodological quality of included reviews

### Quality of included reviews

Of the 51 reviews, we rated 14 (27%) to be high quality on the AMSTAR tool and at low risk of bias on the ROBIS tool (overall 'low risk of bias'). We rated 17 (33%) as being low quality and at high risk of bias (overall 'high risk of bias') using the AMSTAR and ROBIS tools respectively. The remaining 20 (39%) were rated as moderate quality using AMSTAR, and high/low or unclear risk of bias using ROBIS (overall 'intermediate risk of bias') – see Table 3.

Of the 11 Cochrane reviews included in this overview, 10 received a high quality and low risk of bias rating on both tools. The eleventh review was rated as being of moderate quality using AMSTAR and of high risk of bias using ROBIS.

While there were some small discrepancies in ratings in the intermediate category, no review rating was diametrically opposed i.e. low risk of bias using the ROBIS tool and low quality using the AMSTAR tool. With a discrepant rating for reviews of low risk of bias using ROBIS and moderate quality using AMSTAR, common limitations of the reviews identified by AMSTAR were failure to report on duplicate data extraction, publication bias and conflicts of interest. With reviews rated as high risk of bias using ROBIS and moderate quality using AMSTAR, review limitations identified by ROBIS were that only narrative results were presented, concerns about synthesis serious enough to give a high risk of bias rating and failing to interpret results in light of methodological concerns. When a review was rated as being of unclear risk of bias using ROBIS and moderate quality using AMSTAR, the main reasons for lack of clarity were incomplete reporting by the reviews being assessed.

Reviews rated 'low quality' (AMSTAR score three or lower), generally received scores only for:

- 'a priori' designs;
- comprehensive searching of the literature; and/or
- provision of characteristics of included studies;

with concerns common across the other eight AMSTAR criteria.

Reasons for reviews being rated 'high risk of bias' (using ROBIS) related commonly to concerns regarding:

- methods used to identify and/or select studies, and to collect data and appraise studies, particularly: concerns related to range of databases/additional sources searched;
- limited/no efforts made to minimise error in selection of studies, and data collection; and/or
- limited/no efforts made to assess risk of bias (or methodological quality).

See Technical Report for full details of quality assessment for each review.

**Table 3: Review quality assessed by ROBIS and AMSTAR**

| OVERALL QUALITY RATINGS   | N REVIEWS (POOLED RESULTS) | REVIEWS   |
|---------------------------|----------------------------|---|
| Low risk of bias (RL/AH)  | 14 (12)                    | Barlow 2011*; Bee 2014; Bennett 2013*; Bryanton 2013*; Conde-Agudelo 2014*; Dennis 2013*; Elkan 2000; Gagnon 2007*; Miller 2011*; Moore 2013*; Spittle 2012*; Turnbull 2012*; Vanderveen 2009; Wade 1999  |
| High risk of bias (RH/AL) | 17 (10)                    | Bakermans-Kranenburg 2005; Bowie 2005; Das Eiden 1996; Dodd 2005; Douglas 2013; Gardner 2006; Grantham-McGregor 2014; Kemp 2014; Kong 2013; Mejia 2012; Mercer 2006; Pinguart 2010; Piotrowski 2009; Regalado 2001; Reynolds 2009; Suchman 2006; Yoshikawa 1995 |
| Intermediate risk of bias | 20 (10)                    |   |
| • RL/AM                   | 8 (3)                      | Brett 2011; Coren 2003; Evans 2014; Goyal 2013; Niccols 2012; Peacock 2013; Segal 2012; Shaw 2006   |
| • RH/AM                   | 8 (5)                      | Bakermans-Kranenburg 2003; Bernazzani 2001; Doughty 2007; Magill-Evans 2006; Maulik 2009; Mortensen 2014; Wallace 2010; Zoritch 2000*   |
| • RU/AM                   | 4 (2)                      | Knerr 2013; Piquero 2008; Poobalan 2007; Rahman 2013  |

\*Cochrane review

**Abbreviations:** N: number; RL/AH: ROBIS: low risk of bias and AMSTAR: high quality; RH/AL: ROBIS: high risk of bias and AMSTAR: low quality; RL/AM: ROBIS: low risk of bias and AMSTAR: moderate quality; RH/AM: ROBIS: high risk of bias and AMSTAR: moderate quality; RU/AM: ROBIS: unclear risk of bias and AMSTAR: moderate quality

Of the 51 reviews, 32 (63%) were able to contribute pooled results to this overview. Of these 32 reviews, 23 (72%) provided results of formal quantitative methods for pooling (mostly meta-analysis). Some review authors did not give a clear reason for not pooling results, though many reported a conscious decision not to, as they perceived the data as being too heterogeneous. While primary studies whose results were not pooled, but which reported evidence of effectiveness have been excluded from the Evidence Evaluation Report, we believe that only including pooled results has had minimal impact on the findings of the overview. Inclusion of results from single studies would have introduced a lot of 'noise' from underpowered and often poorly reported studies.

### Quality of the evidence in included reviews

As noted above, approximately two-thirds of the 51 reviews were able to provide some form of pooled results and the quality of this pooled evidence was assessed using the GRADE system (Guyatt 2008). As shown in Table 4, there was large variability in the quality of the evidence, reflecting the range of confidence able to be placed in the results (Guyatt 2008). The major limitations in the body of evidence related to the systematic reviews failing to report risk of bias of included studies at all and/or not reporting risk of bias for studies included for a particular outcome. High statistical heterogeneity and small numbers of studies and/or sample sizes were other reasons for downgrading the evidence. In 39 instances, qualitative pooling was reported (e.g. how many studies showed significant results). We included these results in the Evidence Profiles but did not assess the quality of the evidence or formulate evidence statements for these outcomes.

**Table 4: Outcome domains by intervention/population categories, with quality of the evidence (GRADE)**

| <b>OUTCOME DOMAIN</b>   | <b>CATEGORY</b>   | <b>QUALITY OF EVIDENCE*</b>    |
|---|---|--------------------------------|
| <b>Infant social and emotional wellbeing or development up to one year of age</b>   | Home visiting interventions   | Moderate to low                |
|   | Massage interventions   | Low to very low                |
|   | Interventions for treating maternal depression in the perinatal period  | Low                            |
| <b>Development for the infant, as a child, and up to 18 years</b>                   | Home visiting interventions   | Low                            |
|   | Antenatal and postnatal education and/or support interventions          | High, moderate                 |
|   | Kangaroo care interventions   | High, moderate, low            |
|   | Massage interventions   | Low, very low                  |
|   | Day care interventions  | Very low                       |
|   | Skin-to-skin care intervention  | Moderate                       |
|   | Interventions for parents of infants at risk of developmental delays    | Low, very low                  |
|   | Interventions for parents of preterm and low birthweight infants        | Moderate, low, very low        |
|   | Interventions for parents from low and middle income countries          | Unclear                        |
| <b>Behaviour for the infant, as a child, and up to 18 years</b>                     | Home visiting interventions   | Moderate                       |
|   | Antenatal and postnatal education and/or support interventions          | Moderate, low, very low        |
|   | Massage interventions   | Low, very low                  |
|   | Interventions for preventing later antisocial behaviour and delinquency | Moderate                       |
| <b>Physical wellbeing and safety for the infant, as a child, and up to 18 years</b> | Home visiting interventions   | Moderate, low, very low        |
|   | Kangaroo care interventions   | High, moderate, low            |
|   | Interventions for parents with alcohol or drug problems                 | Low                            |
| <b>Parent-infant relationship</b>   | Home visiting interventions   | Moderate to low                |
|   | Antenatal and postnatal education and/or support interventions          | Moderate                       |
|   | Massage interventions   | Low, very low                  |
|   | Interventions for preventing postnatal depression                       | Moderate                       |
|   | Interventions for treating maternal depression in the perinatal period  | Low                            |
|   | NBAS-based interventions  | Low                            |
|   | Interventions for enhancing sensitivity and/or attachment security      | High, moderate,                |
|   | Interventions for parents of preterm and low birthweight infants        | Very low                       |
|   | Interventions for teenage parents                                       | Low, very low                  |
|   | Interventions for parents from low and middle income countries          | Unclear                        |
|   | Interventions for low-income or socially disadvantaged parents          | Low                            |
| <b>Parent/caregiver psychosocial wellbeing</b>                                      | Antenatal and postnatal education and/or support interventions          | High, moderate                 |
|   | Massage interventions   | Very low                       |
|   | Interventions for preventing postnatal depression                       | High, moderate, low            |
|   | Interventions for treating maternal depression in the perinatal period  | Low, very low                  |
|   | Interventions for parents from low and middle income countries          | Moderate to low, unclear       |
| <b>Parent/caregiver knowledge, practices and behaviours</b>                         | Home visiting interventions   | Moderate, moderate to low, low |
|   | Antenatal and postnatal education and/or support interventions          | Moderate, low                  |

|   |  |                     |
|---|--|---------------------|
|   | Kangaroo care interventions                                    | High, moderate, low |
|   | Skin-to-skin care interventions                                | Low, very low       |
|   | Interventions for teenage parents                              | Low, very low       |
|   | Interventions for parents with alcohol or drug problems        | Low, very low       |
| <b>Parent/caregiver views of the intervention</b> | Interventions for preventing postnatal depression              | Very low            |
| <b>Family relationships</b>                       | Antenatal and postnatal education and/or support interventions | High                |
|   | Interventions for preventing postnatal depression              | Moderate            |
| <b>Systems outcomes</b>                           | Home visiting interventions                                    | Very low            |
|   | Antenatal and postnatal education and/or support interventions | High, moderate      |
|   | Interventions for parents with alcohol or drug problems        | Very low            |

\*Assessed using the GRADE system

**Abbreviations:** GRADE: Grading of Recommendations, Assessment, Development and Evaluation; NBAS: Neonatal Behavioral Assessment Scale

No reviews reported evidence eligible for upgrading (Guyatt 2011), so we have not shown the three upgrading components (large magnitude of effect, dose-response gradient and increased confidence in effect estimates due to plausible confounders) in the following Evidence Profiles (Tables 5-25).

## Description of included reviews in the qualitative analysis (Question Two)

Applying the criteria outlined in the Methods for the qualitative analysis, 14 intervention ‘categories’ of the total of 21 categories were identified as leading to improved social and emotional development of the infant, the child and later on as the adolescent:

- Based on intervention types (N=9): home visiting interventions; antenatal and postnatal education and/or support interventions; kangaroo care interventions; massage interventions; interventions for preventing postnatal depression; interventions for treating maternal depression in the perinatal period; NBAS-based interventions; interventions for enhancing sensitivity and/or attachment security; and interventions for preventing later antisocial behaviour and delinquency; and
- Based on population groups (N=5): interventions for parents of infants at risk of developmental delays; interventions for parents of preterm and low birthweight infants; interventions for teenage parents; interventions for parents from low and middle income countries; and interventions for low income/socially disadvantaged parents.

When the criteria were applied, there was insufficient evidence available to determine effectiveness for seven intervention/population categories, due to improvements observed for only one outcome where we were able to use the GRADE system (and this outcome being assessed as very low quality evidence) (N=2: day care interventions; skin-to-skin care interventions), no clear differences seen for pooled outcomes (N=1: interventions for parents with alcohol or drug problems), or no pooled numerical results available (N=4: behavioural sleep interventions; anticipatory guidance interventions; interventions for promoting effective parenting; interventions for fathers).

## Effects of interventions

### Home visiting interventions

#### Description of intervention based on the included evidence

There was considerable variety in the interventions provided through home visiting. Of the five systematic reviews included in this category only three presented pooled results (Elkan 2000; Reynolds 2009; Segal 2012). In the included systematic reviews with pooled numerical results, most home visiting interventions were delivered face-to-face in the home, with a few including parenting group meetings/education classes or the provision of health services (Elkan 2000; Reynolds 2009). Many involved education and counselling for parents about child development; others covered goal setting and anticipatory guidance (although there was no overlap with studies included in the Anticipatory Guidance category). There were also interventions addressing parent-child relationships and interactions and provision of emotional and practical support for parents. Most visits were made across the antenatal and postnatal period, or the postnatal period alone and were delivered to high risk populations, with the risk located in the child (e.g. due to prematurity or sleep problems) or mother (e.g. due to low socioeconomic status, being first time mothers) (Elkan 2000).

#### Evidence summary

Five systematic reviews assessed home visiting interventions (Elkan 2000; Peacock 2013; Reynolds 2009; Segal 2012; Wade 1999). Elkan 2000 and Wade 1999 searched for studies published between 1966 and 1997 or 1998; Peacock 2013 searched for studies published between 1990 and 2012; Reynolds 2009 did not report the review search dates, however only included studies published between 1990 and 2007; and Segal 2012 did not report the review search dates.

The inclusion criteria for the reviews differed, and were as follows:

- Elkan 2000: studies evaluating a home visiting program, with at least one postnatal home visit, with a comparison group, reporting outcomes of relevance to the objectives of British health visitors (increasing rates of uptake of appropriate health and community services; reducing rates of child abuse and unintentional injury in childhood; changing attitudes and beliefs; changing behaviours; improving client satisfaction), with intervention by personnel who undertook responsibilities within the remit of British health visitors and were not members of a professional group other than health visiting (e.g. community psychiatric nursing, midwifery).<sup>6</sup>
- Peacock 2013: studies published in English in or after 1990, involving an evaluation of a home visiting program delivered by paraprofessionals (with credentials not including clinical training, e.g. developmental psychologists, and not licensed), involving mothers and/or children from zero to six years, from socially high-risk families, reporting on birth, perinatal, development, health and/or risk for occurrences of child abuse/neglect, with a control group, pre-test/post-test design, or quasi-experimental design.
- Reynolds 2009<sup>7</sup>: studies with an intervention and control group, assessing programs with an aim of primary prevention of maltreatment, published/reported from 1990 to 2007, implemented when children were under the age of five, measuring the outcomes of abuse or neglect primarily by substantiated reports of maltreatment (with adequate information about the outcomes e.g. the outcome metric reported for program groups), which included coverage of program design, content and implementation quality.

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<sup>6</sup>Elkan 2000 included studies assessing home visiting for parents and young children, as well as for elderly people and their carers; only results from relevant studies are included in this Overview

<sup>7</sup>The majority of included studies in Reynolds 2009 involved home visiting



- Segal 2012: studies with a RCT or quasi-experimental design, of home visiting (of at least two visits by someone other than a relative), with visits commencing during pregnancy or within six months of birth, for the purpose of reducing the risk of child maltreatment or a related outcome, with at least one quantifiable outcome related to maltreatment, or the risk of maltreatment.
- Wade 1999: prospective primary studies, with a comparison group or an established qualitative methodology, evaluating an intervention to support parents of zero to six year old children in promoting child health or development, with intervention by peers or paraprofessionals (excluding nurses, social workers, nutritionists, dieticians, physicians, physiotherapists, teachers, early childhood educators, child development specialists (and United Kingdom or Norwegian ‘health visitors’)), with information on parent and/or child health or developmental outcomes or costs.

Together, these five reviews included 152 relevant studies<sup>8</sup> (including 112 RCTs, one quasi-experimental study, nine CCTs, three cohort study and 26 nRCTs (designs not specified), and one ‘matched group’ design) with a total of more than 27,739 participants<sup>9</sup> in four reviews (and not clearly reported in one review (Segal 2012)) (ranging from 30 to 2,009 in the included studies), published between 1972 and 2011 (Elkan 2000; Peacock 2013; Reynolds 2008; Segal 2012; Wade 1999).

The frequency and duration of home visiting interventions in the included studies across the five reviews varied as follows:

- Elkan 2000: interventions ranged from one visit only, to one weekly visit, for the first three years of life.
- Peacock 2013: interventions varied from weekly to monthly visits, and ranged in duration from six months to three to five years.
- Reynolds: interventions ranged from three to 60 months or more duration (most commonly: 12 to 24 months, commencing within the first week after birth with 15 to 20 visits in total).
- Segal 2012: intervention visits ranged from two to 41, with child age at end of the interventions ranging from one month to five years; Wade 1999: interventions ranged from weekly to monthly visits, and from three months to five years duration.

Four of the reviews were judged to be at low risk of bias (Elkan 2000; Peacock 2013; Segal 2012; Wade 1999), and one review was judged to be at high risk of bias (Reynolds 2009) using ROBIS; two of the reviews were judged to be ‘high’ quality (Elkan 2000; Wade 1999), two reviews were judged to be ‘moderate’ quality (Peacock 2013; Segal 2012), and one review was judged to be ‘low’ quality (Reynolds 2009) using AMSTAR.

Three of the five included systematic reviews provided pooled results:

- Elkan 2000 (low risk of bias; ‘high’ quality) included 50 relevant studies (38 RCTs, 12 nRCTs) with a total of more than 11,851 participants (ranging from 30 to 2,009 in the included studies), published between 1972 and 1996.
- Reynolds 2009 (high risk of bias; ‘low’ quality) included 14 relevant studies (12 RCTs, one quasi-experimental study, one ‘matched group’ design) with a total of 6,407 participants (ranging from 40 to 1,154 in the included studies), published between 1991 and 2007.
- Segal 2012 (low risk of bias; ‘moderate’ quality) included 52 relevant studies (36 RCTs, 14 nRCTs, two cohort studies) with an unclear number of participants, published between 1977 and 2009.

As Segal 2012 did not provide pooled numerical results, we did not assess the quality of the evidence (using the GRADE system) for the outcomes reported by this review.

<sup>8</sup>With some overlap (see Technical Report)

<sup>9</sup>In Elkan 2000, Ns were reported for 49/50 studies; in Wade 1999 Ns were reported for 16/17 studies

For further details regarding the results from single studies from the other two reviews (Peacock 2013; Wade 1999), see the Technical Report.

### ***Primary outcome domain***

#### **Infant social and emotional wellbeing or development up to one year of age**

No clear difference was seen for one outcome, infant temperament (measured using the CITS, with home visiting interventions at four to 16 months (moderate to low quality evidence, downgraded due to high risk of bias, with no information reported to determine inconsistency (Elkan 2000).

### ***Secondary outcomes domains***

#### **Development for the infant, as a child, and up to 18 years**

Improved cognitive development was seen with home visiting interventions in one review; however no clear differences were seen for motor development in the same review (all low quality evidence) (Elkan 2000). Specifically, there were improvements in cognitive development measured using the BSID-MDI scores at nine to 24 months and SB Intelligence Test IQ scores at 12 to 48 months (both outcomes downgraded due to high risk of bias and inconsistency, but no clear differences were observed for motor development measuring using the BSID-PDI scores at nine to 18 months (downgraded due to high risk of bias and imprecision) (Elkan 2000). Children's weight and height up to 48 months also showed no clear improvements with home visiting interventions (both outcomes downgraded due to high risk of bias and imprecision) (Elkan 2000).

#### **Behaviour for the infant, as a child, and up to 18 years**

Fewer sleeping difficulties (reported by mothers) in infants at six to 12 months were seen with home visiting interventions in one review (moderate quality evidence, downgraded due to high risk of bias) (Elkan 2000).

#### **Physical wellbeing and safety for the infant, as a child, and up to 18 years**

Reduced rates of unintentional child injuries up to 48 months were seen with home visiting interventions in one review (moderate quality evidence, downgraded due to risk of bias) (Elkan 2000). There was possibly higher uptake of child immunisation (six months to five years) with home visiting interventions in the same review (low quality evidence, downgraded due to risk of bias and inconsistency), but no clear difference was seen with home visiting interventions for the uptake of other preventative health services (six months to five years) in the same review (very low quality evidence, downgraded due to high risk of bias, inconsistency and imprecision) (Elkan 2000). There were possibly fewer children's hospital admissions (excluding for intentional or unintentional injury) at nine to 46 months with home visiting interventions in one review (low quality evidence, downgraded due to high risk of bias and inconsistency), however no clear differences in use of emergency medical services up to 46 months were seen with home visiting interventions in the same review (moderate quality evidence, downgraded due to high risk of bias) (Elkan 2000).

#### **Parent-infant relationship**

The quality of the home environment (measured using the Home Observation for Measurement of the Environment (HOME) Inventory) was improved at six weeks to 36 months with home visiting interventions in one review (moderate to low quality evidence, downgraded due to high risk of bias, with no information reported to determine inconsistency) (Elkan 2000).

In another review, there was no clear impact of home visiting interventions on the quality of the parenting and interaction (measured using the HOME Inventory) (time of measures not reported)

(quality of the evidence not assessed) (Segal 2012). There were, however, significantly more sensitive parental responses with home visiting interventions (including using the CARE Index) time of measures not reported) (quality of the evidence not assessed) in the same review (Segal 2012).

### **Parent/caregiver psychosocial wellbeing**

There was unclear impact of home visiting interventions on parenting stress (measured using the PSI) from eight weeks to 12 months in one review (quality of the evidence not assessed) (Segal 2012).

### **Parent/caregiver knowledge, practices and behaviours**

There were no clear differences seen for family size (measured as: repeat pregnancy; births two years post-intervention; family size 10 years post-intervention) (one to 10 years post-intervention) and maternal employment (at 12 to 46 months) in one review (moderate to low quality evidence, downgraded due to high risk of bias, with no information reported to determine inconsistency (Elkan 2000). In the same review, there was no clear difference seen for mothers' use/receipt of public assistance (at 12 to 48 months) (low quality evidence, downgraded due to high risk of bias and inconsistency) (Elkan 2000). In this review, home visiting interventions were shown to lead to improvements in breastfeeding at three months of age (moderate quality evidence, downgraded due to high risk of bias (Elkan 2000).

In other review there was no clear impact of home visiting interventions on substance use in one review, where the timing of measures was not reported (quality of the evidence not assessed) (Segal 2012).

### **Parent/caregiver views of the intervention**

No pooled results were available.

### **Family relationships**

No pooled results were available.

### **Systems outcomes**

In one review, there was reduced child maltreatment (measured using reports of substantiated child abuse or neglect) at one to 17 years with home visiting interventions (very low quality evidence, downgraded due to high risk of bias, inconsistency and indirectness) (Reynolds 2009).

### **Potential harms<sup>10</sup>**

In two reviews (Elkan 2000 and Peacock 2013), single study results show significantly poorer outcomes for maternal concern about child behaviour (within the outcome domain of behaviour for the infant, as a child, and up to 18 years), visits to local clinics for sick child care for minor illnesses (within the outcome domain of physical wellbeing and safety for the infant, as a child, and up to 18 years), and child abuse and neglect (within the outcome domain of systems outcomes) with home visiting. However, these results must be interpreted in context and with caution, as other single study results show positive results for the same outcome. For further details regarding potential harms from single studies see the pink shaded rows of the Evidence Tables in the Technical Report.

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<sup>10</sup>In this context, harm refers to a significantly poorer outcome in the intervention group relative to the control group within a pre-specified primary or secondary outcome domain.

**Table 5: Home visiting interventions evidence profile**

| <b>HOME VISITING INTERVENTIONS</b>  |  |  |   |                     |            |
|---|--|--|---|---------------------|------------|
| What is the effectiveness of home visiting interventions for infants in their first year of life for optimal social and emotional development for the infant, and later on as a child and adolescent? |  |  |   |                     |            |
| Comparison  | Usual care   |  |   |                     |            |
| Outcome domain  | Outcome measure used in the review(s)  | Results reported in the review(s) and GRADE  |   |                     | Importance |
|   |  | Result <sup>11,12</sup>  | GRADE   | Quality of evidence |            |
| Infant social and emotional wellbeing or development up to one year of age  | Temperament (CITS <sup>13</sup> ) (4-16 months)  | ES: NR; P (heterogeneity): NR; P (overall): 0.07 (5 RCTs, N=814) (Elkan 2000)  | Risk of bias: -1<br>Inconsistency: NR<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Moderate to low     | IMPORTANT  |
|   | GRADE reasons for downgrading: <b>Risk of bias:</b> studies with methodological limitations; <b>Inconsistency:</b> NR  |  |   |                     |            |
| Development for the infant, as a child, and up to 18 years  | Cognitive development (BSID-MDI) (9-24 months)   | <b>ES: 0.17 (95% CI 0.06, 0.28); P (heterogeneity): &lt; 0.001; P (overall): NR</b> (8 RCTs, N=1,670) (Elkan 2000)                                       | Risk of bias: -1<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Low                 | CRITICAL   |
|   | GRADE reasons for downgrading: <b>Risk of bias:</b> studies with methodological limitations; <b>Inconsistency:</b> substantial heterogeneity ( $P < 0.001$ ) |  |   |                     |            |
|   | Motor development (BSID-PDI) (9-18 months)   | ES: 0.17 (95% CI -0.03, 0.38); P (heterogeneity): 0.09; P (overall): NR (4 RCTs, N=390) (Elkan 2000)   | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Low                 | IMPORTANT  |
|   | GRADE reasons for downgrading: <b>Risk of bias:</b> studies with methodological limitations; <b>Imprecision:</b> studies with small sample sizes             |  |   |                     |            |
|   | Intelligence (SB IQ scores) (12-48 months)   | <b>ES: 0.27 (95% CI 0.12, 0.45); P (heterogeneity): &lt; 0.001; P (overall): NR</b> (5 RCTs, N=870) [1 study in infants > 12 months of age] (Elkan 2000) | Risk of bias: -1<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Low                 | CRITICAL   |
|   | GRADE reasons for downgrading: <b>Risk of bias:</b> studies with methodological limitations; <b>Inconsistency:</b> substantial heterogeneity ( $P < 0.001$ ) |  |   |                     |            |
| Weight (up to 48 months)  | ES: 0.02 (95% CI -0.17, 0.24); P (heterogeneity): 0.63; P (overall): NR (3 RCTs, N=463) [1 study in infants > 12 months of age] (Elkan 2000)                 | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0  | Low   | IMPORTANT           |            |
|   | GRADE reasons for downgrading: <b>Risk of bias:</b> studies with methodological limitations; <b>Imprecision:</b> studies with small sample sizes             |  |   |                     |            |

<sup>11</sup>All Ns reflect the total numbers (i.e. across both the intervention and control groups)

<sup>12</sup>Bolding indicates a statistically significant pooled result in favour of the intervention

<sup>13</sup>Elkan 2000 did not report on which of the nine categories of temperament were measured/reported

|  |   |  |  |          |           |  |
|--|---|--|--|----------|-----------|--|
|  | Height (up to 48 months)  | ES: -0.02 (95% CI -0.24, 0.20); P (heterogeneity): 0.79; P (overall): NR (3 RCTs, N=463) (Elkan 2000)<br><i>[1 study in infants &gt; 12 months of age]</i>   | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0  | Low      | IMPORTANT |  |
| <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Imprecision: studies with small sample sizes</i>  |   |  |  |          |           |  |
| <b>Behaviour for the infant, as a child, and up to 18 years</b>  | Sleeping difficulties (reported by mothers) (at 6-12 months)  | <b>OR: 0.48 (95% CI 0.30, 0.76); P (heterogeneity): 0.89; P (overall): NR</b> (4 RCTs, N=763) <i>[1 study in infants &gt; 12 months of age]</i> (Elkan 2000) | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0   | Moderate | CRITICAL  |  |
| <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations</i>  |   |  |  |          |           |  |
| <b>Physical wellbeing and safety for the infant, as a child, and up to 18 years</b>  | Unintentional injuries (up to 48 months)  | <b>OR: 0.74 (95% CI 0.57, 0.95); P (heterogeneity): 0.31; P (overall): NR</b> (6 RCTs, N=1,836) (Elkan 2000)   | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0   | Moderate | CRITICAL  |  |
|  | <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations</i>   |  |  |          |           |  |
|  | Uptake of immunisation (6 months to 5 years)  | <b>OR: 1.40 (95% CI 1.16, 1.68); P (heterogeneity): 0.005; P (overall): NR</b> (8 RCTs, 1 nRCT, N=2,518) (Elkan 2000)  | Risk of bias: -1<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | Low      | CRITICAL  |  |
|  | <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Inconsistency: substantial heterogeneity (P &lt; 0.005), findings lose significance under a random effects model</i> |  |  |          |           |  |
|  | Uptake of preventive health services (other than immunisation) (6 months to 5 years)  | OR: 1.18 (95% CI 0.69, 2.02); P (heterogeneity): 0.02; P (overall): NR (3 RCTs, N=425) (Elkan 2000)  | Risk of bias: -1<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Very low | IMPORTANT |  |
| <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Inconsistency: substantial heterogeneity (P &lt; 0.02); Imprecision: studies with small sample sizes; wide CIs</i>  |   |  |  |          |           |  |
|  | Uptake of acute care health services: hospital admission (excluding intentional or unintentional injury) (9-46 months)  | <b>OR: 0.73 (95% CI 0.55, 0.98); P (heterogeneity): 0.005; P (overall): NR</b> (4 RCTs, 3 nRCTs, N=2,897) (Elkan 2000)                                       | Risk of bias: -1<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | Low      | CRITICAL  |  |
| <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Inconsistency: substantial heterogeneity (P &lt; 0.005), findings lose significance with a random effects model</i> |   |  |  |          |           |  |

|  |  |  |   |                 |           |
|--|--|--|---|-----------------|-----------|
|  | Uptake of acute care health services: use of emergency medical services (up to 46 months)  | OR: 0.77 (95% CI 0.58, 1.03); P (heterogeneity): 0.12; P (overall): NR (4 RCTs, 1 nRCT, N=1,193) (Elkan 2000)                                | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | Moderate        | IMPORTANT |
| <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations</i>                    |  |  |   |                 |           |
| <b>Parent-infant relationship</b>  | Parenting quality and interaction (HOME Inventory) (6 weeks to 36 months)  | <b>ES: NR; P (heterogeneity): NR; P (overall): &lt; 0.0001</b> (10 RCTs, 2 nRCTs, N: 1,708) (Elkan 2000)                                     | Risk of bias: -1<br>Inconsistency: NR<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Moderate to low | CRITICAL  |
| <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Inconsistency: NR</i> |  |  |   |                 |           |
|  | Parenting quality and interaction (HOME Inventory) (time of measures NR)   | Significantly better total scores in 3 studies (designs NR; N=NR) and no clear differences seen in 7 studies (designs NR; N=NR) (Segal 2012) | Insufficient information to GRADE   | Not assessed    | CRITICAL  |
|  | Maternal sensitivity (1 study: Maternal Child Interaction-CARE Index; 1 study: tool NR) (time of measures NR)                                      | Significantly more sensitive responses in 2 studies (designs NR; N=NR) (Segal 2012)  | Insufficient information to GRADE   | Not assessed    | CRITICAL  |
| <b>Parent/caregiver psychosocial wellbeing</b>   | Parenting stress (PSI) (8 weeks to 12 months)  | Significantly improved total scores in 2 studies (designs NR; N=NR) and no clear differences seen in 1 study (designs NR; N=NR) (Segal 2012) | Insufficient information to GRADE   | Not assessed    | IMPORTANT |
| <b>Parent/caregiver knowledge, practices and behaviours</b>  | Family size (including: repeat pregnancy; births 2 years post-intervention; family size 10 years post-intervention) (1-10 years post-intervention) | ES: NR; P (heterogeneity): NR; P (overall): 0.07 (3 RCTs, 1 nRCT, N=1,282) (Elkan 2000)  | Risk of bias: -1<br>Inconsistency: NR<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Moderate to low | IMPORTANT |
| <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Inconsistency: NR</i> |  |  |   |                 |           |

|  |  |   |  |                 |           |
|--|--|---|--|-----------------|-----------|
|  | Mothers' use of public assistance (12-48 months)   | ES -0.08 (95% CI -0.18, 0.02); P (heterogeneity) < 0.001; P (overall): NR (3 RCTs, N=1,413) (Elkan 2000)  | Risk of bias: -1<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | Low             | IMPORTANT |
| <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Inconsistency: substantial heterogeneity (P &lt; 0.001)</i>   |  |   |  |                 |           |
|  | Maternal employment (12-46 months)   | ES: NR; P (heterogeneity): NR; P (overall): 0.29 (3 RCTs, N=1,413) (Elkan 2000)   | Risk of bias: -1<br>Inconsistency: NR<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | Moderate to low | IMPORTANT |
| <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Inconsistency: NR</i>   |  |   |  |                 |           |
|  | Substance use (time of measures NR)  | Significantly less substance abuse in 1 study (designs NR; N=NR) and no clear differences in 7 studies (designs NR; N=NR) (Segal 2012)  | Insufficient information to GRADE  | Not assessed    | CRITICAL  |
|  | Breastfeeding (at 3 months of age)   | <b>OR: 1.34 (95% CI 1.03, 1.74); P (heterogeneity) 0.13; P (overall): NR</b> (3 RCTs, 1 nRCT, N=938) (Elkan 2000)   | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0   | Moderate        | IMPORTANT |
| <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations</i>  |  |   |  |                 |           |
| <b>Parent/caregiver views of the intervention</b>  | No pooled results were available.  |   |  |                 | IMPORTANT |
| <b>Family relationships</b>  | No pooled results were available.  |   |  |                 | CRITICAL  |
| <b>Systems outcomes</b>  | Child maltreatment (measures of substantiated child abuse and neglect) (1-17 years)  | <b>MD (weighted): -2.9% (control: 9.5%, program: 6.6%); ES: -0.20 SD units (90% CI -0.41, -0.17); Q: 22.23 P=0.03</b> (9 RCTs, 1 quasi-experimental study, 2 matched group design; N=5,661) [1 matched group design study in infants > 1 year] Child and/or parent-focused primary prevention interventions (Reynolds 2009) | Risk of bias: -1<br>Inconsistency: -1<br>Indirectness: -1<br>Imprecision: 0<br>Publication bias: 0 | Very low        | CRITICAL  |
| <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations (including 1 quasi-experimental study; 2 matched group design studies); Inconsistency: substantial heterogeneity (P=0.03); Indirectness: maltreatment measured as several different outcomes</i> |  |   |  |                 |           |
| <b>Evidence statements</b>   |  |   |  |                 |           |
| <b>Infant social and emotional wellbeing or development up to one year of age</b>  | Temperament: Moderate to low quality evidence from one systematic review shows no clear difference in infant temperament (measured using the CITS) at four to 16 months with home visiting interventions (five RCTs, N=814). |   |  |                 |           |

|  |  |
|--|--|
| <p><b>Development for the infant, as a child, and up to 18 years</b></p>                   | <p><u>Cognitive development</u>: Low quality evidence from one systematic review shows improved cognitive development (measured using the BSID-MDI) at nine to 24 months with home visiting interventions (eight RCTs, N=1,670).</p> <p><u>Motor development</u>: Low quality evidence from one systematic review shows no clear differences in motor development (measured using the BSID-PDI) at nine to 18 months with home visiting interventions (four RCTs, N=390).</p> <p><u>Intelligence</u>: Low quality evidence from one systematic review shows higher IQ (measured using the SB Intelligence Test) at 12 to 48 months for children with home visiting interventions (five RCTs, N=870).</p> <p><u>Weight</u>: Low quality evidence from one systematic review shows no clear differences in children’s weight up to 48 months with home visiting interventions (three RCTs, N=463).</p> <p><u>Height</u>: Low quality evidence from one systematic review shows no clear differences in children’s height up to 48 months with home visiting interventions (three RCTs, N=463).</p>   |
| <p><b>Behaviour for the infant, as a child, and up to 18 years</b></p>                     | <p><u>Sleeping difficulties</u>: Moderate quality evidence from one systematic review shows fewer sleeping difficulties (reported by mothers) at six to 12 months in infants with home visiting interventions (four RCTs, N=763).</p>  |
| <p><b>Physical wellbeing and safety for the infant, as a child, and up to 18 years</b></p> | <p><u>Unintentional injuries</u>: Moderate quality evidence from one systematic review shows reduced rates of unintentional child injuries up to 48 months with home visiting interventions (six RCTs, N=1,836).</p> <p><u>Uptake of immunisation</u>: Low quality evidence from one systematic review shows higher uptake of child immunisation (six months to five years) with home visiting interventions (eight RCTs, one nRCT, N=2,518).</p> <p><u>Uptake of preventive health services (other than immunisation)</u>: Very low quality evidence from one systematic review shows no clear differences in uptake of other preventive health services (six months to five years) with home visiting interventions (three RCTs, N=425).</p> <p><u>Uptake of acute care health services: hospital admission (excluding intentional or unintentional injury)</u>: Low quality evidence from one systematic review shows fewer children’s hospital admissions (excluding injury) at nine to 46 months with home visiting interventions (four RCTs, three nRCTs, N=2,897).</p> <p><u>Uptake of acute care health services: use of emergency medical services</u>: Moderate quality evidence from one systematic review shows no clear differences in use of emergency services up to 46 months with home visiting interventions (four RCTs, one nRCT, N=1,193).</p> |
| <p><b>Parent-infant relationship</b></p>   | <p><u>Parenting quality and interaction</u>: Moderate to low quality evidence from one systematic review shows improvement in the parenting quality and interaction (measured using the HOME Inventory) at six weeks to 36 months with home visiting interventions (10 RCTs, two nRCTs, N=1,708).</p>  |



|   |   |
|---|---|
| <b>Parent/caregiver knowledge, practices and behaviours</b> | <p><u>Family size</u>: Moderate to low quality evidence from one systematic review suggests no clear differences in family size (repeat pregnancy; births two years post-intervention; family size 10 years post-intervention) one to 10 years post-intervention with home visiting interventions (three RCTs, one nRCT, N=1,282).</p> <p><u>Mothers' use of public assistance</u>: Low quality evidence from one systematic review shows no clear differences in mothers' use/receipt of public assistance at 12 to 48 months with home visiting interventions (three RCTs, N=1,413).</p> <p><u>Maternal employment</u>: Moderate to low quality evidence from one systematic review shows no clear differences in maternal employment at 12 to 46 months with home visiting interventions (three RCTs, N=1,413).</p> <p><u>Breastfeeding</u>: Moderate quality evidence from one systematic reviews shows that home visiting interventions can increase breastfeeding at three months post birth (three RCTs, one nRCT, N=938).</p> |
| <b>Systems outcomes</b>                                     | <p><u>Substantiated child maltreatment</u>: Very low quality evidence from one systematic review shows that child and/or parent-focused primary prevention interventions can reduce child maltreatment (measured using reports of substantiated child abuse or neglect) at one to 17 years (nine RCTs, one quasi-experimental study, two matched cohorts, N=5,661).</p>   |

**Abbreviations:** CI: confidence interval; CITS: Carey Infant Temperament Scale; ES: effect size; GRADE: Grading of Recommendations Assessment, Development and Evaluation; HOME: Home Observation for Measurement of the Environment; IQ: Intelligence Quotient; MD: mean difference; N: number; nRCT: non-randomised controlled trial; NR: not reported; OR: odds ratio; P: P value; PSI: Parenting Stress Index; Q: Cochran Q test of heterogeneity of the effect size; RCT: randomised control trial; SD: standard deviation; SB: Stanford-Binet (Intelligence Scale).

### **Characteristics that may have contributed to the effectiveness of home visiting interventions for optimal social and emotional development of infants**

***Who** could<sup>14</sup> deliver the intervention, program or messages to optimise infant social and emotional wellbeing and development?*

Across the various categories of types of people delivering home visiting interventions in Elkan 2000 (e.g. professionals, para-professionals or lay home visitors), there were no clear patterns associated with program 'success' (significant results in favour of the intervention in at least one outcome domain). There were no clear patterns of success according to whether there was a single intervenor delivering the intervention or a combination of individuals delivering the intervention. See Table 5b.

<sup>14</sup>We used could here and in the sentences that follow to acknowledge that studies conducted outside of Australia were not precluded. The MHPWC will therefore need to interpret what was found in the literature to the operational realities of the Australian context.

**Table 5b: Who delivered the home visiting interventions in Elkan 2000**

| Who delivered the interventions  | Significant* | Not significant* |
|--|--------------|------------------|
| Community health nurses  |              | ✓                |
| Community women  | ✓            | ✓                |
| Developmental paediatrician, and/or nurse and social worker            |              | ✓                |
| Health visitors  | ✓            | ✓                |
| Health visitors and clinical medical officers                          | ✓            |                  |
| Home visitor/paediatrician/primary care day worker                     |              | ✓                |
| Infant and parent therapists   | ✓            | ✓                |
| Lay home visitors  | ✓            | ✓                |
| Non-professional community members/mothers                             | ✓            | ✓                |
| Non-professionals  | ✓            | ✓                |
| Nurses   | ✓            | ✓                |
| Nurse clinician  |              | ✓                |
| Paediatrician, nurses  | ✓            | ✓                |
| Para-professionals   |              | ✓                |
| Parenting consultants (para-professionals)                             |              | ✓                |
| Psychology graduates   | ✓            | ✓                |
| Public health nurses   | ✓            | ✓                |
| Trained interventionist and teenage, black, female work/study students | ✓            |                  |
| Teachers   | ✓            | ✓                |

\*The ✓ symbols in the above table indicate whether studies with different individuals delivering the interventions in Elkan 2000 demonstrated significant or non-significant results in favour of home visiting interventions for ≥ 1 outcome domain in this overview; in some cases, studies with certain intervenors demonstrated both benefits and no clear effects for overview outcomes, and this is demonstrated above, with ✓ symbols in both the 'Significant' and 'Not significant' columns

***Where*** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?

By definition, all interventions or programs in Elkan 2000 were delivered in the home. A small number of programs also included co-interventions such as parenting group meetings in addition to home visits.

***To whom*** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?

Most home visiting programs that were assessed targeted populations with multiple characteristics, often involving different types of disadvantage. As shown in Table 5c for many population groups, there were both significant and non-significant results for relevant outcome domains observed with the same intervention. This was also the case for infant characteristics such as being preterm, low birthweight or failing to thrive, or indeed in unselected groups of infants. Where a particular group (e.g. infants with sleep difficulties) was represented only in either the significant or non-significant results column, this was usually due to single or small numbers of outcomes reported and so this does not help elucidate the question of to whom could the intervention or program be delivered.

**Table 5c: To whom the home visiting interventions in Elkan 2000 were delivered**

| To whom the interventions were delivered   | Significant* | Not significant* |
|--|--------------|------------------|
| African-American women < 29 weeks gestation, no previous live births and at least 2 socio-demographic characteristics (from unmarried, < 12 years education, unemployed) | ✓            | ✓                |
| Antenatal black unmarried low SES women under 18 years old when giving birth   |              | ✓                |
| At risk of cognitive difficulties  |              | ✓                |
| Black teenage mothers of low SES with preterm infants  | ✓            |                  |
| Black teenage mothers of low SES status with term infants  | ✓            | ✓                |
| Children born to primiparous women who were either teenagers, unmarried or of low SES  | ✓            | ✓                |
| Disadvantaged first-time mothers   | ✓            | ✓                |
| Families of SES  | ✓            | ✓                |
| Families referred to tri-agency intervention program   | ✓            |                  |
| First-born black infants in low income families  | ✓            | ✓                |
| First-time mothers of babies > 2000 g  |              | ✓                |
| Infants with failure to thrive   | ✓            | ✓                |
| Children on health visitors caseloads (3-27 months)  | ✓            | ✓                |
| Infants with sleep problems  |              | ✓                |
| Inner city black families with low incomes   | ✓            | ✓                |
| Low birthweight/preterm infants  | ✓            | ✓                |
| Low income families  |              | ✓                |
| Low SES families   |              | ✓                |
| Mothers at risk of child abuse   |              | ✓                |
| Mothers with antenatal cocaine/heroin use  |              | ✓                |
| Parents of preschool children with multiple psychosocial problems  | ✓            |                  |
| Preterm infants  |              | ✓                |
| Residents in squatter areas  |              | ✓                |
| Unselected infants   | ✓            | ✓                |
| Working class families   | ✓            | ✓                |

\*The ✓ symbols in the above table indicate whether studies delivered to particular groups of individuals in Elkan 2000 demonstrated significant or non-significant results in favour of home visiting interventions for ≥ 1 outcome domain in this overview; in some cases, studies delivered to particular groups of individuals demonstrated both benefits and no clear effects for overview outcomes, and this is demonstrated above, with ✓ symbols in both the 'Significant' and 'Not significant' columns

**Abbreviations:** g: grams; SES: socioeconomic status

***When** could be the best time for the intervention, program, or message delivery to occur? (In regards to caregiver preferences and accessibility; and in regards to improved outcomes for the infant, child and later on as the adolescent, and for the caregiver)*

Very little material about caregiver preferences regarding the 'best time' was reported in Elkan 2000, although there was some indication that weekly home visits were appreciated by parents.

No clear patterns were evident in regards to timing (e.g. visits commencing in the antenatal period compared with the postnatal period), length or duration of the intervention and association with significant and/or not significant results (see Table 5d).

The challenge of unravelling intervention characteristics and success is illustrated by the outcome of sleeping difficulties, where a single intervention (Kerr 1997) and an intervention lasting over three years (Gutelius 1977) both showed significant reductions in sleeping problems. Kerr 1997 used health visitors to deliver a passive intervention of verbal and written information. The observed

‘success’ of the intervention in Kerr 1997, however, may be in part attributed to the large sample size (of 220 babies), in comparison with other studies which may have lacked power to demonstrate differences in outcomes.

**Table 5d: When the home visiting interventions in Elkan 2000 were delivered**

| When the interventions were delivered  | Significant* | Not significant* |
|--|--------------|------------------|
| 1 visit  | ✓            |                  |
| Approximately 2 visits per family  |              | ✓                |
| Antenatal plus 4 visits (1-6 weeks), 5 visits (6 weeks-15 months) [vs postnatal visits only, 10 visits to 15 months]           | ✓            |                  |
| Antenatal plus 4 visits (1-6 weeks), 5 visits (6 weeks-15 months) OR 7 visits (6 weeks-6 months), 3 visits (6 weeks-15 months) | ✓            | ✓                |
| 1 visit per week (0-4 months), 1 visit per 2 weeks (4-9 months), 1 visit per month (9-12 months)                               | ✓            | ✓                |
| Bi-weekly visits for first 4 months postpartum, monthly thereafter (~30 minutes per visit)                                     | ✓            |                  |
| Mean antenatal visits 7 (range 0-18), mean postnatal visits (0-24 months) 26 (range 0-71)                                      | ✓            | ✓                |
| Mean of 9 antenatal visits or 23 antenatal and postnatal visits combined   | ✓            | ✓                |
| Mean of 25 visits from pregnancy to 30 months postpartum   |              | ✓                |
| Bi-weekly for first 6 months postpartum  | ✓            | ✓                |
| Weekly home visits for 1 year (mean 19 [SD 12]), lasting ~1 hour   | ✓            | ✓                |
| Weekly home visits for 1 year  | ✓            | ✓                |
| 1 home visit per week or 1 home visit plus parent group every 2 weeks  |              | ✓                |
| Monthly visits   | ✓            | ✓                |
| Monthly visits for 2 years   |              | ✓                |
| Monthly visits for first year of child’s life  | ✓            | ✓                |
| Dependent on need  | ✓            |                  |
| Mean 3 visits per month in first year and mean 1.5 visits/month in second and third years                                      | ✓            | ✓                |
| 7 months GA to first 3 years of child’s life: 9 visits of at least 1 hour  | ✓            | ✓                |
| 10 visits of 1 hour  |              | ✓                |
| 10 visits in first 2 years   | ✓            | ✓                |
| 1 visit per week for first 3 years   |              | ✓                |
| 3 antenatal visits and 5 postnatal visits  | ✓            | ✓                |
| From end of pregnancy to 6 months  |              | ✓                |
| From end of pregnancy to 6 months (median 11 visits (range 5-20))  |              | ✓                |
| 1 hour visits, 2 antenatal and then biweekly for the first 18 months of life   |              | ✓                |
| 9 visits in the first 3 months of life   |              | ✓                |
| 1 visit per week in year 1; bi-weekly visits in years 2 and 3  |              | ✓                |
| 2 antenatal visits; bi-weekly visits for 18 months (1 hour)  |              | ✓                |
| Mean 5.5 visits (range 1-3)  |              | ✓                |
| Not specified  |              | ✓                |

\*The ✓ symbols in the above table indicate whether studies with certain timings/frequencies/durations in Elkan 2000 demonstrated significant or non-significant results in favour of home visiting interventions for ≥ 1 outcome domain in this overview; in some cases, studies delivered with particular timings/frequencies/durations demonstrated both benefits and no clear effects for overview outcomes, and this is demonstrated above, with ✓ symbols in both the ‘Significant’ and ‘Not significant’ columns

^Elkan 2000 states 6 weeks but may mean 6 months

**Abbreviations:** GA: gestational age; SD: standard deviation

***How could the intervention, program or messages regarding infant social and emotional wellbeing and development be delivered?***

By definition, home visiting interventions are delivered face-to-face, either to mothers alone, mother-infant dyads or families. In the studies assessed by Elkan 2000, it is implied that most

interventions are delivered by a single person (e.g. nurse or community member – see Table 5b) although teams (e.g. paediatricians and nurses) were also used to deliver interventions.

As shown in Table 5e below, the ‘how’ and the ‘what’ of interventions are closely intermingled. The types of interventions assessed in Elkan 2000 spanned advice, counselling, educational modules, problem solving and infant stimulation. In most of the studies assessed, these various types and combinations of interventions showed benefit in at least one outcome domain of relevance.

**Table 5e: How the home visiting interventions in Elkan 2000 were delivered**

| How the interventions were delivered   | Significant* | Not significant* |
|--|--------------|------------------|
| Child development program with modules on educational, language and cognitive development  | ✓            | ✓                |
| Cognitive, language and social development via a program of games and activities   |              | ✓                |
| Counselling and advice on general caretaking, mother-infant interaction, social status and child development   | ✓            | ✓                |
| Counselling/anticipatory guidance/cognitive stimulation of infant  | ✓            | ✓                |
| Counselling, teaching child development, health and behaviour  | ✓            | ✓                |
| Developmental tasks for reading and language/nutrition advice  | ✓            | ✓                |
| Education for mothers on child developmental milestones and rearing practices; teach age appropriate stimulation to their infants; facilitate mother-child interaction | ✓            |                  |
| Emotional support, concrete help, information, enhancing social networks   |              | ✓                |
| Encourage uptake of services   | ✓            | ✓                |
| Enable parents to explore and clarify issues and problems and address strategies   | ✓            |                  |
| Establish positive parent-child relationships to foster development  |              | ✓                |
| Goal setting and attainment strategies   |              | ✓                |
| Health visitors trained in behavioural techniques appropriate to sleeping patterns   |              | ✓                |
| Help women improve their health-related behaviours, care of their children and life course development   | ✓            | ✓                |
| Improve child’s developmental level of functioning and quality of parent child interaction   | ✓            | ✓                |
| Infant stimulation, including caretaking, sensorimotor and mother-infant interaction exercises   | ✓            |                  |
| Information on child health and development, social support and strategies on management of self-identified problems   | ✓            | ✓                |
| Parent education, enhancement of women’s informal support systems and linkages with community services   | ✓            | ✓                |
| Prevention of parent dysfunction, education in maternal and child health   | ✓            |                  |
| Promote mother’s involvement with families and emotional support   |              | ✓                |
| Promote parent problem-solving strategies  |              | ✓                |
| Provide maternal support, promote parenting, child development, utilisation of resources and advocacy  | ✓            | ✓                |
| Routine public health nurse service  |              | ✓                |
| Solve immediate problems, reduce physical dangers, obtain more adequate food or housing, discuss long-term problems or decisions                                       |              | ✓                |
| Teach mothers to give age-appropriate stimulation to their infants; facilitate mother-child interaction  | ✓            | ✓                |
| Teaching module and age-appropriate toys   |              | ✓                |
| Verbal and written information and advice about sleeping and settling behaviour  | ✓            |                  |

\*The ✓ symbols in the above table indicate whether studies delivering interventions in certain formats/with certain content in Elkan 2000 demonstrated significant or non-significant results in favour of home visiting interventions for ≥ 1 outcome domain in this overview; in some cases, studies delivering interventions in certain formats/with certain content demonstrated both benefits and no clear effects for overview outcomes, and this is demonstrated above, with ✓ symbols in both the ‘Significant’ and ‘Not significant’ columns

*How could the intervention, program or messages regarding infant social and emotional wellbeing and development be **framed**?*

There was minimal coverage of framing issues in Elkan 2000. However issues of surveillance bias and social desirability bias were briefly addressed.

Interpretation of results is also relevant to the concept of framing. For example, an increase in maltreatment notifications and health service usage could be interpreted as positive rather than a negative outcome.

*What could **impede** or interfere with engagement with interventions or programs or caregivers enacting upon messages?*

Factors impeding engagement of caregivers with interventions or programs were not covered in Elkan 2000.

*What could **facilitate** or drive engagement with interventions or programs or caregivers enacting upon messages?*

Factors facilitating engagement of caregivers with interventions or programs were not covered in Elkan 2000.

## Antenatal and postnatal education and/or support interventions

### Description of intervention based on the included evidence

Antenatal and postnatal education and/or support interventions encompass a wide range of interventions developed to educate expectant and new parents in parenting skills, on coping with stressors, promoting positive interactions between partners and stimulating child development (Pinquart 2010).

Of the four systematic reviews included in this category, only two presented pooled results (Bryanton 2013; Pinquart 2010). In this overview, these interventions include individual or group based education delivered largely in parental homes or hospitals to the general population (well educated, adult, married, middle class women, couples or men) or families at risk, by a range of professionals, paraprofessionals and lay people, commencing antenatally (Bryanton 2013), provided in various frequencies and durations.

### Evidence summary

Four systematic reviews compared antenatal or postnatal education/support interventions for expectant or new parents of infants with predominately usual care (Bryanton 2013; Gagnon 2007; Pinquart 2010; Shaw 2006). The searches for studies were conducted up to the following years in the reviews: Shaw 2006: 2005; Gagnon 2007: 2006; Pinquart 2010: 2009; Bryanton 2013: 2013.

The inclusion criteria for these reviews differed and were as follows:

- Bryanton 2013: RCTs of any structured postnatal education provided to individual parents or groups of parents within the first two months post-birth related to the health or care of an infant or parent-infant relationships.
- Gagnon 2007: RCTs of any structured educational program provided on an individual or group basis during pregnancy by an educator to either parent that included information related to pregnancy, birth or parenthood.
- Pinquart 2010: studies using randomised designs with a control group receiving no/minimal intervention, with a parenting education component, with the onset of the intervention during pregnancy or the first six months after childbirth, with effect sizes available/able to be computed.
- Shaw 2006: RCTs of postpartum support interventions pertaining directly to therapy or prevention, in women without previously identified mental/physical illnesses, initiated within the first year after birth, following the third stage of labour, reporting on maternal knowledge, attitudes or skills related to parenting, mental health, quality of life or physical health, conducted in Australia, Canada, Europe, New Zealand or the United States.

Together, these four reviews included 191 relevant studies<sup>15</sup> (RCTs) with a total of 34,548 participants<sup>16</sup> (ranging from 10 to 2,064 in the included studies), published between 1973 and 2011 (Bryanton 2013; Gagnon 2007; Pinquart 2010; Shaw 2006).

The types of interventions delivered, along with timing, intensity and durations of the interventions varied across the four reviews as follows:

- Bryanton 2013: postnatal education interventions varied from one 20 minute postpartum session on the third day postpartum, to a 45-minute meeting postpartum followed by weekly phone contact for six weeks.

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<sup>15</sup>With some overlap (see Technical Report)

<sup>16</sup>Estimated sample sizes for Pinquart 2010 based on average sample of N=100 for each of the 133 RCTs

- Gagnon 2007: antenatal education interventions ranged from two 60 minute classes, to seven 90 minute classes.
- Pinqart 2010: interventions with a parenting education component for expectant or new parents varied in their number of meetings (average: 29, range: one to 421), and duration (average: 15.0 months, range: one day to 60 months).
- Shaw 2006: the postpartum support programs ranged from one session, to 18 months duration.

Three of the reviews were judged to be at low risk of bias (Bryanton 2013; Gagnon 2007; Shaw 2006) and one review was judged to be at high risk of bias (Pinqart 2010) using ROBIS. Using AMSTAR, two reviews were judged to be 'high' quality (Bryanton 2013; Gagnon 2007), one review 'moderate' quality (Shaw 2006) and one review 'low' quality (Pinqart 2010).

Two of the four included systematic reviews provided pooled results:

- Bryanton 2013 (low risk of bias; 'high' quality) included 27 relevant studies (RCTs), with a total of 4,048 participants (ranging from 30 to 696 in the included studies), published between 1977 and 2010.
- Pinqart 2010 (high risk of bias; 'low' quality) included 133 studies (RCTs) with an estimated total of 13,300 participants, published between 1973 and 2009.

For further details regarding the results from single studies from the other two reviews (Gagnon 2009; Shaw 2006), see the Technical Report.

### ***Primary outcome domain***

#### **Infant social and emotional wellbeing or development up to one year of age**

No pooled results were available.

### ***Secondary outcome domains***

#### **Development for the infant, as a child, and up to 18 years**

Improvements with parenting education with expectant and new parents were seen in all aspects of development reported in one review (which did not report on risk of bias), specifically:

- Cognitive development (measured using the BSID-MDI, SB Intelligence Scales, and other validated measures) post-intervention (15 months) (moderate quality evidence (assumed), downgraded due to inconsistency) and at follow up (28.6 months later) (high quality evidence (assumed) (Pinqart 2010);
- Motor development (measured using the BSID-PDI and related measures) post-intervention (15 months) and at follow up (28.6 months later) (high quality evidence (assumed), (Pinqart 2010);
- Social development (assessed with measures of social competence and behaviour regulation, e.g. competence subscales of the BITSEA, tests for secure attachment, and measures of communication and peer relation) post-intervention (15 months) and at follow up (28.6 months later) (moderate quality evidence (assumed), downgraded due to inconsistency) (Pinqart 2010);
- Mental health (measured using the CBCL, assessments of child mood states, and other validated scales) post-intervention (15 months) and at follow up (28.6 months later) (moderate quality evidence (assumed), downgraded due to inconsistency) (Pinqart 2010).

#### **Behaviour for the infant, as a child, and up to 18 years**

Sleep education interventions increased infant sleep at six weeks and 12 weeks in one review (low or very low quality evidence, downgraded due to high risk of bias and inconsistency) (Bryanton 2013).



Night-time sleep was increased at six weeks (moderate quality evidence, downgraded due to high risk of bias) and 12 weeks (very low quality evidence, downgraded due to high risk of bias and inconsistency) and day-time sleep was increased at 6 weeks, but not 12 weeks in the same review (very low quality evidence, downgraded due to high risk of bias, inconsistency and imprecision) (Bryanton 2013). These interventions also had no clear impact on increasing length of uninterrupted sleep during the day or the night at six or 12 weeks (all very low quality evidence, downgraded due to high risk of bias, inconsistency and imprecision) (Bryanton 2013). Sleep education interventions also did not have a clear impact on crying time in infants at six weeks or 12 weeks (both low quality evidence, downgraded due to high risk of bias and imprecision) (Bryanton 2013).

### **Physical wellbeing and safety for the infant, as a child, and up to 18 years**

No pooled results were available.

#### **Parent-infant relationship**

Parenting quality (measured using the HOME Inventory, NCATS and other related validated scales) was improved with parenting education with expectant and new parents post-intervention (15 months) and at follow up (28.6 months later) (moderate quality evidence (assumed), downgraded due to inconsistency) (Pinquart 2010).

#### **Parent/caregiver psychosocial wellbeing**

Parenting education with expectant and new parents decreased parental stress (measured using the Parental Distress scale of PSI and related measures) post-intervention (15 months), with no clear effect at follow up (28.6 months later) (both moderate quality evidence (assumed), downgraded due to inconsistency) in one review (Pinquart 2010). In the same review, parenting education with expectant and new parents led to improved parental mental health (measured using the CES-D, STAI, EPDS and other validated measures) post-intervention (15 months) (moderate quality evidence (assumed), downgraded due to inconsistency) and at follow up (28.6 months later) (high quality evidence (assumed)) (Pinquart 2010).

#### **Parent/caregiver knowledge, practices and behaviours**

Maternal knowledge about infant behaviours (measured using 12 to 15 item questionnaires) was increased up to four weeks postpartum with infant behaviour education interventions in one review (low quality evidence, downgraded due to high risk of bias and imprecision) (Bryanton 2013). In another review, health promoting parental behaviour (measured using the percentage of children who received full immunisation or number of paediatric well child visits) was also improved with parenting education with expectant and new parents post-intervention (15 months) in the second review (moderate quality evidence (assumed), downgraded due to inconsistency) (Pinquart 2010).

#### **Parent/caregiver views of the intervention**

No pooled results were available.

#### **Family relationships**

Couple adjustment (measured using the DAS, revised CTS and related scales) was improved with parenting education with expectant and new parents post-intervention (15 months) and at follow up (28.6 months later) in one review (high quality evidence (assumed)) (Pinquart 2010).

#### **Systems outcomes**

Parenting education with expectant and new parents reduced child maltreatment (measured using identified cases of child abuse (e.g. from protective service agencies), or the CAPI) post-intervention (15 months) (moderate quality evidence (assumed), downgraded due to inconsistency) with no clear

effect at follow up (28.6 months later) in one review (high quality evidence (assumed) (Pinquart 2010).

### Potential harms<sup>17</sup>

In one review (Bryanton 2013), single study results show significantly poorer outcomes for maternal stress scores (in the outcome domain of parent/caregiver psychosocial wellbeing) with education on sleep enhancement compared to usual care. For further details regarding potential harms from single studies see the pink shaded rows of the Evidence Tables in the Technical Report.

**Table 6: Antenatal and postnatal education and/or support interventions evidence profile**

| <b>ANTENATAL AND POSTNATAL EDUCATION AND/OR SUPPORT INTERVENTIONS</b>   |  |  |  |                            |                   |
|---|--|--|--|----------------------------|-------------------|
| What is the effectiveness of antenatal and postnatal education and/or support interventions targeted at parents of infants in their first year of life for optimal social and emotional development for the infant, and later on as a child and adolescent? |  |  |  |                            |                   |
| <b>Comparison</b>   | Predominately usual care   |  |  |                            |                   |
| <b>Outcome domain</b>   | <b>Outcome measure used in the review(s)</b>   | <b>Results reported in the review(s) and GRADE</b>   |  |                            | <b>Importance</b> |
|   |  | <b>Result<sup>18,19</sup></b>  | <b>GRADE</b>   | <b>Quality of evidence</b> |                   |
| <b>Infant social and emotional wellbeing or development up to one year of age</b>   | No pooled results were available.  |  |  |                            | CRITICAL          |
| <b>Development for the infant, as a child, and up to 18 years</b>   | Cognitive development (BSID-MDI; SB Intelligence Scales; “other validated measures”) “at the end of the intervention” <sup>#</sup> (15 months) | <b>ES (d): 0.24 (95% CI 0.14, 0.33); Q: 124.98 P&lt;0.001; P &lt; 0.001</b> (38 RCTs, N~3,800`)<br>Interventions: teaching infant care, promoting parental sensitivity and responsiveness; promoting cognitive stimulation of the child, and counselling (Pinquart 2010) | Risk of bias: 0 (assumed)<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Moderate (assumed)         | CRITICAL          |
| <i>GRADE reasons for downgrading: <b>Inconsistency</b>: substantial heterogeneity (P &lt; 0.001)</i>  |  |  |  |                            |                   |

<sup>17</sup>In this context, harm refers to a significantly poorer outcome in the intervention group relative to the control group within a pre-specified primary or secondary outcome domain

<sup>18</sup>All Ns reflect the total numbers (i.e. across both the intervention and control groups)

<sup>19</sup>Bolding indicates a statistically significant pooled result in favour of the intervention

|  |   |  |                    |           |
|--|---|--|--------------------|-----------|
| Cognitive development (BSID-MDI; SB Intelligence Scales; “other validated measures”) “follow up effect”~ (28.6 months)   | <b>ES (d): 0.12 (95% CI 0.06, 0.18); Q: 42.10 P=NS; P &lt; 0.001</b><br>(31 RCTs, N~3,100`)<br>Interventions: teaching infant care, promoting parental sensitivity and responsiveness; promoting cognitive stimulation of the child, and counselling (Pinquart 2010)          | Risk of bias: 0 (assumed)<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | High (assumed)     | CRITICAL  |
| <i>GRADE reasons for downgrading: not downgraded</i>   |   |  |                    |           |
| Motor development (BSID-PDI; “related measures”) “at the end of the intervention”# (15 months)   | <b>ES (d): 0.15 (95% CI 0.07, 0.23); Q: 30.49 P=NS; P &lt; 0.001</b><br>(22 RCTs, N~2,200`)<br>Interventions: teaching infant care, promoting parental sensitivity and responsiveness; promoting cognitive stimulation of the child, and counselling (Pinquart 2010)          | Risk of bias: 0 (assumed)<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | High (assumed)     | IMPORTANT |
| <i>GRADE reasons for downgrading: not downgraded</i>   |   |  |                    |           |
| Motor development (BSID-PDI; “related measures”) “follow up effect”~ (28.6 months)   | <b>ES (d): 0.35 (95% CI 0.21, 0.50); Q: 13.02 P=NS; P &lt; 0.001</b><br>(13 RCTs, N~1,300`)<br>Interventions: teaching infant care, promoting parental sensitivity and responsiveness; promoting cognitive stimulation of the child, and counselling (Pinquart 2010)          | Risk of bias: 0 (assumed)<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | High (assumed)     | IMPORTANT |
| <i>GRADE reasons for downgrading: not downgraded</i>   |   |  |                    |           |
| Social development (measures of social competence and behaviour regulation, e.g. competence subscales of the BITSEA; tests for secure attachment; measures of communication and peer relation) “at the end of the intervention”# (15 months) | <b>ES (d): 0.30 (95% CI 0.19, 0.42); Q: 142.37 P &lt; 0.001; P &lt; 0.001</b><br>(34 RCTs, N~3,400`)<br>Interventions: teaching infant care, promoting parental sensitivity and responsiveness; promoting cognitive stimulation of the child, and counselling (Pinquart 2010) | Risk of bias: 0 (assumed)<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Moderate (assumed) | CRITICAL  |
| <i>GRADE reasons for downgrading: Inconsistency: substantial heterogeneity (P &lt; 0.001)</i>  |   |  |                    |           |

|   |   |   |  |                    |          |
|---|---|---|--|--------------------|----------|
|   | Social development (measures of social competence and behaviour regulation, e.g. competence subscales of the BITSEA; tests for secure attachment; measures of communication and peer relation) "follow up effect"~ (28.6 months)                    | <b>ES (d): 0.28 (95% CI 0.16, 0.40); Q: 40.05 P &lt; 0.01; P &lt; 0.001</b><br>(21 RCTs, N~2,100`)<br>Interventions: teaching infant care, promoting parental sensitivity and responsiveness; promoting cognitive stimulation of the child, and counselling (Pinquart 2010)   | Risk of bias: 0 (assumed)<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Moderate (assumed) | CRITICAL |
| <b>GRADE reasons for downgrading: Inconsistency: substantial heterogeneity (P &lt; 0.01)</b>  |   |   |  |                    |          |
|   | Mental health (CBCL; assessments of child mood states; "other validated scales") "at the end of the intervention"# (15 months)  | <b>ES (d): 0.13 (95% CI 0.18, 0.32); Q: 132.02 P &lt; 0.001; P &lt; 0.001</b><br>(40 RCTs, N~4,000`)<br>Interventions: teaching infant care, promoting parental sensitivity and responsiveness; promoting cognitive stimulation of the child, and counselling (Pinquart 2010) | Risk of bias: 0 (assumed)<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Moderate (assumed) | CRITICAL |
| <b>GRADE reasons for downgrading: Inconsistency: substantial heterogeneity (P &lt; 0.001)</b> |   |   |  |                    |          |
|   | Mental health (CBCL; assessments of child mood states; "other validated scales") "follow up effect"~ (28.6 months)  | <b>ES (d): 0.20 (95% CI 0.11, 0.30); Q: 37.82 P &lt; 0.01; P &lt; 0.001</b><br>(21 RCTs, N~2,100`)<br>Interventions: teaching infant care, promoting parental sensitivity and responsiveness; promoting cognitive stimulation of the child, and counselling (Pinquart 2010)   | Risk of bias: 0 (assumed)<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Moderate (assumed) | CRITICAL |
| <b>GRADE reasons for downgrading: Inconsistency: substantial heterogeneity (P&lt;0.001)</b>   |   |   |  |                    |          |
| <b>Behaviour for the infant, as a child, and up to 18 years</b>                               | Infant sleep in 24 hours (total minutes) (at 6 weeks)   | <b>MD (F): 62.08 (95% CI 42.88, 81.29); I<sup>2</sup> 86%; P &lt; 0.00001</b><br>(3 RCTs, N=NR)<br>Interventions: Education on sleep enhancement (Bryanton 2013)  | Risk of bias: -1<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0          | Very low           | CRITICAL |
|   | <b>GRADE reasons for downgrading: Risk of bias: allocation concealment unclear in 1 RCT; high attrition in 1 RCT; Inconsistency: very substantial heterogeneity (I<sup>2</sup> &gt; 80%); random effects model not used; result driven by 1 RCT</b> |   |  |                    |          |
|   | Infant sleep in 24 hours (total minutes) (at 12 weeks)  | <b>MD (F): 61.41 (95% CI 28.08, 94.73); I<sup>2</sup> 62%; P=0.0003</b><br>(2 RCTs, N=NR)<br>Interventions: Education on sleep enhancement (Bryanton 2013)  | Risk of bias: -1<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0          | Low                | CRITICAL |

|   |  |  |          |          |
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| <i>GRADE reasons for downgrading: Risk of bias: allocation concealment unclear in 1 RCT; high attrition in 1 RCT; Inconsistency: substantial heterogeneity; random effects model not used; result driven by 1 RCT</i>           |  |  |          |          |
| Night-time infant sleep (minutes) in 24 hours (at 6 weeks)  | <b>MD (F): 29.13 (95% CI 18.53, 39.73); I<sup>2</sup> 0% ; P &lt; 0.00001</b><br>(2 RCTs, N=NR)<br>Interventions: Education on sleep enhancement (Bryanton 2013) | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0   | Moderate | CRITICAL |
| <i>GRADE reasons for downgrading: Risk of bias: high attrition in 1 RCT</i>   |  |  |          |          |
| Night-time infant sleep in 24 hours (total minutes) (at 12 weeks)   | <b>MD (F): 16.18 (95% CI 4.41, 27.95); I<sup>2</sup> 84%; P=0.007</b><br>(2 RCTs, N=NR)<br>Interventions: Education on sleep enhancement (Bryanton 2013)         | Risk of bias: -1<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | Very low | CRITICAL |
| <i>GRADE reasons for downgrading: Risk of bias: allocation concealment unclear in 1 RCT; high attrition in 1 RCT; Inconsistency: very substantial heterogeneity (I<sup>2</sup>&gt;80%); random effects model not used</i>       |  |  |          |          |
| Longest uninterrupted night-time infant sleep (minutes) (at 6 weeks)  | MD (F): 13.74 (95% CI -1.11, 28.58); I <sup>2</sup> 62%; P=0.07<br>(2 RCTs, N=NR)<br>Interventions: Education on sleep enhancement (Bryanton 2013)               | Risk of bias: -1<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Very low | CRITICAL |
| <i>GRADE reasons for downgrading: Risk of bias: allocation concealment unclear in 1 RCT; Inconsistency: substantial heterogeneity; random effects model not used; Imprecision: wide CIs</i>                                     |  |  |          |          |
| Longest uninterrupted night-time infant sleep (minutes) (at 12 weeks)   | MD (F): 11.45 (95% CI -5.40, 28.30); I <sup>2</sup> 78%; P=0.18<br>(2 RCTs, N=NR)<br>Interventions: Education on sleep enhancement (Bryanton 2013)               | Risk of bias: -1<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Very low | CRITICAL |
| <i>GRADE reasons for downgrading: Risk of bias: allocation concealment unclear in both RCTs; Inconsistency: substantial heterogeneity; random effects model not used; Imprecision: wide CIs</i>                                 |  |  |          |          |
| Day-time infant sleep in 24 hours (minutes) (at 6 weeks)  | <b>MD (F): 39.59 (95% CI 25.01, 54.17); I<sup>2</sup> 92%; P &lt; 0.00001</b><br>(2 RCTs, N=NR)<br>Interventions: Education on sleep enhancement (Bryanton 2013) | Risk of bias: -1<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | Very low | CRITICAL |
| <i>GRADE reasons for downgrading: Risk of bias: allocation concealment unclear in 1 RCT; Inconsistency: very substantial heterogeneity (I<sup>2</sup> &gt; 80%); random effects model not used</i>                              |  |  |          |          |
| Day-time infant sleep in 24 hours (minutes) (at 12 weeks)   | MD (F): 9.92 (95% CI -1.83, 21.66); I <sup>2</sup> 90%; P=0.098<br>(2 RCTs, N=NR)<br>Interventions: Education on sleep enhancement (Bryanton 2013)               | Risk of bias: -1<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Very low | CRITICAL |
| <i>GRADE reasons for downgrading: Risk of bias: allocation concealment unclear in both trials; Inconsistency: very substantial heterogeneity (I<sup>2</sup> &gt; 80%); random effects model not used; Imprecision: wide CIs</i> |  |  |          |          |

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|---|---|--|--|--------------------|----------|
|   | Longest uninterrupted day-time infant sleep (minutes) (at 6 weeks)  | MD (F): 5.57 (95% CI - 2.31, 13.45); $I^2$ 66%; P=0.17<br>(2 RCTs, N=NR)<br>Interventions: Education on sleep enhancement (Bryanton 2013)  | Risk of bias: -1<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0         | Very low           | CRITICAL |
|   | <i>GRADE reasons for downgrading: Risk of bias: allocation concealment unclear in one trial; Inconsistency: substantial heterogeneity; random effects model not used; Imprecision: wide CIs</i>   |  |  |                    |          |
|   | Longest uninterrupted day-time infant sleep (minutes) (at 12 weeks)   | MD (F): 0.60 (95% CI -3.89, 5.09); $I^2$ 83%; P=0.79<br>(2 RCTs, N=NR)<br>Interventions: Education on sleep enhancement (Bryanton 2013)  | Risk of bias: -1<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0         | Very low           | CRITICAL |
|   | <i>GRADE reasons for downgrading: Risk of bias: allocation concealment unclear in both trials; Inconsistency: substantial heterogeneity; random effects model not used; Imprecision: wide CIs</i> |  |  |                    |          |
|   | Infant crying time in 24 hours (minutes) (at 6 weeks)   | MD (F): 4.36 (95% CI -6.44, 15.16); $I^2$ 0; P=0.43 (2 RCTs, N=NR)<br>Interventions: Education on sleep enhancement (Bryanton 2013)  | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0          | Low                | CRITICAL |
|   | <i>GRADE reasons for downgrading: Risk of bias: allocation concealment unclear in one trial, high attrition in the other trial; Imprecision: wide CIs</i>   |  |  |                    |          |
|   | Infant crying time in 24 hours (minutes) (at 12 weeks)  | MD (F): 0.55 (95% CI -8.38, 9.47) $I^2$ 0; P=0.90<br>(2 RCTs, N=NR)<br>Interventions: Education on sleep enhancement (Bryanton 2013)   | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0          | Low                | CRITICAL |
|   | <i>GRADE reasons for downgrading: Risk of bias: allocation concealment unclear in one trial, high attrition in the other trial; Imprecision: wide CIs</i>   |  |  |                    |          |
| <b>Physical wellbeing and safety for the infant, as a child, and up to 18 years</b> | No pooled results were available.   |  |  |                    | CRITICAL |
| <b>Parent-infant relationship</b>   | Parenting quality (Infant-Toddler HOME; NCATS; "other related validated scales") "at the end of the intervention" <sup>#</sup> (15 months)  | <b>ES (d): 0.35 (95% CI 0.29, 0.42);</b><br><b>Q: 472.63 P &lt; 0.001;</b><br><b>P &lt; 0.001</b><br>(103 RCTs, N=10,300)<br>Interventions: teaching infant care, promoting parental sensitivity and responsiveness; promoting cognitive stimulation of the child, and counselling (Pinquart 2010) | Risk of bias: 0 (assumed)<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Moderate (assumed) | CRITICAL |
|   | <i>GRADE reasons for downgrading: Inconsistency: substantial heterogeneity (P &lt; 0.001)</i>   |  |  |                    |          |

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|--|--|--|--|--------------------|-----------|
|  | Parenting quality (Infant-Toddler HOME; NCATS; “other related validated scales”) “follow up effect”~ (28.6 months)   | <b>ES (d): 0.31 (95% CI 0.22, 0.40); Q: 71.95 P &lt; 0.001; P &lt; 0.001</b><br>(39 RCTs, N~3,900`)<br>Interventions: teaching infant care, promoting parental sensitivity and responsiveness; promoting cognitive stimulation of the child, and counselling (Pinquart 2010) | Risk of bias: 0 (assumed)<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Moderate (assumed) | CRITICAL  |
|  | <i>GRADE reasons for downgrading: <b>Inconsistency: substantial heterogeneity (P &lt; 0.001)</b></i>                 |  |  |                    |           |
| <b>Parent/caregiver psychosocial wellbeing</b> | Parenting stress (Parental Distress scale of PSI; “other measures”) “at the end of the intervention”# (15 months)    | <b>ES (d): 0.20 (95% CI 0.11, 0.29); Q: 45.04 P &lt; 0.01; P &lt; 0.001</b><br>(26 RCTs, N~2,600`)<br>Interventions: teaching infant care, promoting parental sensitivity and responsiveness; promoting cognitive stimulation of the child, and counselling (Pinquart 2010)  | Risk of bias: 0 (assumed)<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Moderate (assumed) | IMPORTANT |
|  | <i>GRADE reasons for downgrading: <b>Inconsistency: substantial heterogeneity (P &lt; 0.01)</b></i>                  |  |  |                    |           |
|  | Parenting stress (Parental Distress scale of PSI; “other measures”) “follow up effect”~ (28.6 months)                | ES (d): 0.31 (95% CI -0.27, 0.89); Q: 64.25 P<0.001; P=NS<br>(6 RCTs, N~600`)<br>Interventions: teaching infant care, promoting parental sensitivity and responsiveness; promoting cognitive stimulation of the child, and counselling (Pinquart 2010)                       | Risk of bias: 0 (assumed)<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Moderate (assumed) | IMPORTANT |
|  | <i>GRADE reasons for downgrading: <b>Inconsistency: substantial heterogeneity (P &lt; 0.001)</b></i>                 |  |  |                    |           |
|  | Parental mental health (CES-D; STAI; EPDS; “other validated measures”) “at the end of the intervention”# (15 months) | <b>ES (d): 0.13 (95% CI 0.06, 0.20); Q: 43.69 P &lt; 0.05; P &lt; 0.001</b><br>(33 RCTs, N~3,300`)<br>Interventions: teaching infant care, promoting parental sensitivity and responsiveness; promoting cognitive stimulation of the child, and counselling (Pinquart 2010)  | Risk of bias: 0 (assumed)<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Moderate (assumed) | IMPORTANT |
|  | <i>GRADE reasons for downgrading: <b>Inconsistency: substantial heterogeneity (P &lt; 0.05)</b></i>                  |  |  |                    |           |

|   |   |  |  |                    |           |
|---|---|--|--|--------------------|-----------|
|   | Parental mental health (CES-D; STAI; EPDS; “other validated measures”) “follow up effect”~ (28.6 months)  | <b>ES (d): 0.15 (95% CI 0.08, 0.22); Q: 16.89 P=NS; P &lt; 0.001</b><br>(12 RCTs, N~1,200)<br>Interventions: teaching infant care, promoting parental sensitivity and responsiveness; promoting cognitive stimulation of the child, and counselling (Pinquart 2010)          | Risk of bias: 0 (assumed)<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | High (assumed)     | IMPORTANT |
|   | <i>GRADE reasons for downgrading: not downgraded</i>  |  |  |                    |           |
| <b>Parent/caregiver knowledge, practices and behaviours</b> | Maternal knowledge of infant behaviour (points: on 12-15 item questionnaires) (up to 4 weeks postpartum)  | <b>MD (F): 2.85 (95% CI 1.78, 3.91); I<sup>2</sup> 0%; P &lt; 0.00001</b><br>(2 RCTs, N=56)<br>Interventions: Education on infant behaviour (Bryanton 2013)  | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0          | Low                | CRITICAL  |
|   | <i>GRADE reasons for downgrading: Risk of bias: allocation concealment unclear in both RCTs; Imprecision: studies with small sample sizes</i>                                     |  |  |                    |           |
|   | Health promoting parental behaviour (percentage of children who received full immunisation; number of paediatric well child visits) “at the end of the intervention”# (15 months) | <b>ES (d): 0.15 (95% CI 0.07, 0.23); Q: 102.28 P &lt; 0.001; P &lt; 0.001</b><br>(30 RCTs, N~3,000)<br>Interventions: teaching infant care, promoting parental sensitivity and responsiveness; promoting cognitive stimulation of the child, and counselling (Pinquart 2010) | Risk of bias: 0 (assumed)<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Moderate (assumed) | CRITICAL  |
|   | <i>GRADE reasons for downgrading: Inconsistency: substantial heterogeneity (P &lt; 0.001)</i>   |  |  |                    |           |
| <b>Parent/caregiver views of the intervention</b>           | No pooled results were available.   |  |  |                    | IMPORTANT |
| <b>Family relationships</b>                                 | Couple adjustment (DAS; revised CTS; “related scales”) “at the end of the intervention”# (15 months)  | <b>ES (d): 0.19 (95% CI 0.06, 0.33); Q: 23.86 P &lt; 0.05; P &lt; 0.01</b><br>(13 RCTs, N~1,300)<br>Interventions: teaching infant care, promoting parental sensitivity and responsiveness; promoting cognitive stimulation of the child, and counselling (Pinquart 2010)    | Risk of bias: 0 (assumed)<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | High (assumed)     | CRITICAL  |
|   | <i>GRADE reasons for downgrading: not downgraded</i>  |  |  |                    |           |



|                         |  |   |  |                    |          |
|-------------------------|--|---|--|--------------------|----------|
|                         | Couple adjustment (DAS; revised CTS; “related scales”) “follow up effect”~ (28.6 months)   | <b>ES (d): 0.22 (95% CI 0.01, 0.43); Q: 4.77 P=NS; P &lt; 0.05</b><br>(4 RCTs, N~400`)<br>Interventions: teaching infant care, promoting parental sensitivity and responsiveness; promoting cognitive stimulation of the child, and counselling (Pinquart 2010)             | Risk of bias: 0 (assumed)<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | High (assumed)     | CRITICAL |
|                         | <i>GRADE reasons for downgrading: not downgraded</i>   |   |  |                    |          |
| <b>Systems outcomes</b> | Child maltreatment (identified cases of child abuse (e.g. from protective service agencies); CAPI) “at the end of the intervention”# (15 months) | <b>ES (d): 0.13 (95% CI 0.05, 0.21); Q: 81.46 P &lt; 0.001; P &lt; 0.01</b><br>(29 RCTs, N~2,900`)<br>Interventions: teaching infant care, promoting parental sensitivity and responsiveness; promoting cognitive stimulation of the child, and counselling (Pinquart 2010) | Risk of bias: 0 (assumed)<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Moderate (assumed) | CRITICAL |
|                         | <i>GRADE reasons for downgrading: <b>Inconsistency: substantial heterogeneity (P &lt; 0.001)</b></i>   |   |  |                    |          |
|                         | Child maltreatment (identified cases of child abuse (e.g. from protective service agencies); CAPI) “follow up effect”~ (28.6 months)             | ES (d): 0.17 (95% CI -0.01, 0.36); Q: 4.29 P=NS; P=NS (7 RCTs, N~700`)<br>Interventions: teaching infant care, promoting parental sensitivity and responsiveness; promoting cognitive stimulation of the child, and counselling (Pinquart 2010)                             | Risk of bias: 0 (assumed)<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | High (assumed)     | CRITICAL |
|                         | <i>GRADE reasons for downgrading: not downgraded</i>   |   |  |                    |          |

| Evidence statements   |  |
|---|--|
| <b>Development for the infant, as a child, and up to 18 years</b> | <p><u>Cognitive development</u>: High and moderate quality evidence from one systematic review shows that parenting education with expectant and new parents can improve cognitive development (measured using the BSID-MDI, SB Intelligence Test and other validated measures) post-intervention (15 months) (38 RCTs, N~3,800`) and at follow up (28.6 months later) (31 RCTs, N~3,100`).</p> <p><u>Motor development</u>: High quality evidence from one systematic review shows that parenting education with expectant and new parents can improve motor development (measured using the BSID-PDI and related measures) post-intervention (15 months) (22 RCTs, N~2,200`) and at follow up (28.6 months later) (13 RCTs, N~1,300`).</p> <p><u>Social development</u>: Moderate quality evidence from one systematic review shows that parenting education with expectant and new parents can improve social development (assessed with measures of social competence and behaviour regulation, e.g. competence subscales of the BITSEA, tests for secure attachment and measures of communication and peer relation) post-intervention (15 months) (34 RCTs, N~3,400`) and at follow up (28.6 months later) (21 RCTs, N~2,100`).</p> <p><u>Mental health</u>: Moderate quality evidence from one systematic review shows that parenting education with expectant and new parents can improve mental health (measured using the CBCL, assessments of child mood states and other validated scales) post-intervention (15 months) (40 RCTs, N~4,000`) and at follow up (28.6 months later) (21 RCTs, N~2,100`).</p> |
| <b>Behaviour for the infant, as a child, and up to 18 years</b>   | <p><u>Sleep</u>: Moderate to very low quality evidence from one systematic review shows that sleep education interventions can increase infant night-time sleep at six and 12 weeks and day-time sleep at six, but not 12, weeks. These interventions do not have a clear impact on increasing length of uninterrupted sleep during the day or the night at six or 12 weeks (two RCTs per outcome, N=NR per outcome).</p> <p><u>Crying</u>: Low quality evidence from one systematic review suggests that sleep education interventions do not have a clear impact on crying time in infants at six to 12 weeks (two RCTs, N=NR).</p>  |
| <b>Parent-infant relationship</b>                                 | <p><u>Parenting quality</u>: Moderate quality evidence from one systematic review shows that parenting education with expectant and new parents can improve parenting quality (measured using the Infant-Toddler HOME Inventory, NCATS and other related validated scales) post-intervention (15 months) (103 RCTs, N~10,300`) and at follow up (28.6 months later) (39 RCTs, N~3,900`).</p>   |
| <b>Parent/caregiver psychosocial wellbeing</b>                    | <p><u>Parental stress</u>: Moderate quality evidence from one systematic review shows that parenting education with expectant and new parents can decrease parental stress (measured using the Parental Distress scale of PSI, and related measures) post-intervention (15.0 months) (26 RCTs, N~2,600`) with no clear effect at follow up (28.6 months later) (six RCTs, N~600`).</p> <p><u>Parental mental health</u>: High and moderate quality evidence from one systematic review shows that parenting education with expectant and new parents can improve parental mental health (measured using the CES-D, STAI, EPDS and other validated measures) post-intervention (15 months) (33 RCTs, N~3,300`) and at follow up (28.6 months later) (12 RCTs, N~1,200`).</p>  |

|   |  |
|---|--|
| <b>Parent/caregiver knowledge, practices and behaviours</b> | <p><u>Maternal knowledge:</u> Low quality evidence from one systematic review shows that interventions for education about infant behaviour can increase maternal knowledge (measured using 12 to 15 item questionnaires) up to four weeks postpartum (two RCTs, N=56).</p> <p><u>Health promoting parental behaviour:</u> Moderate quality evidence from one systematic review shows that parenting education with expectant and new parents can improve health promoting behaviour (measured using the percentage of children who received full immunisation or number of paediatric well child visits) post-intervention (15 months) (30 RCTs, N~3,000`).</p> |
| <b>Family relationships</b>                                 | <p><u>Couple adjustment:</u> High quality evidence from one systematic review shows that parenting education with expectant and new parents can improve couple adjustment (measured using the DAS, revised CTS and related scales) post-intervention (15 months) (13 RCTs, N~1,300`) and at follow up (28.6 months later) (four RCTs, N~400`).</p>   |
| <b>Systems outcomes</b>                                     | <p><u>Child maltreatment:</u> High and moderate quality evidence from one systematic review shows that parenting education with expectant and new parents can reduce child maltreatment (measured using identified cases of child abuse (e.g. from protective service agencies), or the CAPI) post-intervention (15 months) (29 RCTs, N~2,900`) with no clear effect at follow up (28.6 months later) (seven RCTs, N~700`).</p>  |

<sup>†</sup>Estimated sample sizes for Pinquart 2010 based on average sample of N=100 for each of the 133 RCTs

<sup>#</sup>Average length of intervention was 15.0 months (SD: 13.7)

<sup>~</sup>Follow up effects – average time interval between end of intervention and follow up was 28.6 months (SD: 42.6)

**Abbreviations:** BITSEA: Brief Infant-Toddler Social and Emotional Assessment; BSID-MDI: Bayley Scales of Infant Development-Mental Health Index; BSID-PDI: Bayley Scales of Infant Development-Psychomotor Development Index; CAPI: Child Abuse Potential Inventory; CBCL: Child Behavior Checklist; CES-D: Center for Epidemiological Studies Depression Scale; CI: confidence interval; CTS: Conflict Tactics Scale; DAS: Dyadic Adjustment Scale; ES (d): effect size; EPDS: Edinburgh Postnatal Depression Scale; (F): fixed effect; GRADE: Grading of Recommendations Assessment, Development and Evaluation; HOME: Home Observation for Measurement of the Environment; MD: mean difference; N: number; NCATS: Nursing Child Assessment Teaching Scale; NR: not reported; NS: not significant; P: P value; PSI: Parenting Stress Index; Q: Cochran Q test of heterogeneity of the effect size; RCT: randomised controlled trial; RR: risk ratio; SB: Stanford-Binet (Intelligence Scale); STAI: State-Trait Anxiety Inventory

### **Characteristics that may have contributed to the effectiveness of antenatal or postnatal education and/or support interventions for optimal social and emotional development of infants**

Pinquart 2010 showed benefits of parenting education with expectant and new parents and concluded the following related to characteristics of the interventions: “early parenting education interventions work and produce practically meaningful effects, even if these are small in a statistical sense... interventions had stronger effects on outcomes that related directly to the intervention goals... 3 to 6 months is an optimal length of interventions for promoting positive parenting and social development of the child... selective/indicated prevention with professional staff... is recommended for promoting mental health of the child and interventions with an after-birth component are suggested for the promotion of cognitive development.” However, Pinquart 2010 also discussed that, given the small average effect sizes observed, “more effort is needed to improve the intervention effects... which group of parents would benefit most from what kind of intervention with regards to which outcomes remains to be tested.”

Bryanton 2013 revealed possible benefits with postnatal parent education in relation to infant sleep and mothers’ knowledge, however concluded that largely (due to small sample sizes and poor methodology of many current studies), “The benefits of educational programs to participants and their newborns remain unclear.”

***Who could<sup>20</sup> deliver the intervention, program or messages to optimise infant social and emotional wellbeing and development?***

In Bryanton 2013, an increase in maternal knowledge about infant behaviours was seen (up to four weeks postpartum) with infant behaviour interventions. The two studies that contributed data to the meta-analysis had interventions delivered by a nurse practitioner or “experimenter” (Bryanton 2013). Sleep education interventions were also shown to increase infant night-time sleep (at six and 12 weeks), infant day-time sleep (at six but not 12 weeks); while no clear impacts on uninterrupted sleep during the day or night or crying were observed (at six and 12 weeks). There were a total of four studies which contributed data to these outcomes; in two studies a nurse/research nurse delivered the intervention (and in the other two studies, participants were given a video or pamphlet/booklet; and it was unclear who by) (Bryanton 2013).

In Pinquart 2010, benefits of parenting education with expectant and new parents were seen for all outcome measures: children’s cognitive, motor and social development and their mental health, along with child abuse/neglect, parental stress, parental mental health, parenting quality, health promoting behaviour and couples adjustment. Pinquart 2010 conducted weighted multiple linear regression analyses to test for moderating effects of study characteristics; it was observed that interventions led by professionals had stronger effects than those led by paraprofessionals/lay persons with regard to child mental health ( $P < 0.05$ ). In addition selective prevention programs led by professionals were shown to have stronger effects on child mental health than selective prevention led by paraprofessionals ( $P < 0.02$ ) (Pinquart 2010).

***Where could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?***

One of the studies that demonstrated a benefit for maternal knowledge about infant behaviours in Bryanton 2013 was delivered in an examination room of a paediatrician’s office, while the other was held in the mothers’ room for the mothers, and a small room near the nursery for the fathers; both were conducted in the United States (Bryanton 2013).

Two of the four studies reporting on infant sleep or crying were conducted in both the hospital and home (in Canada and the United States), and two were conducted in the hospital (in Australia and the United Kingdom).

In Pinquart 2010 it was reported that most interventions were delivered exclusively in parental homes. Only 16 of the 133 interventions were in hospitals; six in the community; and 26 combined home visits with other locations (e.g. support group meetings in the community).

***To whom could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?***

In one of the studies that demonstrated a benefit for maternal knowledge about infant behaviours in Bryanton 2013, mothers (well educated, adult, married, white, middle class American) and their newborns in the first two weeks of life were included. In the other study, middle-class married couples who had just had their first baby were included (Bryanton 2013).

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<sup>20</sup>We used could here and in the sentences that follow to acknowledge that studies conducted outside of Australia were not precluded. The MHPWC will therefore need to interpret what was found in the literature to the operational realities of the Australian context.

Three of the four studies reporting on sleep and/or crying in Bryanton 2013 included women who had given birth at greater than or equal to 37 weeks gestation, while the fourth study included families within two weeks of giving birth at greater than or equal to 36 weeks gestation (with mothers planning to provide full-time care to the infant for more than 12 weeks post-birth).

In Pinquart 2010, it was reported that approximately two thirds of the interventions worked with families at risk (82/133) and that the majority included only mothers (107/133). On average, parents in the interventions were 24.3 years, 78.8% were expecting or had just given birth to their first child; 58% were married; 21% cohabiting; 59% were members of ethnic minorities; and 56% had completed high school (Pinquart 2010).

The weighted multiple linear regression analyses revealed that interventions focused exclusively on mothers had larger effects on parental mental health than interventions with couples ( $P < 0.05$ ) (Pinquart 2010).

***When** could be the best time for the intervention, program, or message delivery to occur? (In regards to caregiver preferences and accessibility; and in regards to improved outcomes for the infant, child and later on as the adolescent, and for the caregiver)*

One of the studies that demonstrated a benefit for maternal knowledge about infant behaviours in Bryanton 2013 delivered an individual two hour session with each mother-infant dyad within five days of the newborn being two weeks old. In the second study, a 45-60 minute session was given after the second day post-birth but before departure home at day four (Bryanton 2013). In Bryanton 2013, the four studies reporting on infant sleep or crying delivered interventions as follows: provision of leaflet or guide on the postnatal ward; provision of a 30-minute video in hospital postnatally (to take home to view also); a 45 minute consultation at two to three weeks postpartum; and a 45 minute meeting followed by weekly phone contact.

Pinquart 2010 reported that most interventions commenced after childbirth (86/133) (with only 10 held in pregnancy exclusively and 28 held during pregnancy and after childbirth). The average length of intervention was 15.0 months (range: one day to 60 months), and on average parents attended 20 meetings (range: one to 421).

Tests for moderating effects of study characteristics in Pinquart 2010 suggested that the inclusion of a before-birth component did not moderate the size of the observed effects for any of the outcomes (parenting quality, parental stress, child abuse/neglect, health promoting behaviour, cognitive development, social development, child mental health or parental mental health). However, interventions that started after childbirth were shown to have stronger effects on cognitive development of the child than other interventions ( $P < 0.05$ ). Longer interventions were shown on average to have weaker effects on parenting quality ( $P < 0.001$ ) and on social development ( $P < 0.001$ ). Pinquart 2010 reported that interventions lasting three to six months had the greatest effects on parenting quality, followed by shorter and longer interventions; and similarly interventions lasting three to six months had the greatest effects on social development, followed by shorter and longer interventions (Pinquart 2010).

***How** could the intervention, program or messages regarding infant social and emotional wellbeing and development be delivered?*

In one of the studies that showed a benefit for maternal knowledge about infant behaviours in Bryanton 2013, a teaching plan with specific goals (but delivered in a flexible order) was used involving 1) a 25 minute film, 2) an oral and visual presentation of difference states of infant

behaviour and appropriate maternal response, and 3) demonstration of selected items from the NBAS and return demonstration by mothers. In the second study, mothers or fathers (in separate interventions groups) were taught how to administer most items of the NBAS, with information supportive information about infant development related to the infant's performance given (Bryanton 2013). NBAS interventions are also covered later under their own separate category.

The interventions delivered in the four studies contributing to sleep and crying outcomes in Bryanton 2013 were as follows: a leaflet describing a nine point prescriptive program (for crying and sleeping), or a 10-page guide (with written advice and suggestions that could be adapted) to crying and sleeping developed with local health professionals, and a telephone number for CRYISIS (voluntary organisation for parents and young babies); a video to view in hospital and then take home with specific instructions about five steps to soothe infants during crying; a consultation on normal sleep patterns and a 50-page book reinforcing the information; a discussion (TIPS: Tips for Infant and Parent Sleep) regarding sleep information and strategies, together with a 11-page booklet and phone contact to reinforce information and problem solve.

In Pinquart 2010, the main goals of the interventions included:

- Teaching infant care (e.g. ways to soothe the baby, 86%);
- Promoting parental sensitivity and responsiveness (reading baby's signals and responding adequately, 82%);
- Promoting cognitive stimulation of the child (45%);
- Counselling (38%);
- Discussion of future planning/family planning (25%);
- Health promotion (27%);
- Prevention of child abuse (21%);
- Promotion of couple adjustment/marital adjustment (17%).

Tests for moderating effects of study characteristics suggested that the inclusion of a prevention focus (universal versus selective) did not moderate the size of the observed effects for any outcomes (parenting quality, parental stress, child abuse/neglect, health promoting behaviour, cognitive development, social development, child mental health or parental mental health) (Pinquart 2010). However, interventions held in a group format were shown to have larger effects than those delivered to an individual/couple on parental health promoting behaviours ( $P < 0.05$ ), but weaker effect on social development of the child ( $P < 0.05$ ) (Pinquart 2010).

*How could the intervention, program or messages regarding infant social and emotional wellbeing and development be **framed**?*

Bryanton 2013 and Pinquart 2010 did not report on intervention framing.

*What could **impede** or interfere with engagement with interventions or programs or caregivers enacting upon messages?*

Pinquart 2010 suggested that the lower effects of longer interventions on parenting quality and social development for the child could indicate that "longer interventions focus on families with more severe problems that are difficult to change... As a second explanation, longer interventions may be associated with lower retention rates, which could reduce intervention effects... the longest interventions may not be very goal directed, which could impair their results."

*What could **facilitate** or drive engagement with interventions or programs or caregivers enacting upon messages?*

Pinquart 2010 discussed possible benefits of starting interventions after childbirth “As parenting demands and opportunities for promoting child development emerge after the birth of the child, interventions starting after birth seem to be well suited for reducing parenting stress and promoting positive parenting and child development.”

It was also discussed in Pinquart 2010 that interventions delivered in a group format may be “sufficient” to encourage health promoting behaviours, “as many health promoting behaviors are easy to learn (e.g. child immunization schedules).”

## Kangaroo care interventions

### Description of intervention based on the included evidence

Kangaroo care interventions promote skin-to-skin contact, most often between a mother and her newborn, frequent breastfeeding and sometimes, where possible, earlier discharge from hospital (Conde-Agudelo 2014). Of the two systematic reviews included in this category only one presented pooled results (Conde-Agudelo 2014). In this overview kangaroo care interventions are discussed separately to skin-to-skin care interventions as they include skin-to-skin contact and the encouragement of breastfeeding in low birthweight (less than 2500 g), often preterm infants (mostly only after stabilisation), with skin-to-skin contact commencing shortly after birth up to 74 days after birth,<sup>21</sup> most often used intermittently (rather than continuously) for less than two to more than 20 hours per day, in combination with radiant warmer/incubator. The interventions were delivered mostly to mothers cared for by doctors and nurses, in the neonatal intensive care units of hospitals or specific 'kangaroo wards' in hospitals (Conde-Agudelo 2014). The studies were conducted in low, middle and high income countries.

### Evidence summary

Two systematic reviews compared kangaroo care (intermittent and continuous) with no kangaroo care in low birthweight and/or preterm newborns (Conde-Agudelo 2014; Dodd 2005). Dodd 2005 included studies published up to 2003, while Conde-Agudelo 2014 included studies published up to 2014.

Conde-Agudelo 2014 included only RCTs comparing kangaroo care with conventional neonatal care, or early onset with late consent kangaroo care in low birthweight infants; while Dodd 2005 included RCTs, pre-test/post-test designs and other comparative studies of kangaroo care also in low birthweight and/or preterm infants.

Together, these two reviews included 50 relevant studies<sup>22</sup> (31 RCTs, three quasi-experimental, 12 non-experimental, four other comparative studies) with a total of 6,332 participants (ranging from five to 777 in the included studies), published between 1989 and 2012 (Conde-Agudelo 2014; Dodd 2005).

In regards to the timing and intensity of the interventions in Conde-Agudelo 2014 the mean/median age of the infants at initiation of kangaroo care varied from 10 hours to 32 days (median 12 days), while the mean/median duration of intermittent kangaroo care per day was less than two hours in six studies, four to seven hours in two studies, eight to 14 hours in five studies, and at least 20 hours in three studies, with two studies assessing continuous kangaroo care. In Dodd 2005, limited detail was provided regarding the interventions, though it appeared that they ranged in intensity from 10 minutes to continuous kangaroo care.

One of the reviews was judged to be at low risk of bias (Conde-Agudelo 2014) and one review was judged to be at high risk of bias (Dodd 2005) using ROBIS. Using AMSTAR, one review was judged to be 'high' quality (Conde-Agudelo 2014) and one review 'low' quality (Dodd 2005).

One of the two included systematic reviews provided pooled results (Conde-Agudelo 2014). This review (low risk of bias; 'high' quality) included 18 relevant studies (RCTs), with a total of 2,751

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<sup>21</sup>As opposed to the review included under skin-to-skin care interventions where the intervention was delivered to healthy term or late preterm infants beginning soon after birth

<sup>22</sup>With some overlap (see Technical Report)



participants (ranging from 28 to 777 in the included studies), published between 1989 and 2012 (Conde-Agudelo 2014).

For further details regarding the results from single studies from the other review (Dodd 2005), see the Technical Report.

### ***Primary outcome domain***

#### **Infant social and emotional wellbeing or development up to one year of age**

No pooled results were available.

### ***Secondary outcomes domains***

#### **Development for the infant, as a child, and up to 18 years**

Weight, length and head circumference gains were all increased with kangaroo care interventions for low birthweight infants in one review: weight gain at latest follow up (at discharge or 40 weeks' postmenstrual age up to six months of age or six month follow up) (low quality evidence, downgraded due to inconsistency), length gain at latest follow up (40 weeks' postmenstrual age to three months of age) (high quality evidence, not downgraded) and head circumference gain at latest follow up (at discharge or 40 weeks' postmenstrual age to three months of age) (moderate quality evidence, downgraded due to inconsistency) (Conde-Agudelo 2014).

#### **Behaviour for the infant, as a child, and up to 18 years**

No pooled results were available.

#### **Physical wellbeing and safety for the infant, as a child, and up to 18 years**

Kangaroo care for low birthweight infants reduced infant mortality at discharge or 40 to 41 weeks' postmenstrual age (high quality evidence) and at latest follow up (discharge or 40 to 41 weeks' postmenstrual age up to 12 months corrected age) (moderate quality evidence due to imprecision), though the effect of kangaroo care was unclear at six months of age or six month follow up in one review (moderate quality evidence, downgraded due to risk of publication bias) (Conde-Agudelo 2014). In the same review, kangaroo care for low birthweight infants reduced severe infection/sepsis at latest follow up (discharge or 40 to 41 weeks' postmenstrual age to six months' corrected age) and nosocomial infection/sepsis at discharge or 40 to 41 weeks' postmenstrual age (both high quality evidence, not downgraded), however there was no clear effect of kangaroo care for low birthweight infants on mild/moderate infection or illness at latest follow up (40 to 41 weeks' postmenstrual age to six months of age) (low quality evidence, downgraded due to inconsistency) (Conde-Agudelo 2014).

#### **Parent-infant relationship**

No pooled results were available.

#### **Parent/caregiver psychosocial wellbeing**

No pooled results were available.

#### **Parent/caregiver knowledge, practices and behaviours**

In Conde-Agudelo 2014, kangaroo care for low birthweight infants significantly increased breastfeeding at discharge or 40 to 41 weeks' postmenstrual age (low quality evidence, downgraded due to inconsistency) and at three month follow up (moderate quality evidence, downgraded due to inconsistency). There was also an increase in breastfeeding with borderline statistical significance at one to two month follow up (moderate quality evidence, downgraded due to inconsistency).

However, there was no clear effect of kangaroo care for low birthweight infants on breastfeeding at six month follow up (high quality evidence, not downgraded) (Conde-Agudelo 2014).

**Parent/caregiver views of the intervention**

No pooled results were available.

**Family relationships**

No pooled results were available.

**Systems outcomes**

No pooled results were available.

**Potential harms<sup>23</sup>**

In one review (Dodd 2005), single study results show significantly poorer outcomes for growth at three months and one year (within the outcome domain of development for the infant, as a child, and up to 18 years); total sleep (within the outcome domain of behaviour for the infant, as a child, and up to 18 years); and social support (within the outcome domain of family relationships) with kangaroo care compared to standard care. However, these results must be interpreted in context and with caution, as other single study results show positive results for some of these outcomes. For further details regarding potential harms from single studies see the pink shaded rows of the Evidence Tables in the Technical Report.

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<sup>23</sup>In this context, harm refers to a significantly poorer outcome in the intervention group relative to the control group within a pre-specified primary or secondary outcome domain.

**Table 7: Kangaroo care interventions evidence profile**

| <b>KANGAROO CARE INTERVENTIONS</b>  |  |  |  |                            |                   |
|---|--|--|--|----------------------------|-------------------|
| What is the effectiveness of kangaroo care interventions in the first year of an infant's life for optimal social and emotional development for the infant, child and adolescent? |  |  |  |                            |                   |
| <b>Comparison</b>   | No kangaroo care   |  |  |                            |                   |
| <b>Outcome domain</b>   | <b>Outcome measured used in the review(s)</b>  | <b>Results reported in the review(s)</b>   |  |                            | <b>Importance</b> |
|   |  | <b>Result<sup>24,25</sup></b>  | <b>GRADE</b>   | <b>Quality of evidence</b> |                   |
| <b>Infant social and emotional wellbeing or development up to one year of age</b>   | No pooled results were available.  |  |  |                            | CRITICAL          |
| <b>Development for the infant, as a child, and up to 18 years</b>   | Weight gain (g/day) (stabilised infants) ("at latest follow up": at discharge or 40 weeks' postmenstrual age up to 6 months of age or 6 month follow up) | <b>MD (R): 3.74 (95% CI 1.92, 5.56); I<sup>2</sup> 87%; P=0.000056</b><br>(10 RCTs, N=1,072)<br>(Conde-Agudelo 2014) | Risk of bias: 0<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Low                        | IMPORTANT         |
|   | <i>GRADE reasons for downgrading: Inconsistency: very substantial heterogeneity (I<sup>2</sup> &gt; 80%)</i>   |  |  |                            |                   |
|   | Length gain (cm/week) (stabilised infants) ("at latest follow up") (40 weeks' postmenstrual age to 3 months of age)                                      | <b>MD (F): 0.29 (95% CI 0.27, 0.31); I<sup>2</sup> 0%; P &lt; 0.00001</b><br>(2 RCTs, N=251)<br>(Conde-Agudelo 2014) | Risk of bias: 0<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | High                       | IMPORTANT         |
|   | <i>GRADE reasons for downgrading: not downgraded</i>   |  |  |                            |                   |
| <b>Behaviour for the infant, as a child, and up to 18 years</b>   | Head circumference gain (cm/week) (stabilised infants) ("at latest follow up") (at discharge or 40 weeks' postmenstrual age to three months of age)      | <b>MD (R): 0.18 (95% CI 0.09, 0.27); I<sup>2</sup> 71%; P=0.000092</b><br>(3 RCTs, N=369)<br>(Conde-Agudelo 2014)    | Risk of bias: 0<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Moderate                   | CRITICAL          |
|   | <i>GRADE reasons for downgrading: Inconsistency: substantial heterogeneity</i>   |  |  |                            |                   |

<sup>24</sup>All Ns reflect the total numbers (i.e. across both the intervention and control groups)

<sup>25</sup>Bolding indicates a statistically significant pooled result in favour of the intervention

|   |   |   |  |          |           |
|---|---|---|--|----------|-----------|
| Physical wellbeing and safety for the infant, as a child, and up to 18 years  | Mortality (at discharge or 40-41 weeks' postmenstrual age)  | <b>RR (F): 0.60 (95% CI 0.39, 0.92); I<sup>2</sup> 0%; P=0.02</b><br>(8 RCTs, N=1,736)<br>(Conde-Agudelo 2014)  | Risk of bias: 0<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | High     | CRITICAL  |
|   | <i>GRADE reasons for downgrading: not downgraded</i>  |   |  |          |           |
|   | Mortality (at 6 months' of age or 6 month follow up)  | RR (F): 0.99 (95% CI 0.48, 2.02); I <sup>2</sup> 0%;<br>P=0.96<br>(2 RCTs, N=354)<br>(Conde-Agudelo 2014)       | Risk of bias: 0<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Moderate | CRITICAL  |
|   | <i>GRADE reasons for downgrading: Imprecision: wide CIs</i>   |   |  |          |           |
|   | Mortality ("at latest follow up") (discharge or 40-41 weeks' postmenstrual age up to 12 months' corrected age)                                | <b>RR (F): 0.67 (95% CI 0.48, 0.95); I<sup>2</sup> 0%; P=0.03</b><br>(11 RCTs, N=2,167)<br>(Conde-Agudelo 2014) | Risk of bias: 0<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: -1 | Moderate | CRITICAL  |
|   | <i>GRADE reasons for downgrading: Publication bias: funnel plot asymmetry<sup>26</sup></i>  |   |  |          |           |
|   | Severe infection/sepsis (stabilised infants) ("at latest follow up") (discharge or 40-41 weeks' postmenstrual age to 6 months' corrected age) | <b>RR (F): 0.56 (95% CI 0.40, 0.78); I<sup>2</sup> 0%; P=0.008</b><br>(7 RCTs, N=1,343)<br>(Conde-Agudelo 2014) | Risk of bias: 0<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | High     | CRITICAL  |
|   | <i>GRADE reasons for downgrading: not downgraded</i>  |   |  |          |           |
|   | Nosocomial infection/sepsis (stabilised infants) (at discharge or 40-41 weeks' postmenstrual age)   | <b>RR (F): 0.45 (95% CI 0.27, 0.76); I<sup>2</sup> 0%; P=0.001</b><br>(3 RCTs, N=913)<br>(Conde-Agudelo 2014)   | Risk of bias: 0<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | High     | CRITICAL  |
| <i>GRADE reasons for downgrading: not downgraded</i>  |   |   |  |          |           |
| Mild/moderate infection or illness (stabilised infants) "at latest follow up" (40-41 weeks' postmenstrual age to 6 months of age) | RR (R): 1.28 (95% CI 0.87, 1.88); I <sup>2</sup> 82%;<br>P=0.21<br>(4 RCTs, N=1,266)<br>(Conde-Agudelo 2014)                                  | Risk of bias: 0<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0                | Low  | CRITICAL |           |
| <i>GRADE reasons for downgrading: Inconsistency: very substantial heterogeneity (I<sup>2</sup> &gt; 80%)</i>                      |   |   |  |          |           |
| Parent-infant relationship  | No pooled results were available.   |   |  |          | CRITICAL  |
| Parent/caregiver psychosocial wellbeing   | No pooled results were available.   |   |  |          | IMPORTANT |

<sup>26</sup> Assessed by the Evidence Reviewer

|   |   |   |  |           |           |
|---|---|---|--|-----------|-----------|
| Parent/caregiver knowledge, practices and behaviours              | Any breastfeeding (stabilised infants) (at discharge or 40-41 weeks' postmenstrual age)   | <b>RR (R): 1.20 (95% CI 1.06, 1.36); I<sup>2</sup> 81%; P=0.0054</b><br>(9 RCTs, N=1,576)<br>(Conde-Agudelo 2014) | Risk of bias: 0<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Low       | IMPORTANT |
|   | <i>GRADE reasons for downgrading: Inconsistency: very substantial heterogeneity (I<sup>2</sup> &gt; 80%)</i>  |   |  |           |           |
|   | Any breastfeeding (stabilised infants) (at 1-2 month follow up)   | RR (R): 1.33 (95% CI 1.00, 1.78); I <sup>2</sup> 78%; P=0.051<br>(6 RCTs, N=538)<br>(Conde-Agudelo 2014)          | Risk of bias: 0<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Moderate  | IMPORTANT |
|   | <i>GRADE reasons for downgrading: Inconsistency: substantial heterogeneity</i>  |   |  |           |           |
|   | Any breastfeeding (stabilised infants) (at 3 month follow up)   | <b>RR (F): 1.14 (95% CI 1.06, 1.23); I<sup>2</sup> 41%; P=0.00028</b><br>(5 RCTs, N=924)<br>(Conde-Agudelo 2014)  | Risk of bias: 0<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Moderate  | IMPORTANT |
|   | <i>GRADE reasons for downgrading: Inconsistency: substantial heterogeneity</i>  |   |  |           |           |
| Any breastfeeding (stabilised infants) (at 6 month follow up)     | RR (F): 1.12 (95% CI 0.98, 1.29); I <sup>2</sup> 24%; P=0.095<br>(5 RCTs, N=952)<br>(Conde-Agudelo 2014)  | Risk of bias: 0<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0                   | High   | IMPORTANT |           |
| <i>GRADE reasons for downgrading: not downgraded</i>              |   |   |  |           |           |
| Parent/caregiver views of the intervention                        | No pooled results were available.   |   |  |           | IMPORTANT |
| Family relationships  | No pooled results were available.   |   |  |           | CRITICAL  |
| Systems outcomes  | No pooled results were available.   |   |  |           | IMPORTANT |
| <b>Evidence statements</b>  |   |   |  |           |           |
| <b>Development for the infant, as a child, and up to 18 years</b> | <p><u>Weight</u>: Low quality evidence from one systematic review shows that weight gain at latest follow up (at discharge or 40 weeks' postmenstrual age up to six months of age or six month follow up) is increased with kangaroo care for low birthweight infants (10 RCTs, N=1,072).</p> <p><u>Length</u>: High quality evidence from one systematic review shows that length gain at latest follow up (40 weeks' postmenstrual age to three months of age) is increased with kangaroo care for low birthweight infants (two RCTs, N=251).</p> <p><u>Head circumference</u>: Moderate quality evidence from one systematic review shows that head circumference gain at latest follow up (at discharge or 40 weeks' postmenstrual age to three months of age) is increased with kangaroo care for low birthweight infants (three RCTs, N=369).</p> |   |  |           |           |

|   |   |
|---|---|
| <b>Physical wellbeing and safety for the infant, as a child, and up to 18 years</b> | <p><b>Mortality:</b> High quality evidence from one systematic review shows that infant mortality is reduced at discharge or 40 to 41 weeks' postmenstrual age with kangaroo care for low birthweight infants (eight RCTs, N=1,736) with moderate quality evidence at latest follow up (discharge or 40 to 41 weeks' postmenstrual age up to 12 months corrected age) (11 RCTs, N=2,167), though the effect of kangaroo care on mortality at six months of age or six month follow up is unclear (moderate quality evidence: two RCTs, N=354).</p> <p><b>Infection:</b> High quality evidence from one systematic review shows that severe infection/sepsis at latest follow up (discharge or 40 to 41 weeks' postmenstrual age to six months' corrected age) (seven RCTs, N=1,343) and nosocomial infection/sepsis at discharge or 40 to 41 weeks' postmenstrual age (three RCTs, N=913) are reduced with kangaroo care for low birthweight infants, though low quality evidence from the same systematic review indicates no clear effect of kangaroo care on mild/moderate infection or illness at latest follow up (40 to 41 weeks' postmenstrual age to six months of age) (four RCTs, N=1,266).</p> |
| <b>Parent/caregiver knowledge, practices and behaviours</b>                         | <p><b>Breastfeeding:</b> Low quality evidence from one systematic review shows that breastfeeding at discharge or 40 to 41 weeks' postmenstrual age is increased with kangaroo care for low birthweight infants (nine RCTs, N=1,576), and moderate quality evidence shows a probable increase at one to two month follow up (six RCTs, N=538) and at three month follow up (five RCTs, N=924), though high quality evidence shows that the effect at six month follow up is unclear (six RCTs, N=952).</p>  |

**Abbreviations:** cm: centimetre; CI: confidence interval; (F): fixed effect; g: grams; GRADE: Grading of Recommendations Assessment, Development and Evaluation; MD: mean difference; N: number; P: P value; (R): random effects; RCT: randomised controlled trial; RR: risk ratio

**Characteristics that may have contributed to the effectiveness of kangaroo care interventions for optimal social and emotional development of infants**

Conde-Agudelo 2014 suggested that evidence from the review “supports the use of [kangaroo mother care] in [low birthweight] infants as an alternative to conventional neonatal care mainly in resource-limited settings.”

***Who** could<sup>27</sup> deliver the intervention, program or messages to optimise infant social and emotional wellbeing and development?*

Mothers and their infants were cared for by both doctors and nurses in all but two studies in Conde-Agudelo 2014. In one of these studies, the infants in the kangaroo care group were cared for solely by their mothers, supervised by a trained nurse. In the other study, the supportive intervention that promoted kangaroo holding of preterm infants by their mothers was performed by an experienced nurse (Conde-Agudelo 2014).

***Where** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?*

Thirteen studies were conducted in low- or middle-income countries (including India, Ethiopia, Malaysia, Madagascar, Indonesia, Ecuador, Colombia and Mexico) and five in high-income countries

<sup>27</sup>We used could here and in the sentences that follow to acknowledge that studies conducted outside of Australia were not precluded. The MHPWC will therefore need to interpret what was found in the literature to the operational realities of the Australian context.

(United States, United Kingdom and Australia) (Conde-Agudelo 2014). We conducted subgroup analyses based on where the studies were conducted (low/middle income versus high income countries) for the outcomes mortality at discharge or 40 to 41 weeks' postmenstrual age and at latest follow up; no clear subgroup differences were observed for either outcome.

Ten studies in Conde-Agudelo 2014 were performed in neonatal intensive care units of tertiary care, public, maternity, or university hospitals; four were conducted in neonatal units of university hospitals; two in "kangaroo wards" (for kangaroo mother care infants) and neonatal intensive/intermediate care units of tertiary care hospitals (controls); one in both hospital and home; and one in a special care nursery of a hospital.

***To whom*** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?

All infants in the included studies in Conde-Agudelo 2014 were low birthweight. Sixteen studies evaluated kangaroo care in low birthweight infants after stabilisation, and one study evaluated kangaroo mother care in low birthweight infants before stabilisation (Conde-Agudelo 2014). Only five of the studies included infants from multiple pregnancies (Conde-Agudelo 2014). The mean birthweights of infants at recruitment ranged from 968 g to 2,076 g (median 1,595 g) (Conde-Agudelo 2014).

We conducted subgroup analyses based on whether the infants entered the trial before or after stabilisation for the outcomes of mortality at discharge or 40 to 41 weeks' postmenstrual age and at latest follow up. No clear subgroup differences were observed for either outcome.

***When*** could be the best time for the intervention, program, or message delivery to occur? (In regards to caregiver preferences and accessibility; and in regards to improved outcomes for the infant, child and later on as the adolescent, and for the caregiver)

The mean/median age of the low birthweight infants at enrolment in Conde-Agudelo 2014 varied from 10 hours to 32 days (median of the medians 12 days); mean/median age was less than 10 days in nine studies, 11 to 20 days in six studies, and 20 to 32 days in three studies. In the one study that compared early onset kangaroo care with late onset kangaroo care, the mean age at initiation was 19.8 hours in the early onset group, compared with 33.0 hours in the late onset group (Conde-Agudelo 2014). The mean/median duration of intermittent kangaroo care per day was less than two hours in six studies, four to seven hours in two studies, eight to 14 hours in five studies and at least 20 hours in three studies. Two additional studies used continuous kangaroo care (Conde-Agudelo 2014).

We conducted subgroup analyses based on the duration of kangaroo care (less than two hours per day versus eight to 15 hours per day versus at least 20 hours per day) and the infant age at initiation (10 days or younger versus older than 10 days) for the outcomes mortality at discharge or 40 to 41 weeks' postmenstrual age and at latest follow up. No clear subgroup differences were observed for either outcome.

***How*** could the intervention, program or messages regarding infant social and emotional wellbeing and development be delivered?

The studies in Conde-Agudelo 2014 were conducted under a variety of hospital conditions, regulations, and routines. In all studies, the interventions involved skin-to-skin care and encouraged breastfeeding. Among the studies evaluating the intervention in stabilised infants, 13 used

intermittent kangaroo care and three used continuous kangaroo care. In the studies evaluating intermittent kangaroo care, the intervention was a combination of skin-to-skin care and radiant warmer/incubator (Conde-Agudelo 2014).

Conde-Agudelo 2014 performed subgroup analyses based on whether the intervention was intermittent or continuous kangaroo care for the outcomes: mortality, severe infection/sepsis, nosocomial infection/sepsis, mild/moderate infection or illness, weight gain and breastfeeding. No clear subgroup differences were observed for any of these outcomes, except for breastfeeding at one to two month follow up, and three month follow up; for these outcomes the 'intermittent' kangaroo care subgroup showed a significant effect for breastfeeding which was not observed for the 'continuous' subgroup. However, this may reflect the small number of studies in the later subgroup.

*How could the intervention, program or messages regarding infant social and emotional wellbeing and development be **framed**?*

Intervention framing was not covered in Conde-Agudelo 2014.

*What could **impede** or interfere with engagement with interventions or programs or caregivers enacting upon messages?*

Factors impeding intervention engagement were not covered in Conde-Agudelo 2014.

*What could **facilitate** or drive engagement with interventions or programs or caregivers enacting upon messages?*

Factors facilitating intervention engagement were not covered in Conde-Agudelo 2014.



## Massage interventions

### Description of intervention based on the included evidence

Infant massage is the systematic tactile stimulation of the infant with human hands, with the practice varying across the world and great variability in techniques used (for example, from the use of nurturing touch and respectful communication, to the promotion of yoga-based movements and flexibility) (Bennett 2013). Only one systematic review was included in this category and it provided pooled results (Bennett 2013). In this overview infant massage interventions were assessed in the general infant population, specifically full-term infants of a healthy weight under the age of six months with no underlying health conditions, most often commencing within one week of birth and conducted in a community setting (rather than a hospital setting), ranging from brief to long-term. Massage technique (including intensity or amount of pressure) varied (Bennett 2013).

### Evidence summary

One systematic review compared infant massage interventions with usual care (Bennett 2013). Bennett 2013 searched for studies published up to 2011, and included studies that randomised healthy parent-infant dyads (where the infant was under the age of six months) to an infant massage group or a 'no-treatment' control group, which used a standardised outcome measure of infant mental or physical development.

This review included 34 studies<sup>28</sup> (25 RCTs and nine qRCTs) with a total of 3,984 participants (ranging from 21 to 400 in the included studies), published between 1988 and 2010 (Bennett 2013).

The massage interventions included in Bennett 2013 varied in terms of frequency and duration, from 'brief' interventions (single session), to 'short-term' interventions (up to four weeks), 'medium-term' interventions (four to 12 weeks) and 'long-term' interventions (12 to 26 weeks).

This review was judged to be at low risk of bias using ROBIS and of 'high' quality using AMSTAR (Bennett 2013).

Bennett 2013 provided pooled results.

### Primary outcome domain

#### Infant social and emotional wellbeing or development up to one year of age

No clear impact on infant temperament (measured using the CCTI, IBQ and RITQ) in regard to activity (very low quality evidence, downgraded due to high risk of bias, inconsistency and imprecision), persistence (low quality evidence, downgraded due to high risk of bias and imprecision), and soothability (very low quality evidence, downgraded due to high risk of bias, inconsistency and imprecision) was seen with massage interventions post-intervention (four weeks to three months) (Bennett 2013).

### Secondary outcomes domains

#### Development for the infant, as a child, and up to 18 years

Several measures of infant growth were improved with massage interventions post-intervention in one review: weight (four weeks to six months), length (four weeks to three months) and head

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<sup>28</sup>For the majority of studies, massage was provided by parents; in a small number of studies, massage was provided by researchers; in a number of studies, the massage provider was not clear.

circumference (four to six weeks) (all very low quality evidence, downgraded due to high risk of bias and inconsistency) (Bennett 2013). In the same review, psychomotor development (measured using the BSID or Levin PDI) was improved post-intervention (three to six months) (low quality evidence, downgraded due to high risk of bias), but there was no clear difference in cognitive development (measured using the BSID or Levin MDI) post-intervention (three to six months) (very low quality evidence, downgraded due to high risk of bias, inconsistency and imprecision) (Bennett 2013). There were also improved gross motor and fine motor scores seen in this review (both low quality evidence, downgraded due to high risk of bias), but no clear differences in language scores (very low quality evidence, downgraded due to high risk of bias, inconsistency and imprecision) (all measured using the GDS or Capital Institute Mental check-list) post-intervention (one to two months) (Bennett 2013).

### **Behaviour for the infant, as a child, and up to 18 years**

Social, crying and sleep behaviour all showed some improvements with massage interventions in one review. Personal-social behaviour (measured using the GDS) or Capital Institute Mental Checklist) was improved post-intervention (one to two months) (very low quality evidence, downgraded due to high risk of bias and inconsistency), crying or fussing time was reduced post-intervention (one to 16 weeks) (low quality evidence, downgraded due to high risk of bias) and infant sleep duration over 24 hours was increased post-intervention (four weeks to three months) (very low quality evidence, downgraded due to high risk of bias and inconsistency) (Bennett 2013). In the same review, there was no clear difference in the increase in 24 hours sleep or duration of night sleep post-intervention at four weeks (very low quality evidence, downgraded due to inconsistency and imprecision) (Bennett 2013).

### **Physical wellbeing and safety for the infant, as a child, and up to 18 years**

No pooled results were available.

### **Parent-infant relationship**

Massage interventions did not appear have any impact on parent-infant relationships in one review, specifically on the combined mother-infant interactions (measured using the NCATS and Murray GRS) post-intervention (five to six weeks) (very low quality evidence, downgraded due to high risk of bias, inconsistency and imprecision) or at follow up (12 to 24 months) (low quality evidence, downgraded due to high risk of bias and imprecision), maternal sensitivity (measured using the Murray GRS subscales) post-intervention (five to six weeks) (very low quality evidence, downgraded due to high risk of bias, inconsistency and imprecision) and infant interactions with their mothers (infant contribution, measured using the Murray BRS subscales) post-intervention (five to six weeks) (very low quality evidence, downgraded due to high risk of bias, inconsistency and imprecision) (Bennett 2013).

### **Parent/caregiver psychosocial wellbeing**

Massage interventions showed no clear impact on parenting stress (measured using the PSI) post-intervention (four weeks to two months) in one review (very low quality evidence, downgraded due to high risk of bias, inconsistency and imprecision) (Bennett 2013).

### **Parent/caregiver knowledge, practices and behaviours**

No pooled results were available.

### **Parent/caregiver views of the intervention**

No pooled results were available.

## Family relationships

No pooled results were available.

## Systems outcomes

No pooled results were available.

**Table 8: Massage interventions evidence profile**

| <b>MASSAGE INTERVENTIONS</b>  |   |   |  |                     |            |
|---|---|---|--|---------------------|------------|
| What is the effectiveness of massage interventions for infants in their first year of life for optimal social and emotional development for the infant, and later on as a child and adolescent? |   |   |  |                     |            |
| Comparison  | 'No treatment' control  |   |  |                     |            |
| Outcome domain  | Outcome measure used in the review(s)   | Results reported in the review(s) and GRADE   |  |                     | Importance |
|   |   | Result <sup>29,30</sup>   | GRADE  | Quality of evidence |            |
| <b>Infant social and emotional wellbeing or development up to one year of age</b>   | Infant temperament: activity (CCTI; IBQ; RITQ) (post-intervention: 4 weeks to 3 months)   | SMD (R): 0.39 (95% CI -0.34, 1.13); I <sup>2</sup> 75%; P=0.20 (1 RCT, 2 qRCTs, N=121) (Bennett 2013) | Risk of bias: -2<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Very low            | IMPORTANT  |
|   | <i>GRADE reasons for downgrading: <b>Risk of bias:</b> 1 RCT with unclear allocation concealment; two qRCTs; <b>Inconsistency:</b> substantial heterogeneity; <b>Imprecision:</b> studies with small sample sizes; wide CIs</i> |   |  |                     |            |
|   | Infant temperament: persistence (CCTI; RITQ) (post-intervention: 6 weeks to 3 months)   | SMD (R): 0.24 (95% CI -0.20, 0.67); I <sup>2</sup> 0%; P=0.29 (1 RCT, 1 qRCT, N=81) (Bennett 2013)    | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0  | Low                 | IMPORTANT  |
|   | <i>GRADE reasons for downgrading: <b>Risk of bias:</b> 1 RCT with unclear allocation concealment and 1 qRCT; <b>Imprecision:</b> studies with small sample sizes; wide CIs</i>  |   |  |                     |            |
| <b>Infant temperament: soothability (CCTI; IBQ) (post-intervention: 4-6 weeks)</b>  | SMD (R): -0.30 (95% CI -0.94, 0.35); I <sup>2</sup> 52%; P=0.37 (2 qRCTs, N=80) (Bennett 2013)  | Risk of bias: -2<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0    | Very low   | IMPORTANT           |            |
|   | <i>GRADE reasons for downgrading: <b>Risk of bias:</b> 2 qRCTs; <b>Inconsistency:</b> substantial heterogeneity; <b>Imprecision:</b> studies with small sample sizes; wide CIs</i>  |   |  |                     |            |

<sup>29</sup> All Ns reflect the total numbers (i.e. across both the intervention and control groups)

<sup>30</sup> Bolding indicates a statistically significant pooled result in favour of the intervention

|  |   |   |   |          |           |
|--|---|---|---|----------|-----------|
| Development for the infant, as a child, and up to 18 years   | Weight (g) (post-intervention: 4 weeks to 6 months)   | <b>MD (R): -965.25 (95% CI -1360.52, -569.98); I<sup>2</sup> 100%; P &lt; 0.00001</b><br>(15 RCTs, 3 qRCTs, N=2,271) (Bennett 2013) | Risk of bias: -2<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Very low | IMPORTANT |
|  | <i>GRADE reasons for downgrading: Risk of bias: most RCTs with probable or unclear lack of allocation concealment and 3 qRCTs; Inconsistency: very substantial heterogeneity (I<sup>2</sup> &gt; 80%)</i> |   |   |          |           |
|  | Length (cm) (post-intervention: 4 weeks to 3 months)  | <b>MD (R): -1.30 (95% CI -1.60, -1.00); I<sup>2</sup> 80%; P &lt; 0.00001</b><br>(9 RCTs, 2 qRCTs, N=1,683) (Bennett 2013)          | Risk of bias: -2<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Very low | IMPORTANT |
|  | <i>GRADE reasons for downgrading: Risk of bias: most RCTs with probable or unclear lack of allocation concealment and 2 qRCTs; Inconsistency: substantial heterogeneity</i>                               |   |   |          |           |
|  | Head circumference (cm) (post-intervention: 4-6 weeks)  | <b>MD (R): -0.81 (95% CI -1.18, -0.45); I<sup>2</sup> 87%; P &lt; 0.0001</b><br>(7 RCTs, 2 qRCTs, N=1,423) (Bennett 2013)           | Risk of bias: -2<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Very low | IMPORTANT |
|  | <i>GRADE reasons for downgrading: Risk of bias: most RCTs with probable or unclear lack of allocation concealment and 2 qRCTs; Inconsistency: very substantial heterogeneity (I<sup>2</sup> &gt; 80%)</i> |   |   |          |           |
|  | Psychomotor development (BSID-PDI; Levin PDI) (post-intervention: 3-6 months)   | <b>SMD (R): -0.35 (95% CI -0.54, -0.15); I<sup>2</sup> 1%; P=0.0004</b><br>(3 RCTs, 1 qRCT, N=466) (Bennett 2013)                   | Risk of bias: -2<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | Low      | IMPORTANT |
|  | <i>GRADE reasons for downgrading: Risk of bias: 3 RCTs with probable or unclear lack of allocation concealment and 1 qRCT</i>   |   |   |          |           |
| Cognitive development (BSID-MDI; Levin MDI) (post-intervention (3-6 months)  | <b>SMD (R): -0.27 (95% CI -0.64, 0.11); I<sup>2</sup> 69%; P=0.06</b><br>(3 RCTs, 1 qRCT, N=466) (Bennett 2013)   | Risk of bias: -2<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0                                  | Very low  | CRITICAL |           |
| <i>GRADE reasons for downgrading: Risk of bias: 3 RCTs with probable or unclear lack of allocation concealment and 1 qRCT; Inconsistency: substantial heterogeneity; Imprecision: wide CIs</i> |   |   |   |          |           |

|   |   |   |  |          |           |
|---|---|---|--|----------|-----------|
|   | Gross motor development (GDS; Capital Institute Mental Checklist) (post-intervention: 1-2 months)   | <b>SMD (R): -0.44 (95% CI -0.70, -0.18); I<sup>2</sup> 0%; P=0.0008</b><br>(2 RCTs, N=237) (Bennett 2013)       | Risk of bias: -2<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0   | Low      | IMPORTANT |
|   | <i>GRADE reasons for downgrading: Risk of bias: 2 RCTs with probable lack of allocation concealment</i>   |   |  |          |           |
|   | Fine motor development (GDS; Capital Institute Mental Checklist) (post-intervention: 1-2 months)  | <b>SMD (R): -0.61 (95% CI -0.87, -0.35); I<sup>2</sup> 0%; P &lt; 0.00001</b><br>(2 RCTs, N=237) (Bennett 2013) | Risk of bias: -2<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0   | Low      | IMPORTANT |
|   | <i>GRADE reasons for downgrading: Risk of bias: 2 RCTs with probable lack of allocation concealment</i>   |   |  |          |           |
|   | Language development (GDS; Capital Institute Mental Checklist) (post-intervention: 1-2 months)  | SMD (R): -0.82 (95% CI -1.67, 0.03); I <sup>2</sup> 86%; P < 0.06<br>(2 RCTs, N=237) (Bennett 2013)             | Risk of bias: -2<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Very low | CRITICAL  |
|   | <i>GRADE reasons for downgrading: Risk of bias: 2 RCTs with probable lack of allocation concealment; Inconsistency: very substantial heterogeneity (I<sup>2</sup> &gt; 80%); Imprecision: studies with small sample sizes; wide CIs</i> |   |  |          |           |
| <b>Behaviour for the infant, as a child, and up to 18 years</b> | Personal-social behaviour (GDS; Capital Institute Mental Checklist) (post-intervention: 1-2 months)   | <b>SMD (R): -0.90 (95% CI -1.16, -0.18); I<sup>2</sup> 80%; P=0.01</b><br>(2 RCTs, N=237) (Bennett 2013)        | Risk of bias: -2<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | Very low | CRITICAL  |
|   | <i>GRADE reasons for downgrading: Risk of bias: RCTs with probable lack of allocation concealment; Inconsistency: substantial heterogeneity</i>   |   |  |          |           |
|   | Crying (crying or fussing time (hours per day)) (post-intervention: 1-16 weeks)   | <b>MD (R): -0.36 (95% CI -0.52, -0.19); I<sup>2</sup> 5%; P &lt; 0.0001</b><br>(4 RCTs, N=341) (Bennett 2013)   | Risk of bias: -2<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0   | Low      | CRITICAL  |
|   | <i>GRADE reasons for downgrading: Risk of bias: 2 RCTs with probable lack of allocation concealment, 1 RCT with unclear allocation concealment</i>  |   |  |          |           |

|   |  |   |  |          |          |
|---|--|---|--|----------|----------|
|   | Sleep (sleep duration over 24 hours (hours)) (post-intervention: 4 weeks to 3 months)  | <b>MD (R): -0.91 (95% CI -1.15, -0.30); I<sup>2</sup> 94%; P &lt; 0.00001</b><br>(4 RCTs, N=634) (Bennett 2013) | Risk of bias: -2<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | Very low | CRITICAL |
|   | <i>GRADE reasons for downgrading: Risk of bias: three RCTs with probable lack of allocation concealment; Inconsistency: very substantial heterogeneity (I<sup>2</sup> &gt; 80%)</i>              |   |  |          |          |
|   | Sleep (mean increase in 24 hour sleep (hours)) (post-intervention: 4 weeks)  | SMD (R): -1.47 (95% CI -4.43, 1.49); I <sup>2</sup> 99%; P=0.33<br>(2 RCTs, N=225) (Bennett 2013)               | Risk of bias: 0<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0  | Very low | CRITICAL |
|   | <i>GRADE reasons for downgrading: Inconsistency: very substantial heterogeneity (I<sup>2</sup> &gt; 80%); Imprecision: studies with small sample sizes; wide CIs</i>                             |   |  |          |          |
|   | Sleep (mean increase in duration of night sleep (hours)) (post-intervention: 4 weeks)  | SMD (R): -1.28 (95% CI -3.66, 1.10); I <sup>2</sup> 98%; P=0.29<br>(2 RCTs, N=225) (Bennett 2013)               | Risk of bias: 0<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0  | Very low | CRITICAL |
|   | <i>GRADE reasons for downgrading: Inconsistency: very substantial heterogeneity (I<sup>2</sup> &gt; 80%); Imprecision: studies with small sample sizes; wide CIs</i>                             |   |  |          |          |
| <b>Physical wellbeing and safety for the infant, as a child, and up to 18 years</b> | No pooled results were available.  |   |  |          | CRITICAL |
| <b>Parent-infant relationship</b>   | Combined mother-infant interactions (total NCATS; Murray GRS) (post-intervention: 5-16 weeks)  | SMD (R): -0.26 (95% CI -1.01, 0.48); I <sup>2</sup> 75%<br>P=0.49<br>(2 RCTs, 1 qRCT; N=131) (Bennett 2013)     | Risk of bias: -1<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Very low | CRITICAL |
|   | <i>GRADE reasons for downgrading: Risk of bias: 1 RCT with unclear allocation concealment and 1 qRCT; Inconsistency: substantial heterogeneity; Imprecision: studies with small sample sizes</i> |   |  |          |          |
|   | Combined mother-infant interactions (total NCATS; Murray GRS) (follow up at 12-24 months)  | SMD (R): -0.20 (95% CI -0.69, 0.29); I <sup>2</sup> 0%; P=0.43<br>(1 RCT, 1 qRCT, N=65) (Bennett 2013)          | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0  | Low      | CRITICAL |
|   | <i>GRADE reasons for downgrading: Risk of bias: 1 qRCT; Imprecision: studies with small sample sizes</i>   |   |  |          |          |
|   | Maternal sensitivity (Murray GRS subscale: warm to cold) (post-intervention: 5-6 weeks)  | MD (R): -0.34 (95% CI -1.07, 0.40); I <sup>2</sup> 91%; P=0.37<br>(1 RCT, 1 qRCT, N=84) (Bennett 2013)          | Risk of bias: -1<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Very low | CRITICAL |

|   |  |  |          |          |
|---|--|--|----------|----------|
| <p><i>GRADE reasons for downgrading: Risk of bias: 1 RCT with unclear allocation concealment and 1 qRCT; Inconsistency: very substantial heterogeneity (<math>I^2 &gt; 80\%</math>); Imprecision: studies with small sample sizes</i></p> |  |  |          |          |
| Maternal sensitivity (Murray GRS subscale: non-intrusive to intrusive) (post-intervention: 5-6 weeks)   | MD (R): -0.10 (95% CI -0.85, 0.66); $I^2$ 90%; P=0.80 (1 RCT, 1 qRCT, N=84) (Bennett 2013) | Risk of bias: -1<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Very low | CRITICAL |
| <p><i>GRADE reasons for downgrading: Risk of bias: 1 RCT with unclear allocation concealment and 1 qRCT; Inconsistency: very substantial heterogeneity (<math>I^2 &gt; 80\%</math>); Imprecision: studies with small sample sizes</i></p> |  |  |          |          |
| Infant interactions with mother (infant contribution: Murray GRS subscale: attentive to non-attentive) (post-intervention: 5-6 weeks)   | MD (R): -0.47 (95% CI -1.47, 0.52); $I^2$ 84%; P=0.35 (1 RCT, 1 qRCT, N=84) (Bennett 2013) | Risk of bias: -1<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Very low | CRITICAL |
| <p><i>GRADE reasons for downgrading: Risk of bias: 1 RCT with unclear allocation concealment and 1 qRCT; Inconsistency: very substantial heterogeneity (<math>I^2 &gt; 80\%</math>); Imprecision: studies with small sample sizes</i></p> |  |  |          |          |
| Infant interactions with mother (infant contribution: Murray GRS subscale: lively to inert) (post-intervention: 5-6 weeks)  | MD (R): -0.46 (95% CI -1.45, 0.53); $I^2$ 86%; P=0.36 (1 RCT, 1 qRCT, N=84) (Bennett 2013) | Risk of bias: -1<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Very low | CRITICAL |
| <p><i>GRADE reasons for downgrading: Risk of bias: 1 RCT with unclear allocation concealment and 1 qRCT; Inconsistency: very substantial heterogeneity (<math>I^2 &gt; 80\%</math>); Imprecision: studies with small sample sizes</i></p> |  |  |          |          |
| Infant interactions with mother (Murray GRS subscale: happy to distressed) (post-intervention: 5-6 weeks)   | MD (R): -0.35 (95% CI -1.29, 0.59); $I^2$ 84%; P=0.46 (1 RCT, 1 qRCT, N=84) (Bennett 2013) | Risk of bias: -1<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Very low | CRITICAL |
| <p><i>GRADE reasons for downgrading: Risk of bias: 1 RCT with unclear allocation concealment and 1 qRCT; Inconsistency: very substantial heterogeneity (<math>I^2 &gt; 80\%</math>); Imprecision: studies with small sample sizes</i></p> |  |  |          |          |

|   |  |  |  |          |           |
|---|--|--|--|----------|-----------|
| <b>Parent/caregiver psychosocial wellbeing</b>                                    | Parenting stress (PSI: child characteristics subscale) (post-intervention: 4 weeks to 2 months)  | MD (R): -10.85 (95% CI -53.86, 32.16); I <sup>2</sup> 90%; P=0.62 (1 RCT, 1 qRCT, N=55) (Bennett 2013) | Risk of bias: -1<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Very low | IMPORTANT |
|   | <i>GRADE reasons for downgrading: Risk of bias: 1 qRCT; Inconsistency: very substantial heterogeneity (I<sup>2</sup> &gt; 80%); Imprecision: studies with small sample sizes; wide CIs</i>   |  |  |          |           |
| <b>Parent/caregiver knowledge, practices and behaviours</b>                       | No pooled results were available.  |  |  |          | CRITICAL  |
| <b>Parent/caregiver views of the intervention</b>                                 | No pooled results were available.  |  |  |          | IMPORTANT |
| <b>Family relationships</b>   | No pooled results were available.  |  |  |          | CRITICAL  |
| <b>Systems outcomes</b>   | No pooled results were available.  |  |  |          | IMPORTANT |
| <b>Evidence statements</b>  |  |  |  |          |           |
| <b>Infant social and emotional wellbeing or development up to one year of age</b> | <u>Temperament</u> : Low to very low quality evidence from one systematic review suggests no clear impact of massage interventions on infant temperament post-intervention (measured using the CCTI, IBQ and RITQ) (activity: four weeks to three months (one RCT, two qRCTs, N=121); persistence: six weeks to three months (one RCT, one qRCT, N=81); or soothability: four to six weeks (two qRCTs, N=80).  |  |  |          |           |
| <b>Development for the infant, as a child, and up to 18 years</b>                 | <u>Weight, length and head circumference</u> : Very low quality evidence from one systematic review shows post-intervention increases in weight (four weeks to six months) (15 RCTs, three qRCTs, N=2,271); length (four weeks to three months) (nine RCTs, two qRCTs, N=1,683) and head circumference (four to six weeks) (seven RCTs, two qRCTs, N=1,423) with massage interventions.<br><u>Psychomotor development</u> : Low quality evidence from one systematic review shows improved psychomotor development with massage interventions (measured using the BSID or Levin PDI) post-intervention (three to six months) (three RCTs, one qRCT, N=466).<br><u>Cognitive development</u> : Very low quality evidence from one systematic review shows no clear difference in cognitive development with massage interventions (measured using the BSID or Levin MDI) post-intervention (three to six months) (three RCTs, one qRCT, N=466).<br><u>Motor and language development</u> : Low to very low quality evidence from one systematic review shows improved gross motor and fine motor development with massage interventions but no clear difference in language development (measured using the GDS and Capital Institute Mental Checklist) post-intervention (at one to two months) (two RCTs, N=237). |  |  |          |           |



|  |  |
|--|--|
| <p><b>Behaviour for the infant, as a child, and up to 18 years</b></p> | <p><u>Personal-social behaviour</u>: Very low quality evidence from one systematic review shows improved personal-social behaviour with massage interventions (measured using the GDS and Capital Institute Mental Checklist) post-intervention (at one to two months) (two RCTs, N=237).</p> <p><u>Crying</u>: Low quality evidence from one systematic review shows a reduction in crying or fussing time with massage interventions post-intervention (one to 16 weeks) (four RCTs, N=341).</p> <p><u>Sleep</u>: Very low quality evidence from one systematic review shows increased infant sleep duration over 24 hours with massage interventions post-intervention (four weeks to three months) (four RCTs, N=634), but no mean increase in 24 hour sleep (two RCTs, N=225) or duration of night sleep post-intervention (four weeks) (two RCTs, N=225).</p>  |
| <p><b>Parent-infant relationship</b></p>                               | <p><u>Mother-infant interactions</u>: Low to very low quality evidence from one systematic review shows no clear differences in mother and child interactions (measured using the NCATS and Murray GRS) with massage interventions post-intervention (at five to 16 weeks) (two RCTs, one qRCT, N=131) or follow up (12 to 24 months) (one RCT, one qRCT, N=65).</p> <p><u>Maternal sensitivity</u>: Very low quality evidence from one systematic review shows no clear differences in maternal sensitivity (warm/cold and non-intrusive/intrusive maternal behaviours: measured using the Murray GRS) with massage interventions post-intervention (at five to six weeks) (one RCT, one qRCT, N=84).</p> <p><u>Infant interactions with mother (infant contribution)</u>: Very low quality evidence from one systematic review shows no clear differences in infants' interactions with their mothers (attentive/non-attentive; lively/inert and happy/distressed infant responses: measured using the Murray GRS) with massage interventions post-intervention (five to six weeks) (one RCT, one qRCT, N=84).</p> |
| <p><b>Parent/caregiver psychosocial wellbeing</b></p>                  | <p><u>Parenting stress</u>: Very low quality evidence from one systematic review shows no clear differences in parenting stress (measured using the PSI) with massage interventions post-intervention (at four weeks to two months) (one RCT, one qRCT, N=55).</p>   |

**Note:** results shown as negative and bolded favour the massage intervention; post-intervention was generally up to four weeks

**Abbreviations:** BSID: Bayley Scales of Infant Development; CCTI: Colorado Child Temperament Inventory; CI: confidence interval; cm: centimetres; g: grams; GDS: Gesell Developmental Schedules; GRADE: Grading of Recommendations Assessment, Development and Evaluation; GRS: Global Rating Scale; IBQ: Infant Behaviour Questionnaire; MD: mean difference; MDI: mental development index; N: number; NCATS: Nursing Child Teaching Assessment Scale; P: P value; PDI: psychomotor development index; PSI: Parenting Stress Index; qRCT: quasi-randomised controlled trial; (R): random effects; RCT: randomised controlled trial; RITQ: Revised Infant Temperament Questionnaire; SMD: standardised mean difference

### **Characteristics that may have contributed to the effectiveness of massage interventions for optimal social and emotional development of infants**

Bennett 2013 focussed on general infant populations, excluding preterm and low birthweight infants in hospital settings. The available evidence, of poor quality, largely does not support the use of infant massage interventions with low-risk groups of parents and infants. Due to variability in settings, populations and interventions together with the poor methodological quality of the included trials, it is difficult to determine the characteristics that may have contributed to the effectiveness observed for some outcomes.

We have explored these characteristics for infant temperament (as a measure of our primary outcome), and also for weight, length and head circumference (as measures of development,

demonstrating benefit, and with sufficient studies to justify the conduct of subgroup analyses). No clear difference with massage interventions was shown for infant temperament overall (Bennett 2013). Infant weight, length (both at four weeks to six months) and head circumference (at four to six weeks) were all significantly higher following massage interventions (Bennett 2013).

***Who*** could<sup>31</sup> deliver the intervention, program or messages to optimise infant social and emotional wellbeing and development?

In two of the trials, where mothers delivered the massage intervention significant improvements in infant temperament were observed. In a third trial, researchers delivered the massage intervention and no clear difference was found in infant temperament (Bennett 2013).

We constructed subgroup analyses comparing trials where mothers, researchers and/or staff, and researchers then mothers performed massage on infants. While the subgroup interaction test between these groups was not significant for infant weight, significant interaction tests for length and head circumference suggested that researchers/staff massaging infants may have a greater effect on this outcome than mothers.

***Where*** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?

Two trials showing a significant difference in infant temperament were located in community hospitals and parenting classes respectively. The third trial, showing no clear difference, was located in a day care/nursery school. All three trials were conducted in the United States (Bennett 2013).

Of the 18 trials reporting infant weight, 13 were conducted in China, two in the United States and one each in India, Korea and Iran (Bennett 2013). Four trials were located in community hospitals or clinics and one trial each was located in primary care (with postnatal care in hospital), maternity ward and then home, day care/nursery school and an orphanage. The remaining 10 trials did clearly state where they were located (Bennett 2013).

***To whom*** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?

The two trials showing a significant difference in infant temperament included newborn infants of primiparous women and babies less than nine months, while the third non-significant trial included full-term infants aged one to three months with adolescent depressed mothers (Bennett 2013).

We constructed subgroup analyses comparing trials in newborns with trials in infants between two weeks and three months of age. None of the subgroup interaction tests for infant weight, length or head circumference were significant.

***When*** could be the best time for the intervention, program, or message delivery to occur? (In regards to caregiver preferences and accessibility; and in regards to improved outcomes for the infant, child and later on as the adolescent, and for the caregiver)

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<sup>31</sup>We used could here and in the sentences that follow to acknowledge that studies conducted outside of Australia were not precluded. The MHPWC will therefore need to interpret what was found in the literature to the operational realities of the Australian context.

Two trials assessing infant temperament had a medium duration – one trial showing a positive effect on infant temperament involved five to seven minutes massage daily until the baby reached three months of age, and the other non-significant trial involved 15 minutes massage a day over six weeks. The third trial, of 45 to 60 minute sessions once a week over four weeks (with mothers encouraged to practise massaging their babies between sessions), had a significant benefit on infant temperament (Bennett 2013).

We constructed subgroup analyses comparing trials of short, medium and long duration of intervention and, assessing the impact of duration of follow up. None of the subgroup interaction tests for infant weight, length or head circumference were significant for intervention duration. Subgroup interaction tests indicated that longer follow up (six to eight months) was more effective than shorter follow up for infant head circumference, but not for infant weight or length. However these results were largely driven by one trial.

***How** could the intervention, program or messages regarding infant social and emotional wellbeing and development be delivered?*

In one of three arms of a trial with a positive effect on infant temperament, massage was accompanied by multisensory stimulation during expected sleep periods. The other positive trial did not address how the intervention was delivered. The single non-significant trial employed a complete face and body massage using mineral body oil (Bennett 2013).

In one trial, infant weight, height and head circumference were significantly increased with a massage intervention that also involved auditory (female voice) and visual (eye-to-eye) stimulation. In another trial, where infants were massaged over their body with sesame oil, infant weight and length (but not head circumference) showed significant increases with massage. One trial only assessed infant weight and length and these were both significantly increased with a massage intervention that used a set of training programs adapted to the age and development of the infant. Considering the three trials with non-significant results, one used herbal oil, sesame oil, mustard oil or mineral oil when infants were massaged, one used complete face and body massage using mineral body oil, and one added multisensory stimulation during expected sleep periods in one of three arms of the trial. The latter two trials only assessed infant weight. The remaining trials did not report details relating to how their massage intervention was delivered (Bennett 2013).

*How could the intervention, program or messages regarding infant social and emotional wellbeing and development be **framed**?*

Intervention framing was not covered in Bennett 2013.

*What could **impede** or interfere with engagement with interventions or programs or caregivers enacting upon messages?*

Bennett 2013 did not address impeding factors.

*What could **facilitate** or drive engagement with interventions or programs or caregivers enacting upon messages?*

Bennett 2013 did not address enabling factors.

## **Interventions for preventing postnatal depression**

### **Description of intervention based on the included evidence**

Non-pharmaceutical interventions for preventing postnatal depression may include psychological and psychosocial interventions, with an aim of reducing the number of women with depression postnatally, and thus preventing poor maternal-infant interactions and adverse child developmental outcomes (Dennis 2013). Only one systematic review was included in this category and it provided pooled results (Dennis 2013).

In this review, specific psychosocial interventions include antenatal and postnatal classes/groups, professional and lay-based home visits, telephone support early postpartum follow-up and continuity/models of care; while specific psychological interventions include debriefing, cognitive behaviour therapy and interpersonal therapy. Such interventions target either 'at-risk' women (based on various factors believed to put them at additional likelihood of developing postpartum depression), as well as women from the general population (Dennis 2013), and may be provided by professionals or lay individuals, to individuals or to groups of women, most often with multiple contacts across the antenatal and postpartum period, or the first month postpartum (Dennis 2013). Most interventions were delivered in classes as group sessions (with additional phone support in one study) or in clinics as individual sessions (22 studies overall). In five studies, the interventions were provided as home visits, with additional phone support in one study. One study delivered the intervention solely by phone and another study delivered a complex intervention through local government.

### **Evidence summary**

One systematic review compared psychosocial and psychological interventions for preventing postnatal depression with predominately usual care (Dennis 2013). Dennis 2013 searched for studies up to 2011, and included published/unpublished RCTs of acceptable quality comparing a psychosocial or psychological preventive intervention for postpartum depression with usual antenatal, intrapartum or postpartum care.

This review included 30 relevant studies (RCTs, including three cRCTs) with a total of 51,369 participants (ranging from 37 to 19,193 in the included studies), published between 1995 and 2011.

In Dennis 2013 the interventions varied, with a few providing only an antenatal component, and the majority providing antenatal and postnatal components, or a postnatal component only; the majority of interventions provided multiple contacts.

This review was judged to be at low risk of bias using ROBIS, and was judged to be 'high' quality using AMSTAR (Dennis 2013).

Dennis 2013 provided pooled results.

### **Primary outcome domain**

#### **Infant social and emotional wellbeing or development up to one year of age**

No pooled results were available.

## **Secondary outcomes domains**

### **Development for the infant, as a child, and up to 18 years**

No pooled results were available.

### **Behaviour for the infant, as a child, and up to 18 years**

No pooled results were available.

### **Physical wellbeing and safety for the infant, as a child, and up to 18 years**

No pooled results were available.

### **Parent-infant relationship**

Psychological and psychosocial interventions did not have a clear effect on maternal-infant attachment (measured using the Dysfunction Interaction Scale of the PSI) (at 24 to 52 weeks postpartum) (moderate quality evidence, downgraded due to imprecision).

### **Parent/caregiver psychosocial wellbeing**

Psychological and psychosocial interventions reduced depressive symptomatology (measured using the BDI, EPDS, HADS or K10) at final assessment (three to 52 weeks postpartum) (moderate quality evidence, downgraded due to inconsistency) in one review, however no clear effect was seen at final study assessment (six to 52 weeks postpartum) on depression scores (measured using the BDI, CES-D, EPDS, HADS, SF-36) (low quality evidence, downgraded due to inconsistency) in the same review (Dennis 2013). These interventions prevented postnatal depression (diagnosed using the SCID or SCAN) (at 12 to 24 weeks postpartum) (high quality evidence) and reduced anxiety (measured using the HADS or STAI) (at 24 to 52 weeks postpartum) (high quality evidence, not downgraded) in this review (Dennis 2013). However, these interventions did not have a clear effect on reducing parental stress (measured using the PSI) (at 52 weeks postpartum) in the same review (moderate quality evidence, downgraded due to inconsistency) (Dennis 2013).

### **Parent/caregiver knowledge, practices and behaviours**

No pooled results were available.

### **Parent/caregiver views of the intervention**

Psychological and psychosocial interventions did not have a clear effect on maternal dissatisfaction with care (tool(s) for measurement not reported) provided at zero to eight weeks postpartum, but a potential reduction in dissatisfaction was shown at eight to 24 weeks postpartum in one review (both very low quality evidence, downgraded due to high risk of bias and inconsistency) (Dennis 2013).

### **Family relationships**

Psychological and psychosocial interventions did not have a clear effect on reducing marital discord (measured using one question, or a VAS developed by a researcher) (at 24 to 52 weeks postpartum) (moderate quality evidence, downgraded due to imprecision), perceived social support (measured using the Duke FSSQ) and maternal health service contact (at 12 to 24 weeks postpartum) (moderate quality evidence, downgraded due to high risk of bias) or social support scores (measured using maternal views, SRS, Duke FSSQ, SSQ6, and a subscale of Satisfaction with Motherhood Scale) (at 24 to 52 weeks postpartum) in one review (moderate quality evidence, downgraded due to inconsistency) (Dennis 2013).

### **Systems outcomes**

No pooled results were available.

**Table 9: Interventions for preventing postnatal depression evidence profile**

| <b>INTERVENTIONS FOR PREVENTING POSTNATAL DEPRESSION</b>  |   |   |  |                            |                   |
|---|---|---|--|----------------------------|-------------------|
| What is the effectiveness of interventions targeted at preventing postnatal depression in the first year of an infant’s life for optimal social and emotional development for the infant, child and adolescent? |   |   |  |                            |                   |
| <b>Comparison</b>   | Usual antenatal, intrapartum or postpartum care   |   |  |                            |                   |
| <b>Outcome domain</b>   | <b>Outcome measured used in the review(s)</b>   | <b>Results reported in the review(s)</b>  |  |                            | <b>Importance</b> |
|   |   | <b>Result<sup>32,33</sup></b>   | <b>GRADE</b>   | <b>Quality of evidence</b> |                   |
| <b>Infant social and emotional wellbeing or development up to one year of age</b>   | No pooled results were available.   |   |  |                            | CRITICAL          |
| <b>Development for the infant, as a child, and up to 18 years</b>   | No pooled results were available.   |   |  |                            | CRITICAL          |
| <b>Behaviour for the infant, as a child, and up to 18 years</b>   | No pooled results were available.   |   |  |                            | CRITICAL          |
| <b>Physical wellbeing and safety for the infant, as a child, and up to 18 years</b>   | No pooled results were available.   |   |  |                            | CRITICAL          |
| <b>Parent-infant relationship</b>   | Maternal-infant attachment (Dysfunction Interaction Scale of PSI in 1 RCT; 1 RCT: NR) (at final study assessment: 24-52 weeks postpartum) | SMD: -0.18 (95% CI -0.42, 0.06); I <sup>2</sup> 0%; P=0.52 (2 RCTs, N=268) (Dennis 2013)              | Risk of bias: 0<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Moderate                   | CRITICAL          |
|   | <i>GRADE reasons for downgrading: <b>Imprecision:</b> studies with small samples sizes; wide CIs</i>                                      |   |  |                            |                   |
| <b>Parent/caregiver psychosocial wellbeing</b>  | Depression (symptomatology) (BDI; EPDS; HADS; K10) (at final study assessment: 3-52 weeks postpartum)                                     | <b>RR (R): 0.78 (95% CI 0.66, 0.93); I<sup>2</sup> 64%; P=0.005</b> (20 RCTs, N=14,727) (Dennis 2013) | Risk of bias: 0<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Moderate                   | CRITICAL          |
|   | <i>GRADE reasons for downgrading: <b>Inconsistency:</b> substantial heterogeneity</i>   |   |  |                            |                   |
|   | Depression (scores) (BDI; CES-D; EPDS; HADS; SF-36) (at final study assessment: 6-52 weeks postpartum)                                    | SMD: -0.13 (95% CI -0.28, 0.01); I <sup>2</sup> 91%; P=0.077 (19 RCTs, N=12,376) (Dennis 2013)        | Risk of bias: 0<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Low                        | CRITICAL          |

<sup>32</sup>All Ns reflect the total numbers (i.e. across both the intervention and control groups)

<sup>33</sup>Bolding indicates a statistically significant pooled result in favour of the intervention

|   |   |   |   |          |           |
|---|---|---|---|----------|-----------|
|   | <i>GRADE reasons for downgrading: <b>Inconsistency</b>: very substantial heterogeneity (<math>I^2 &gt; 80\%</math>)</i>   |   |   |          |           |
|   | Clinical diagnosis of depression (SCID; SCAN) (at final study assessment: 12-24 weeks postpartum)   | <b>RR (R): 0.50 (95% CI 0.32, 0.78); <math>I^2</math> 0%; P=0.002</b><br>(5 RCTs, N=939) (Dennis 2013)    | Risk of bias: 0<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0   | High     | CRITICAL  |
|   | <i>GRADE reasons for downgrading: not downgraded</i>  |   |   |          |           |
|   | Anxiety (HADS subscale; STAI) (at final study assessment: 24-52 weeks postpartum)   | <b>SMD (R): -0.16 (95% CI -0.30, -0.03); <math>I^2</math> 0%; P=0.02</b><br>(4 RCTs, N=815) (Dennis 2013) | Risk of bias: 0<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0   | High     | CRITICAL  |
|   | <i>GRADE reasons for downgrading: not downgraded</i>  |   |   |          |           |
|   | Parental stress (PSI) (at final study assessment: 52 weeks postpartum)  | SMD (R): 0.11 (95% CI -0.25, 0.48); $I^2$ 71%; P=0.54<br>(3 RCTs, N=465) (Dennis 2013)                    | Risk of bias: 0<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | Moderate | IMPORTANT |
|   | <i>GRADE reasons for downgrading: <b>Inconsistency</b>: substantial heterogeneity</i>   |   |   |          |           |
| <b>Parent/caregiver knowledge, practices and behaviours</b> | No pooled results were available.   |   |   |          | CRITICAL  |
| <b>Parent/caregiver views of the intervention</b>           | Maternal dissatisfaction with care provided (measuring tool(s) NR) (at 0-8 weeks)   | RR (R): 0.56 (95% CI 0.29, 1.09); $I^2$ 90%; P=0.90<br>(2 RCTs, N=825) (Dennis 2013)                      | Risk of bias: -1<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Very low | IMPORTANT |
|   | <i>GRADE reasons for downgrading: <b>Risk of bias</b>: 1 RCT at high risk of attrition bias; <b>Inconsistency</b>: very substantial heterogeneity (<math>I^2 &gt; 80\%</math>)</i>  |   |   |          |           |
|   | Maternal dissatisfaction with care provided (measuring tool(s) NR) (at final study assessment: 8-24 weeks)  | RR (R): 0.67 (95% CI 0.44, 1.00); $I^2$ 83%; P=0.051<br>(4 RCTs, N=3,014) (Dennis 2013)                   | Risk of bias: -1<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Very low | IMPORTANT |
|   | <i>GRADE reasons for downgrading: <b>Risk of bias</b>: 2 RCTs at high risk of attrition bias; <b>Inconsistency</b>: very substantial heterogeneity (<math>I^2 &gt; 80\%</math>)</i> |   |   |          |           |
| <b>Family relationships</b>                                 | Marital discord (1 item question; VAS development by researcher) (at final study assessment: 24-52 weeks postpartum)  | SMD (R): -0.14 (95% CI -0.37, 0.09); $I^2$ 0%; P=0.23<br>(3 RCTs, N=291) (Dennis 2013)                    | Risk of bias: 0<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0  | Moderate | CRITICAL  |
|   | <i>GRADE reasons for downgrading: <b>Imprecision</b>: studies with small samples sizes</i>  |   |   |          |           |

|  |  |  |  |          |           |
|--|--|--|--|----------|-----------|
|  | Perceived social support (Duke FSSQ; maternal health service contact) (at final study assessment: 12-24 weeks postpartum)  | RR (R): 0.72 (95% CI 0.48, 1.08); I <sup>2</sup> 0%; P=0.11 (2 RCTs, N=718) (Dennis 2013)      | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Moderate | IMPORTANT |
| <i>GRADE reasons for downgrading: Risk of bias: 1 RCT with probable lack of allocation concealment</i> |  |  |  |          |           |
|  | Perceived social support (maternal views; SRS; Duke FSSQ; SSQ6; subscale of Satisfaction with Motherhood Scale) (at final study assessment: 24-52 weeks postpartum)  | SMD (R): 0.01 (95% CI -0.08, 0.10); I <sup>2</sup> 45%; P=0.82 (7 RCTs, N=8,290) (Dennis 2013) | Risk of bias: 0<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Moderate | IMPORTANT |
| <i>GRADE reasons for downgrading: Inconsistency: substantial heterogeneity</i>                         |  |  |  |          |           |
| <b>Systems outcomes</b>  | No pooled results were available.  |  |  |          | IMPORTANT |
| <b>Evidence statements</b>   |  |  |  |          |           |
| <b>Parent-infant relationship</b>  | <u>Maternal-infant attachment:</u> Moderate quality evidence from one systematic review shows that psychological and psychosocial interventions do not have a clear effect on maternal-infant attachment (measured using the Dysfunction Interaction Scale of the PSI) at 24 to 52 weeks postpartum (two RCTs, N=268).   |  |  |          |           |
| <b>Parent/caregiver psychosocial wellbeing</b>   | <u>Depression and anxiety:</u> High quality evidence from one systematic review shows that psychological and psychosocial interventions can prevent postnatal depression (diagnosed using the SCID or SCAN) at 12 to 24 weeks postpartum (five RCTs, N=939) and anxiety (measured using the HADS or STAI) at 24 to 52 weeks postpartum (four RCTs, N=815); and moderate quality evidence indicates these interventions can reduce depressive symptoms (measured using the BDI, EPDS, HADS or K10) at three to 52 weeks postpartum (20 RCTs, N=14,727), however low quality evidence also shows no clear effect on depression scores (measured using the BDI, CES-D, EPDS, HADS, SF-36) at six to 52 weeks postpartum (19 RCTs, N=12,376).<br><u>Parental stress:</u> Moderate quality evidence from one systematic review indicates that psychological and psychosocial interventions do not have a clear effect on reducing stress (measured using the PSI) at 52 weeks postpartum (three RCTs, N=465). |  |  |          |           |
| <b>Parent/caregiver views of the intervention</b>  | <u>Maternal dissatisfaction with care:</u> Very low quality evidence from one systematic review indicates that psychological and psychosocial interventions have no clear effect on reducing maternal dissatisfaction with care provided (tool(s) for measurement NR) at zero to eight weeks postpartum (two RCTs, N=825), but may decrease dissatisfaction at eight to 24 weeks postpartum (four RCTs, N=3,014).  |  |  |          |           |



|                             |  |
|-----------------------------|--|
| <b>Family relationships</b> | <p><u>Marital discord</u>: Moderate quality evidence from one systematic review indicates that psychological and psychosocial interventions do not have a clear effect on reducing marital discord (measured using one question, or a VAS developed by a researcher) at 24 to 52 weeks postpartum (three RCTs, N=291).</p> <p><u>Social support</u>: Moderate quality evidence from one systematic review indicates that psychological and psychosocial interventions do not have a clear effect on perceived social support at 12 to 24 weeks postpartum (two RCTs, N=718; measured using the Duke FSSQ and maternal health service contact) and at 24 to 52 weeks postpartum (seven RCTs, N=8,290; measured using maternal views, the SRS, Duke FSSQ, SSQ6, and a subscale of Satisfaction with Motherhood Scale).</p> |
|-----------------------------|--|

**Abbreviations:** BDI: Beck Depression Inventory; CES-D: Center for Epidemiological Studies Depression Scale; CI: confidence intervals; Duke FSSQ: Functional Social Support Questionnaire; EPDS: Edinburgh Postnatal Depression Scale; GRADE: Grading of Recommendations Assessment, Development and Evaluation; HADS: Hospital Anxiety and Depression Scale; K10: Kessler Psychological Distress Scale; N: number; NR: not reported; P: P value; PSI: Parenting Stress Index; SCAN: Schedule for Assessment in Neuropsychiatry; SCID: Structured Clinical Interview for DSM-IV; SRS: Social Relationship Scale; SSQ6: Social Support Questionnaire 6; (R): random effects; RCT: randomised controlled trial; RR: risk ratio; SF-36: 36-Item Short Form Health Survey; SMD: standardised mean difference; STAI: State Trait Anxiety Inventory; VAS: Visual Analogue Scale

### **Characteristics that may have contributed to the effectiveness of interventions for preventing postnatal depression for optimal social and emotional development of infants**

Dennis 2013 highlighted several “promising interventions” for preventing postnatal depression, which included: 1) the provision of intensive, individualised postpartum home visits provided by public health nurses or midwives, 2) lay (peer)-based telephone support, and 3) interpersonal psychotherapy.

***Who** could<sup>34</sup> deliver the intervention, program or messages to optimise infant social and emotional wellbeing and development?*

Dennis 2013 conducted subgroup analyses to explore the effects of variations of intervention providers (lay-based; professionally-based interventions) and variations of professionally-based intervention providers (nurses; physicians; midwives; mental health specialists). Though some variation in effects were observed between the categories, no clear subgroup effects were observed for the outcomes depressive symptomatology, mean depression scores or clinical diagnosis of depression (all at final study assessment) (Table 9b).

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<sup>34</sup>We used could here and in the sentences that follow to acknowledge that studies conducted outside of Australia were not precluded. The MHPWC will therefore need to interpret what was found in the literature to the operational realities of the Australian context.

**Table 9b: Results of subgroup interaction tests from Dennis 2013 based on variations of intervention providers and professionally-based intervention providers**

| Outcome                          | Overall effect | Subgroups             |   | Effect for subgroup | Subgroup interaction tests <sup>1</sup> |
|----------------------------------|----------------|-----------------------|---|---------------------|---|
| Depression (symptomatology)      | S              | Intervention provider | Lay-based interventions                                       | S                   | NS                                      |
|                                  |                |                       | Professionally-based interventions                            | NS                  |   |
| Mean depression scores           | NS             | Intervention provider | Nurses; physicians; midwives; mental health nurse specialists | NS                  | NS                                      |
|                                  |                |                       | Professionally-based provider                                 | NS                  |   |
| Clinical diagnosis of depression | S              | Intervention provider | Professionally-based interventions                            | S                   | NS                                      |
|                                  |                |                       | Lay-based interventions                                       | NS                  |   |

<sup>1</sup>A test of interaction examines whether the treatment effect varies across subgroups of participants

**Abbreviations:** NS: non-significant; S: significant

***Where*** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?

No subgroup interactions tests were performed based on variations of where the intervention could be delivered.

***To whom*** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?

Dennis 2013 explored the effects of variations in sample selection criteria by conducting subgroup analyses for the outcomes depressive symptomatology and mean depression scores (both at final study assessment). Though beneficial effects were seen for these outcomes when delivered to ‘at-risk’ women (and no clear effects seen when delivered to the general population), the subgroup interactions tests did not support clear effects of sample selection criteria on these outcomes (see Table 9c).

**Table 9c: Results of subgroup interaction tests from Dennis 2013 based on variations of selection criteria**

| Outcome                     | Overall effect | Subgroups          |                    | Effect for subgroup | Subgroup interaction tests <sup>1</sup> |
|-----------------------------|----------------|--------------------|--------------------|---------------------|---|
| Depression (symptomatology) | S              | Selection criteria | At-risk women      | S                   | NS                                      |
|                             |                |                    | General population | NS                  |   |
| Mean depression scores      | NS             | Selection criteria | At-risk women      | S                   | NS                                      |
|                             |                |                    | General population | NS                  |   |

<sup>1</sup>A test of interaction examines whether the treatment effect varies across subgroups of participants

**Abbreviations:** NS: non-significant; S: significant

***When*** could be the best time for the intervention, program, or message delivery to occur? (In regards to caregiver preferences and accessibility; and in regards to improved outcomes for the infant, child and later on as the adolescent, and for the caregiver)

The intervention duration (multiple contacts versus single contact) and intervention onset (antenatal only versus antenatal and postnatal versus postnatal only) were explored as possible effect

modifiers in Dennis 2013 for the outcomes depressive symptomatology, mean depression scores or clinical diagnosis of depression (all at final study assessment).

For depressive symptomatology, though a beneficial effect was seen with multiple contact interventions (which was not observed with single contact interventions), the subgroup interaction test did not indicate a clear effect of intervention duration (Dennis 2013). Similarly, though interventions in the postnatal period were shown to be beneficial (and interventions in the antenatal and postnatal period not shown to be beneficial), no clear effect of intervention onset was shown for this outcome (Dennis 2013). For mean depression scores, no clear effects of intervention duration or onset were observed. In regards to clinical diagnosis of depression, while interventions in both the antenatal and postnatal period were shown to be beneficial (and no clear effects seen for with interventions in the antenatal or postnatal period only), no clear effect was based on intervention onset was observed (Dennis 2013) (see Table 9d).

**Table 9d: Results of subgroup interaction tests from Dennis 2013 based on variations in intervention duration and onset**

| Outcome                          | Overall effect | Subgroups             |  | Effect for subgroup | Subgroup interaction tests <sup>1</sup> |
|----------------------------------|----------------|-----------------------|--|---------------------|---|
| Depression (symptomatology)      | S              | Intervention duration | Multiple contact intervention  | S                   | NS                                      |
|                                  |                |                       | Single contact intervention  | NS                  |   |
|                                  |                | Intervention onset    | Postnatal intervention only  | S                   | NS                                      |
|                                  |                |                       | Antenatal and postnatal intervention   | NS                  |   |
| Mean depression scores           | NS             | Intervention duration | Single contact intervention; multiple contact intervention                                     | NS                  | NS                                      |
|                                  |                | Intervention onset    | Antenatal intervention only; antenatal and postnatal intervention; postnatal intervention only | NS                  |   |
| Clinical diagnosis of depression | S              | Intervention onset    | Antenatal and postnatal intervention   | S                   | NS                                      |
|                                  |                |                       | Antenatal intervention only; postnatal intervention only                                       | NS                  |   |

<sup>1</sup>A test of interaction examines whether the treatment effect varies across subgroups of participants

**Abbreviations:** NS: non-significant; S: significant

***How could the intervention, program or messages regarding infant social and emotional wellbeing and development be delivered?***

Dennis 2013 explored whether the type of psychosocial or psychological intervention or the intervention mode, impacted on the outcomes: depressive symptomatology, mean depression scores or clinical diagnosis of depression (all at final study assessment).

For depressive symptomatology, the subgroup interaction test indicated a possible effect based on type of psychosocial intervention:

- Benefits were seen with: postpartum professional-based home visits; postpartum lay-based telephone support;
- No clear benefits were seen with: antenatal and postnatal classes; postpartum lay-based home visits; early postpartum follow-up; continuity/model of care.

For this outcome, no clear effects of the type of psychological intervention (psychological debriefing versus cognitive behavioural therapy) were observed. Considering intervention mode, while individually based interventions were associated with benefits (and no clear benefits seen with

group-based intervention) no clear effect based of mode of intervention was observed (Dennis 2013).

The type of psychosocial intervention did not have a clear impact on mean depression scores. For this outcome, a possible effect based of type of psychological interventions was observed:

- Benefits were seen with: interpersonal psychotherapy;
- No clear benefits were seen with: cognitive behavioural therapy.

For this outcome, no clear impact of the intervention mode (individually-based versus group based) was observed.

While a benefit was seen for clinical diagnosis of depression with individually-based interventions (and no clear benefit seen with group-based interventions), no clear impact of intervention mode was observed (Dennis 2013).

**Table 9e: Results of subgroup interaction tests from Dennis 2013 based on variations of types of psychosocial and psychological interventions and intervention mode**

| Outcome                          | Overall effect | Subgroups                   |   | Effect for subgroup | Subgroup interaction tests <sup>1</sup> |    |
|----------------------------------|----------------|-----------------------------|---|---------------------|---|----|
| Depression (symptomatology)      | S              | Psychosocial interventions  | Postpartum professional-based home visits; postpartum lay-based telephone support                                       | S                   | S                                       |    |
|                                  |                |                             | Antenatal and postnatal classes; postpartum lay-based home visits; early postpartum follow-up; continuity/model of care | NS                  |   |    |
|                                  |                | Psychological interventions | Psychological debriefing; cognitive behavioural therapy   | NS                  |   | NS |
|                                  |                | Intervention mode           | Individually-based interventions  | S                   |   | NS |
|                                  |                |                             | Group-based interventions   | NS                  |   |    |
| Mean depression scores           | NS             | Psychosocial interventions  | Antenatal and postnatal classes; antenatal and postnatal lay-based home visits and telephone support                    | NS                  | NS                                      |    |
|                                  |                | Psychological interventions | Interpersonal psychotherapy   | S                   | NS*                                     |    |
|                                  |                |                             | Cognitive behavioural therapy   | NS                  |   |    |
|                                  |                | Intervention mode           | Individually-based interventions; group-based interventions   | NS                  | NS                                      |    |
| Clinical diagnosis of depression | S              | Intervention mode           | Individually-based interventions  | S                   | NS                                      |    |
|                                  |                |                             | Group-based interventions   | NS                  |   |    |

<sup>1</sup>A test of interaction examines whether the treatment effect varies across subgroups of participants

\*A possible trend was observed (Chi<sup>2</sup>: 3.50, P: 0.06, I<sup>2</sup>: 71%)

**Abbreviations:** NS: non-significant; S: significant

*How could the intervention, program or messages regarding infant social and emotional wellbeing and development be **framed**?*

Intervention framing was not covered in Dennis 2013.

*What could **impede** or interfere with engagement with interventions or programs or caregivers enacting upon messages?*

Factors impeding engagement of caregivers with interventions or programs were not covered in Dennis 2013.

What could **facilitate** or drive engagement with interventions or programs or caregivers enacting upon messages?

Factors facilitating engagement of caregivers with interventions or programs were not covered in Dennis 2013.

## Interventions for treating maternal depression in the perinatal period

### Description of intervention based on the included evidence

Non-pharmaceutical interventions for treating maternal depression in the perinatal period may include community-based, health, social care or educational interventions, with aims including the improvement and maintenance of quality of life, health and development for infants (Bee 2014). Of the two systematic reviews included in this category only one presented pooled results (Bee 2014). In this overview, specific interventions for treating severe maternal depression, most often in the postnatal period, include psychotherapeutic interventions, aimed at reducing the severity of depressive symptoms (such as planned cognitive behaviour and interpersonal therapies/approaches, psychodynamic and non-directive supportive therapies), and less often psychoeducational and extended care interventions; with interventions commonly delivered individually, face to face, across homes, community and clinic settings, by a broad range of health and social care professionals, with mostly weekly frequency, duration of sessions usually between one to two hours and total duration ranging from four to 24 hours. Intervention length ranged from five weeks to 11 months (where reported) (Bee 2014).

### Evidence summary

Two systematic reviews compared interventions to treat maternal depression in the perinatal period with usual care and other controls (Bee 2014; Poobalan 2007). Poobalan 2007 searched for studies from 1966 to 2005, while Bee 2014 searched for studies up to 2012.

The inclusion criteria for these reviews differed and were as follows:

- Bee 2014 included studies with children or adolescents aged zero to 17 with a parent with a serious mental illness or severe depression, assessing any community-based (psychological or psychosocial) intervention that involved professionals or paraprofessionals and parents or children for the purposes of changing knowledge, attitudes, beliefs, emotions, skills or behaviours related to health and wellbeing (with priority given to designs in which a comparator/control group was present).
- Poobalan 2007 only included RCTs or CCTs assessing treatment interventions for mothers with postpartum depression.

Together, these two reviews included 24 relevant studies<sup>35</sup> (19 RCTs, four qRCTs and one CCT) with a total of 2,848 participants (ranging from 20 to 903 in the included studies), published between 1989 and 2011 (Bee 2014; Poobalan 2007).

The majority of relevant trials in Bee 2014 assessed psychotherapeutic interventions (e.g. planned cognitive behavioural and interpersonal approaches, psychodynamic and non-directive supportive therapies), with interventions ranging in session number and length (for example, from five to eight weekly sessions of one hour (6.5 hours total contact; total duration of five to eight weeks) to seven weekly sessions and then monthly sessions of unclear duration (total duration of 11 months). In Poobalan 2007 a range of interventions were assessed (e.g. cognitive behavioural therapy, non-directive supportive counselling, and psychodynamic therapy) and where reported, intervention durations ranged, such as from 30 minute weekly sessions for five weeks, to 60 minute weekly sessions for 12 weeks, or three visits over 18 weeks.

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<sup>35</sup>With some overlap (see Technical Report)

One of the reviews was judged to be at low risk of bias (Bee 2014) and one review was judged to be at unclear risk of bias (Poobalan 2007) using ROBIS; one review was judged to be 'high' quality (Bee 2014) and one review 'moderate' quality (Poobalan 2007) using AMSTAR.

One of two included systematic reviews provided pooled results (Bee 2014). Bee 2014 (low risk of bias; 'high' quality) included 17 relevant studies (13 RCTs and 4 qRCTs) with a total of 2,293 participants (ranging from 20 to 903 in the included studies), published between 1989 and 2011.

For further details regarding the results from single studies from the other review (Poobalan 2007), see the Technical Report.

### ***Primary outcome domain***

#### **Infant social and emotional wellbeing or development up to one year of age**

There was no clear effect on children's emotional wellbeing (measured using observer ratings of infant affect PCERA) in the relevant studies), behaviour or social function (measured using observer rating of infant behaviour (PCERA) in the relevant studies) up to six months post-randomisation when their mother's maternal depression was treated in the perinatal period in one review (low quality evidence, downgraded due to high risk of bias and imprecision) (Bee 2014).

### ***Secondary outcomes domains***

#### **Development for the infant, as a child, and up to 18 years**

No pooled results were available.

#### **Behaviour for the infant, as a child, and up to 18 years**

No pooled results were available.

#### **Physical wellbeing and safety for the infant, as a child, and up to 18 years**

No pooled results were available.

#### **Parent-infant relationship**

When maternal depression in the perinatal period was treated, there was an improvement in the quality of parenting behaviours (measured using PCERA and the Maternal Attachment Inventory (MAI)), up to six months post-randomisation in one review (low quality evidence, downgraded due to high risk of bias and inconsistency) (Bee 2014).

#### **Parent/caregiver psychosocial wellbeing**

There was an improvement in parental mental health (parents' depressive symptoms, measured using the BDI, EPDS or HDRS up to six months post-randomisation when maternal depression in the perinatal period was treated in one review (low quality evidence, downgraded due to high risk of bias and inconsistency), but no clear effect was seen at six to 12 months post-randomisation (very low quality evidence, downgraded due to high risk of bias, inconsistency and imprecision), or at more than 12 months post-randomisation (low quality evidence, downgraded due to high risk of bias and imprecision) in the same review (Bee 2014).

#### **Parent/caregiver knowledge, practices and behaviours**

No pooled results were available.

### Parent/caregiver views of the intervention

No pooled results were available.

### Family relationships

No pooled results were available.

### Systems outcomes

No pooled results were available.

**Table 10: Interventions for treating maternal depression in the perinatal period evidence profile**

| <b>INTERVENTIONS FOR TREATING MATERNAL DEPRESSION IN THE PERINATAL PERIOD</b>  |   |   |   |                            |                   |          |
|--|---|---|---|----------------------------|-------------------|----------|
| What is the effectiveness of treating maternal depression in the perinatal period for optimal social and emotional development for the infant, and later on as a child and adolescent? |   |   |   |                            |                   |          |
| <b>Comparison</b>  | Usual care and other controls   |   |   |                            |                   |          |
| <b>Outcome domain</b>  | <b>Outcome measure used in the review(s)</b>  | <b>Results reported in the review(s) and GRADE</b>  |   |                            | <b>Importance</b> |          |
|  |   | <b>Result<sup>36,37</sup></b>   | <b>GRADE</b>  | <b>Quality of evidence</b> |                   |          |
| <b>Infant social and emotional wellbeing or development up to one year of age</b>  | Children's emotional well-being (observer ratings of infant affect; PCERA) (0-6 months post-randomisation)  | SMD (R): 0.06 (95% CI -0.20 to 0.33); I <sup>2</sup> 0%; P=NR (5 trials, N=212) [1 RCT, 2 qRCTs, N=152 in relevant age group: ES for relevant studies ranging from 0.08 to 0.36] (Bee 2014) | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Low                        | CRITICAL          |          |
|  | <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Imprecision: studies with small sample sizes (especially for relevant age group)</i> |   |   |                            |                   |          |
|  | Children's behaviour and social function (observer ratings of infant behaviour; PCERA) (0-6 months post-randomisation)  | SMD (R): 0.23 (95% CI 0.00, 0.46); I <sup>2</sup> 0%; P=NR (8 trials, N=397) [1 RCT, 2 qRCTs, N=151 in relevant age group: ES for relevant studies ranging from -0.53 to 0.60] (Bee 2014)   | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Low                        |                   | CRITICAL |
| <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Imprecision: studies with small sample sizes (especially for relevant age group)</i>          |   |   |   |                            |                   |          |
| <b>Development for the infant, as a child, and up to 18 years</b>  | No pooled results were available.   |   |   |                            | CRITICAL          |          |

<sup>36</sup> All Ns reflect the total numbers (i.e. across both the intervention and control groups)

<sup>37</sup> Bolding indicates a statistically significant pooled result in favour of the intervention



|  |  |  |  |          |          |          |
|--|--|--|--|----------|----------|----------|
| Behaviour for the infant, as a child, and up to 18 years   | No pooled results were available.  |  |  |          | CRITICAL |          |
| Physical wellbeing and safety for the infant, as a child, and up to 18 years   | No pooled results were available.  |  |  |          | CRITICAL |          |
| Parent-infant relationship   | Quality of parent-child interactions: parenting behaviours (PCERA; MAI) (0-6 months post-randomisation)  | <b>SMD (R): 0.67 (95% CI 0.32, 1.02); I<sup>2</sup> 50.8%; P=NR</b><br>(6 trials, N=378)<br>[3 RCTs, 2qRCTs, N=359 in relevant age group; ES for relevant studies ranging from: 0.08 to 1.83]<br>(Bee 2014)        | Risk of bias: -1<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | Low      | CRITICAL |          |
|  | GRADE reasons for downgrading: <b>Risk of bias:</b> studies with methodological limitations; <b>Inconsistency:</b> substantial heterogeneity   |  |  |          |          |          |
| Parent/caregiver psychosocial wellbeing  | Parental mental health (parents' depressive symptom outcomes: BDI; EPDS; HDRS) (0-6 months post-randomisation)   | <b>SMD (R): 0.73 (95% CI 0.51, 0.94); I<sup>2</sup> 67.8%; P=NR</b><br>(17 trials, N=1,855)<br>[11 RCTs, 3 qRCTs, N=1,698 in relevant age group; ES for relevant studies ranging from: 0.08 to 2.56]<br>(Bee 2014) | Risk of bias: -1<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | Low      | CRITICAL |          |
|  | GRADE reasons for downgrading: <b>Risk of bias:</b> studies with methodological limitations; <b>Inconsistency:</b> substantial heterogeneity   |  |  |          |          |          |
|  | Parental mental health (parents' depressive symptom outcomes: EPDS; HDRS) (6-12 months post-randomisation)   | SMD (R): 0.34 (95% CI 0.00, 0.68); I <sup>2</sup> 64.9%; P=NR<br>(4 trials, N=1,098)<br>[2 RCTs, N=975 in relevant age group; ES for relevant studies ranging from 0.07 to 0.72]<br>(Bee 2014)                     | Risk of bias: -1<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Very low |          | CRITICAL |
|  | GRADE reasons for downgrading: <b>Risk of bias:</b> studies with methodological limitations; <b>Inconsistency:</b> substantial heterogeneity; <b>Imprecision:</b> wide CIs             |  |  |          |          |          |
| Parental mental health (parents' depressive symptom outcomes: BDI; EDPS) (> 12 months post-randomisation)  | SMD (R): 0.17 (95% CI -0.04, 0.39); I <sup>2</sup> 0%; P=NR<br>(3 trials, N=373)<br>[1 RCT, 1 qRCT, N=273 in relevant age group; ES for relevant studies: 0.00 and 0.49]<br>(Bee 2014) | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0  | Low  | CRITICAL |          |          |
| GRADE reasons for downgrading: <b>Risk of bias:</b> studies with methodological limitations; <b>Imprecision:</b> low sample size (especially for relevant age group); wide CIs |  |  |  |          |          |          |
| Parent/caregiver knowledge, practices and behaviours   | No pooled results were available.  |  |  |          | CRITICAL |          |

|   |   |           |
|---|---|-----------|
| <b>Parent/caregiver views of the intervention</b>                                 | No pooled results were available.   | IMPORTANT |
| <b>Family relationships</b>   | No pooled results were available.   | CRITICAL  |
| <b>Systems outcomes</b>   | No pooled results were available.   | IMPORTANT |
| <b>Evidence statements</b>  |   |           |
| <b>Infant social and emotional wellbeing or development up to one year of age</b> | <p><u>Emotional well-being</u>: Low quality evidence from one systematic review indicates no clear effect on children’s emotional wellbeing (measured using observer ratings of infant affect: PCERA) up to six months when maternal depression in the perinatal period is treated (one RCT, two qRCTs, N=152).</p> <p><u>Behaviour and social function</u>: Low quality evidence from one systematic review indicates no clear effect on children’s behaviour or social function (measured using observer rating of infant behaviour: PCERA) up to six months when maternal depression in the perinatal period is treated (one RCT, two qRCTs, N=151).</p> |           |
| <b>Parent-infant relationship</b>   | <p><u>Quality of parenting behaviours</u>: Low quality evidence from one systematic review shows an improvement in the quality of parenting behaviours (measured using the PCERA or MAI) up to six months when maternal depression in the perinatal period is treated (three RCTs, two qRCTs, N=359).</p>   |           |
| <b>Parent/caregiver psychosocial wellbeing</b>                                    | <p><u>Parental mental health</u>: Low to very low quality evidence from one systematic review shows an improvement in parental mental health (parents’ depressive symptoms measured using the BDI, EPDS or HDRS) up to six months when maternal depression in the perinatal period is treated (11 RCTs, three qRCTs, N=1698), but no clear effect at six to 12 months (two RCTs, N=975), or &gt; 12 months (one RCT, one qRCT, N=273).</p>  |           |

**Abbreviations:** BDI: Beck Depression Inventory; CCT: controlled clinical trial; CI: confidence interval; EPDS: Edinburgh Postnatal Depression Scale; GRADE: Grading of Recommendations Assessment, Development and Evaluation; HDRS: Hamilton Depression Rating Scale; MAI: Maternal Attachment Inventory; N: number; NR: not reported; P: P value; PCERA: Parent-Child Early Relational Assessment; qRCT: quasi-randomised controlled trial; (R): random-effects; RCT: randomised controlled trial; SMD: standardised mean difference

### **Characteristics that may have contributed to the effectiveness of interventions for treating maternal depression in the perinatal period for optimal social and emotional development of infants**

Bee 2014 showed possible benefits in the short-term for the quality of parent-child interactions and parental mental health (parents’ depressive symptoms) with interventions for treating maternal depression in the perinatal period (and no clear effects on children’s emotional wellbeing or behaviour and social function), however highlighted the “limited number of comparisons... in conjunction with the heterogeneous mix of interventions, populations and outcomes” and thus concluded that “that these results should be interpreted with caution.”

***Who could<sup>38</sup> deliver the intervention, program or messages to optimise infant social and emotional wellbeing and development?***

No clear effect of interventions for children of parents with severe depression was seen for the outcomes children’s emotional well-being or children’s behaviour and social function (zero to

<sup>38</sup>We used could here and in the sentences that follow to acknowledge that studies conducted outside of Australia were not precluded. The MHPWC will therefore need to interpret what was found in the literature to the operational realities of the Australian context.

six months post-randomisation) (Bee 2014). In the three relevant trials that contributed to the meta-analyses for these outcomes (which all had effects that were not significant, except for one study showing a possible benefit for children's behaviour and social function) the interventions were delivered by psychologists/psychiatry residents, psychology interns, child development trainees in two studies, and psychotherapists with clinical/counselling psychology degrees in one study (Bee 2014).

Overall, a benefit of interventions for children of parents with severe depression was seen for the outcome quality of parent-child interactions (parenting behaviours, zero to six months post-randomisation) (Bee 2014). In the five relevant studies (one of which had two intervention arms, and one of which had three interventions arms: eight interventions in total), three of the five studies showed significant benefits individually; in those studies, the interventions were delivered by psychologists/psychiatry residents, psychology interns, child development trainees, and cognitive behavioural therapy specialists and non-specialists (Bee 2014). In one of the two studies showing no clear benefits individually, interventions were delivered by psychotherapists with clinical/counselling psychology degrees; in the other study the intervenor was not reported (Bee 2014).

A benefit was seen for parental mental health (at zero to six months post-randomisation), which was not sustained at follow up. There were 14 relevant studies that contributed to the meta-analysis, eight which individually suggested efficacy in favour of the intervention (Bee 2014). Interventions in studies showing benefits were delivered by a range of intervenors including health visitors, community health workers, psychotherapists, psychology masters students, psychologists/psychiatry residents, psychology interns, child development trainees, clinical psychologists, doctoral/masters-level clinicians (Bee 2014). Similarly, interventions in studies showing benefits were delivered by a range of intervenors, including nurses, midwives or nursed, psychologists, cognitive behaviour therapy specialists and non-specialists, and psychologists, social workers, psychology interns, post doc fellows (Bee 2014). No clear patterns were observed for intervention effect based on type of intervenor.

***Where*** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?

The two studies which did not show a clear benefit of interventions on children's emotional wellbeing or children's behaviour and social function were conducted in the United States, in the community setting (Bee 2014). The third study which showed no benefit for children's emotional wellbeing, but a possible benefit for children's behaviour and social function was also conducted in the United States, and the setting was not reported (Bee 2014).

Two of the three showing some benefits individually for the quality of parent-child interventions were conducted in the United States (community setting), and the third in the United Kingdom (home setting). In the two studies not showing clear benefits for this outcome, one was conducted in the United States (unclear setting), and the other in Australia (community setting) (Bee 2014).

In the eight studies showing benefits for parental mental health, three were conducted in the home (France, Pakistan, United Kingdom), two in the community (Australia, United States) and two in the clinic (Australia, United States), and one in an unclear setting (United States) (Bee 2014). For those studies not showing clear benefits, one was conducted in the home (United Kingdom), one in the community (United States), three in the clinic (Australia, Canada, Chile), and one in the clinic and home (Sweden) (Bee 2014). No clear pattern of intervention effect based on where the interventions were delivered was observed.

***To whom*** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?

In all relevant studies contributing to the meta-analyses sample populations were 100% female, and in the majority of studies (except four of the 14 studies reporting parental mental health), 100% of the sample suffered severe depression (Bee 2014). In most studies, women were included in the postpartum period or the first year of their child's life, though in a small number of studies, women were included during pregnancy (Bee 2014).

***When*** could be the best time for the intervention, program, or message delivery to occur? (In regards to caregiver preferences and accessibility; and in regards to improved outcomes for the infant, child and later on as the adolescent, and for the caregiver)

In two of the three studies that did not show a clear benefit of interventions on children's emotional wellbeing or behaviour and social function there were 12 weekly, two hour sessions (total contact: 24 hours) (one of the studies had a second intervention arm, where the sessions were shorter, total contact: 18 hours) (Bee 2014). In the third study, which showed no benefit for children's emotional wellbeing, but a possible benefit for children's behaviour and social function, there were also 12 weekly sessions, of one hour (total contact: 12 hours) (Bee 2014).

In two of the three studies showing benefits for parent-child interactions, there were 12 weekly, two hour sessions (total contact: 24 hours) (one of the studies had a second intervention arm, where the sessions were shorter, total contact: 18 hours); in the third, there were 10 weekly sessions, of unclear length (Bee 2014). The two studies not showing clear benefits had 12 weekly sessions, of one hour (total contact: 12 hours), and two hour sessions over eight weeks (total contact: 22 hours) (Bee 2014).

The number of intervention sessions, length of sessions (along with total contact hours, and total duration of the interventions) is presented in Table 10b for the 14 studies which reported on parental mental health (Bee 2014). No clear pattern was observed for intervention effect according to these characteristics.

***How*** could the intervention, program or messages regarding infant social and emotional wellbeing and development be delivered?

In the two studies that did not show a clear benefit of interventions on children's emotional wellbeing or behaviour and social function the intervention mode was psychotherapy, the content was mother-infant therapy (though one study had a second intervention arm with interpersonal therapy), the objective was parenting and parent wellbeing, the targets were the parent and child (though one study had a second intervention arm with a target of the parent), and the delivery/format was face to face in groups (Bee 2014). In the third study, which showed no benefit for children's emotional wellbeing, but a possible benefit for children's behaviour and social function, while the intervention mode was also psychotherapy, the content was interpersonal therapy, the objective was parent well-being, the target was the parent, and the delivery/format was individual face to face (Bee 2014).

In the three studies showing benefits (across four intervention arms) for quality of parent-child interactions the interventions varied, as follows: mode: psychotherapy (all interventions); content: mother-infant therapy (two interventions), interpersonal therapy (one intervention), cognitive behavioural therapy (one intervention); objective: parenting and parent wellbeing (two interventions), parent wellbeing (two interventions); target: parent and child

(two interventions), parent only (two interventions); delivery/format: face to face (all interventions), in groups (three interventions) to individuals (one intervention) Bee 2014. Similarly, in these studies showing no clear benefits (across four intervention arms), the interventions varied (Bee 2014). In the 14 studies reporting on parental mental health the interventions (mode, objective, content, target, delivery and format) differed, and there was notable variation within the groups of studies that did or did not show clear benefits (see Table 10b) (Bee 2014). For all interventions, the mode was psychotherapy, and for the majority, the objective was parent wellbeing, with the target being the parent; in all studies, the intervention was delivered face to face either individually or in a group format (Bee 2014).

Relevant subgroup analyses conducted by Bee 2014 included an analysis based on intervention objective (comparing interventions focused on parent well-being, and those with dual focus) and target (comparing interventions targeting the parent alone and those targeting the parent and child). No clear differences were observed, and Bee 2014 did not conduct/report results of subgroup interaction tests.

**10b: ‘When’ and ‘how’ the interventions reporting on parents’ depressive symptoms were delivered in Bee 2014 (14 studies, 18 interventions)**

| Intervention mode                                | Intervention objective         | Intervention content      | Target           | Delivery                  | Format     | Session number, session length (total contact, total duration) |
|--|--------------------------------|---------------------------|------------------|---------------------------|------------|--|
| <b>Interventions showing significant benefit</b> |                                |                           |                  |                           |            |  |
| Psychotherapy                                    | Parent wellbeing               | Mixed CBT PD              | Parent           | Face to face              | Individual | 5-8 weekly sessions, 1 hour (6.5 hours, 5-8 weeks)             |
|  | Parenting and parent wellbeing | Mother-infant therapy     | Parent and child | Face to face              | Group      | 12 weekly sessions, 2 hours (24 hours, 12 weeks)               |
|  | Parent wellbeing               | Brief IPT                 | Parent           | Face to face or telephone | Individual | 8 weekly then bi-weekly/monthly, unclear (unclear, 8 weeks)    |
|  |                                |                           | Parent           | Face to face              | Individual | 8 weekly, 30 minutes (4 hours, 8 weeks)                        |
|  |                                | CBT                       | Parent           | Face to face              | Group      | 10 weekly sessions, 1.5 hours (15 hours, 10 weeks)             |
|  |                                | IPT                       | Parent           | Face to face              | Individual | Unclear, 2 hours (22 hours, 8 weeks)                           |
|  |                                | IPT                       | Parent           | Face to face              | Individual | 12 weekly, 1 hour (12 hours, 12 weeks)                         |
|  |                                | CBT techniques            | Parent           | Face to face              | Individual | 7 weekly and then monthly, unclear (unclear, 11 months)        |
| <b>Interventions not showing clear benefits</b>  |                                |                           |                  |                           |            |  |
| Psychotherapy                                    | Parent wellbeing               | IPT                       | Parent           | Face to face              | Group      | 12 weekly sessions, 1.5-2 hours (18 hours, 12 weeks)           |
|  | Parenting and parent wellbeing | Mother-infant therapy     | Parent and child | Face to face              | Group      | 12 weekly sessions, 2 hours (24 hours, 12 weeks)               |
|  | Parent wellbeing               | CBT                       | Parent           | Face to face              | Individual | 10 weekly sessions, unclear (unclear, 10 weeks)                |
|  |                                |                           | Parent           | Face to face              | Individual | 10 weekly sessions, unclear (unclear, 10 weeks)                |
|  |                                | Non-directive counselling | Parent           | Face to face              | Individual | 10 weekly sessions, unclear (unclear, 10 weeks)                |
|  |                                | CBT (nurse)               | Parent           | Face to face              | Individual | 6 weekly, unclear (unclear, 6 weeks)                           |
|  |                                | CBT (psychologist)        | Parent           | Face to face              | Individual | 6 weekly, unclear (unclear, 6 weeks)                           |
|  |                                | CBT and paroxetine        | Parent           | Face to face              | Individual | 12 weekly, 1 hour (12 hours, 12 weeks)                         |

|  |  |                      |        |              |            |  |
|--|--|----------------------|--------|--------------|------------|--|
|  |  | Brief CBT, education | Parent | Face to face | Group      | 8 weekly, 50 minutes (6 hours 40 minutes, 8 weeks) |
|  |  | ST counselling       | Parent | Face to face | Individual | 6 weekly, 1 hour (6 hours, 6 weeks)                |

**Abbreviations:** CBT: cognitive behavioural therapy; IPT: interpersonal therapy; PD: personality disorder; ST: supportive therapy

*How could the intervention, program or messages regarding infant social and emotional wellbeing and development be **framed**?*

Intervention framing was not covered in Bee 2014.

*What could **impede** or interfere with engagement with interventions or programs or caregivers enacting upon messages?*

Bee 2014 assessed the acceptability of interventions for children of parents with serious mental illness using qualitative and quantitative data. A limited number of relevant studies reported findings relating to factors impeding engagement, including: two studies of short-term psychotherapeutic interventions, in which women highlighted a perceived sense of culpability and a fear of how others may react to their experiences as potential barriers; one study of a cognitive behavioural therapy program in which one woman dropped out early due to discomfort in talking openly in a group format; and one study, also of a cognitive behavioural therapy program, in which some couples expressed dissatisfaction with the open format of a couples evening (Bee 2014).

*What could **facilitate** or drive engagement with interventions or programs or caregivers enacting upon messages?*

In assessing the acceptability of interventions for children of parents with serious mental illness, Bee 2014 also reported on factors facilitating engagement from a number of relevant studies. In regards to qualitative data:

- Four relevant studies emphasised the importance of establishing an emotionally supportive alliance between parents and staff, such that parents were afforded the freedom to discuss their concerns;
- Three relevant studies focusing on short-term psychotherapeutic interventions highlighted the need for staff to facilitate the provision of a safe and non-judgemental environment for mothers to share their feelings;
- In one study of an extended care intervention, women identified the importance of approachable and communicative staff, with unbiased and affirming professionals who practically and routinely enquired about the mothers' feelings considered particularly valuable in overcoming the stigma experiences;
- In four relevant studies addressing issues relating to group therapy, all were largely supportive of this delivery format – parents were relatively consistent in perceiving group interventions to provide a route for much needed peer support and positive interpersonal relationships; in addition, these studies discussed the benefits of sharing parenting or illness concerns, and the role the group membership had played in overcoming stigma and normalising parents' experiences;
- In one relevant study evaluating a short-term parent intervention a preference for greater couple or family focused participation was highlighted;
- In one study following a cognitive behavioural therapy program all women found at least one session helpful, with sessions on 'crooked thinking' and self-esteem most highly valued.

In regards to the qualitative data Bee 2014 concluded that “Overall, a notable number of studies provided data for the synthesis of parents’ views, although very few high-quality in-depth studies were found. Key topics emerging from the available qualitative data highlighted the significance of establishing high-quality relationships between staff and parents, and the importance of delivering interventions in such a way that stigma and social isolation could be reduced.”

Limited quantitative data related to acceptability of interventions were provided in Bee 2014, and only in relation to satisfaction in relevant studies:

- In one study assessing cognitive behavioural therapy delivered by a nurse or psychologist, the majority of women indicated that treatment was sufficient, with a trend towards higher satisfaction in the intervention groups;
- In one study assessing a multicomponent intervention, almost all women reported feeling satisfied with their care, and reported that they would like the treatment again;
- In three uncontrolled studies women reported high satisfaction (interpersonal therapy program), that the intervention was an acceptable way to address their problems (interpersonal therapy program), and that they would recommend the intervention a friend (supportive therapy program);
- In one study of home-based cognitive behaviour therapy program, mothers reported that there was an excellent collaboration between therapists and routine home visitors and an appropriate level of confidentiality had been maintained.

Bee 2014 concluded that “The vast majority of qualitative studies remained focused on overall satisfaction or on satisfaction with particular aspects of an intervention program. No large-scale satisfaction surveys were found. The available quantitative data, like the qualitative data, thus remain limited in both number and quality.”

## **NBAS-based interventions**

### **Description of intervention based on the included evidence**

The NBAS is a measure of neonatal interactive capabilities which can be used as an intervention tool. During administration of the NBAS, parents become aware of the infant's developmental and interactive capabilities, with the aim of improving parental responsiveness and parent-infant interactions (Das Eiden 1996). Only one systematic review was included in this category and it provided a pooled result (Das Eiden 1996). In this overview, NBAS-based interventions include where the NBAS was administered to infants by trained examiners in the parents' presence and the training of parents to administer the NBAS to their infants (Das Eiden 1996). The interventions were delivered to parents and their infants from high (e.g. low socioeconomic status or preterm birth) and low risk groups (Das Eiden 1996).

### **Evidence summary**

One systematic review compared NBAS-based interventions (training parents to administer the NBAS or have them observe an examiner administer the NBAS) with control conditions (e.g. giving parents only a verbal report of the NBAS administration) (Das Eiden 1996). Das Eiden 1996 did not report the search dates for this review, however only included published studies of parenting interventions based on the NBAS reporting on outcomes revolving around the theme of parenting quality (Das Eiden 1996).

Das Eiden 1996 identified 13 relevant studies (11 RCTs and two qRCTs), with a total of 688 participants (ranging from 20 to 125 in the included studies), published between 1980 and 1995. Limited detail was provided regarding the timing, duration or frequency of interventions; however only four of the 13 included studies used repeated intervention episodes, and follow up ranged from eight to 10 days post-intervention to nine months postpartum (Das Eiden 1996).

This review was judged to be at high risk of bias using ROBIS, and was judged to be 'low' quality using AMSTAR (Das Eiden 1996).

### ***Primary outcome domain***

#### **Infant social and emotional wellbeing or development up to one year of age**

No pooled results were available.

### ***Secondary outcomes domains***

#### **Development for the infant, as a child, and up to 18 years**

No pooled results were available.

#### **Behaviour for the infant, as a child, and up to 18 years**

No pooled results were available.

#### **Physical wellbeing and safety for the infant, as a child, and up to 18 years**

No pooled results were available.

#### **Parent-infant relationship**

Parenting quality (measured using various outcomes including observations of parent-child interactions, self-report measures of parenting, and four scales from the Cohler MAS) was enhanced



with NBAS-based training in one review (low quality evidence (assumed), downgraded due to indirectness, with no information reported to determine risk of bias) (Das Eiden 1996).

**Parent/caregiver psychosocial wellbeing**

No pooled results were available.

**Parent/caregiver knowledge, practices and behaviours**

No pooled results were available.

**Parent/caregiver views of the intervention**

No pooled results were available.

**Family relationships**

No pooled results were available.

**Systems outcomes**

No pooled results were available.

**Table 11: NBAS-based interventions evidence profile**

| <b>NBAS-BASED INTERVENTIONS</b>   |  |  |              |                            |                   |
|---|--|--|--------------|----------------------------|-------------------|
| What is the effectiveness of NBAS-based interventions for parents of infants in their first year of life for optimal social and emotional development for the infant, and later on as a child and adolescent? |  |  |              |                            |                   |
| <b>Comparison</b>   | Largely giving parents only a verbal report of the NBAS administration |  |              |                            |                   |
| <b>Outcome domain</b>   | <b>Outcome measure used in the review(s)</b>                           | <b>Results reported in the review(s) and GRADE</b> |              |                            | <b>Importance</b> |
|   |  | <b>Result</b> <sup>39,40</sup>                     | <b>GRADE</b> | <b>Quality of evidence</b> |                   |
| <b>Infant social and emotional wellbeing or development up to one year of age</b>   | No pooled results were available.                                      |  |              | CRITICAL                   |                   |
| <b>Development for the infant, as a child, and up to 18 years</b>   | No pooled results were available.                                      |  |              | CRITICAL                   |                   |
| <b>Behaviour for the infant, as a child, and up to 18 years</b>   | No pooled results were available.                                      |  |              | CRITICAL                   |                   |
| <b>Physical wellbeing and safety for the infant, as a child, and up to 18 years</b>   | No pooled results were available.                                      |  |              | CRITICAL                   |                   |

<sup>39</sup> All Ns reflect the total numbers (i.e. across both the intervention and control groups)

<sup>40</sup> Bolding indicates a statistically significant pooled result in favour of the intervention

|   |  |   |   |               |           |
|---|--|---|---|---------------|-----------|
| <b>Parent-infant relationship</b>   | Parenting quality (e.g. rated observations of parent-child interactions; self-report measures of parenting; 4 scales from the Cohler MAS <sup>41</sup> ) (follow up: 8-10 days to 9 months postpartum)   | <b>Correlation coefficient (r): 0.203; P=0.00001</b> (11 RCTs, 2 qRCTs, N=668) (Das Eiden 1996) | Risk of bias: -1 (assumed)<br>Inconsistency: 0<br>Indirectness: -1<br>Imprecision: 0<br>Publication bias: 0 | Low (assumed) | CRITICAL  |
| <i>GRADE reasons for downgrading: Risk of bias (assumed): downgraded due to inclusion of qRCTs; Indirectness: outcome measures varied widely across studies</i> |  |   |   |               |           |
| <b>Parent/ caregiver psychosocial wellbeing</b>   | No pooled results were available.  |   |   |               | IMPORTANT |
| <b>Parent/caregiver knowledge, practices and behaviours</b>   | No pooled results were available.  |   |   |               | CRITICAL  |
| <b>Parent/caregiver views of the intervention</b>   | No pooled results were available.  |   |   |               | IMPORTANT |
| <b>Family relationships</b>   | No pooled results were available.  |   |   |               | CRITICAL  |
| <b>Systems outcomes</b>   | No pooled results were available.  |   |   |               | IMPORTANT |
| <b>Evidence statement</b>   |  |   |   |               |           |
| <b>Parent-infant relationship</b>   | <u>Parenting quality</u> : Low quality evidence indicates that parenting quality (measured using outcomes including observations of parent-child interactions, self-report measures of parenting, and four scales from the Cohler MAS) is enhanced with NBAS-based training at eight days post-intervention to nine months postpartum (11 RCTs, two qRCTs, N=668). |   |   |               |           |

**Abbreviations:** GRADE: Grading of Recommendations Assessment, Development and Evaluation; MAS: Maternal Attitude Scale; NBAS: Neonatal Behavioural Assessment Scale; N: number; NR: not reported; P: P value; qRCT: quasi-randomised controlled trial; RCT: randomised controlled trial

### Characteristics that may have contributed to the effectiveness of NBAS-based interventions for optimal social and emotional development of infants

Das Eiden 1996 reported that “even though one could plausibly come up with variables that might moderate the effect of the intervention on parenting quality (e.g. length of follow-up, risk status of the sample, parental involvement in the intervention), the present results provide no statistical basis for pursuing moderator analyses.”

**Who** could<sup>42</sup> deliver the intervention, program or messages to optimise infant social and emotional wellbeing and development?

There was no clear pattern in effect sizes according to whether trained professionals demonstrated the NBAS to parents (nine studies) or whether mothers administered the NBAS directly to their infants (three studies) (Das Eiden 1996). A single study in Das Eiden 1996 compared demonstration of the NBAS by trained professionals with parental administration of NBAS, with the results

<sup>41</sup>Das Eiden 1996 noted that outcome measures varied across studies but revolved around the theme of parenting

<sup>42</sup>We used could here and in the sentences that follow to acknowledge that studies conducted outside of Australia were not precluded. The MHPWC will therefore need to interpret what was found in the literature to the operational realities of the Australian context.

supporting maternal administration (increased mother-infant contingent interactions during home visits).

***Where*** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?

From the descriptions of the outcome(s) in Das Eiden 1996, it could be surmised that NBAS was offered or administered in the home in four of the 13 included studies. No further detail regarding where the interventions could be delivered was available (Das Eiden 1996).

***To whom*** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?

Das Eiden 1996 reported that “both high-risk and low-risk groups have yielded a similar pattern of mixed results with respect to the impact of NBAS-based interventions on parenting.” Nine included studies targeted mothers, two studies reported the involvement of parents, and the remaining two studies involved fathers (Das Eiden 1996). In five of the 13 included studies, parents and their children were at risk, for example due to low socioeconomic status or preterm birth, and one study included both low and high risk parents and children (Das Eiden 1996).

***When*** could be the best time for the intervention, program, or message delivery to occur? (In regards to caregiver preferences and accessibility; and in regards to improved outcomes for the infant, child and later on as the adolescent, and for the caregiver)

While durations of interventions were not reported, four of the 13 studies used repeated intervention episodes, “with variable results” (Das Eiden 1996). Follow up in the included studies ranged from eight to 10 days post-intervention, to nine months postpartum, with duration of observations at follow up ranging from two minutes to one hour (where reported). Das Eiden 1996 discussed that “in general”, studies with shorter follow up lengths had higher effect sizes, although their basis for this statement was not particularly strong.

***How*** could the intervention, program or messages regarding infant social and emotional wellbeing and development be delivered?

The only information in Das Eiden 1996 regarding how the intervention could be delivered was in relation to parental involvement (i.e. parental administration of the NBAS compared with passive observation and explanation), which has been discussed above.

***How*** could the intervention, program or messages regarding infant social and emotional wellbeing and development be ***framed***?

Framing of the intervention was not covered in Das Eiden 1996.

***What*** could ***impede*** or interfere with engagement with interventions or programs or caregivers enacting upon messages?

Factors impeding engagement of caregivers with interventions or programs were not covered in Das Eiden 1996.

What could **facilitate** or drive engagement with interventions or programs or caregivers enacting upon messages?

Factors facilitating engagement of caregivers with interventions or programs were not covered in Das Eiden 1996.

## **Interventions for enhancing sensitivity and/or attachment security**

### **Description of intervention based on the included evidence**

Interventions to enhance sensitivity and/or attachment security are those aiming to enhance positive parental behaviours, including responsiveness, sensitivity, or involvement, and in turn benefit children's social and emotional development and in particular, attachment security (Bakermans-Kranenburg 2003; Bakermans-Kranenburg 2005). Of the three systematic reviews included in this category only two presented pooled results (Bakermans-Kranenburg 2003; Bakermans-Kranenburg 2005). In this overview, these interventions include those focused on sensitivity, support, representation and combinations of, delivered at home and in other settings, to the general population and populations 'at risk' due to infant (e.g. prematurity, adoption, irritability), or maternal characteristics (e.g. adolescent motherhood, maternal depression, poverty or single parenthood). Interventions were delivered by professionals and non-professionals (lay people), commencing prenatally and postnatally, delivered according to various frequencies and durations, ranging from less than five to more than 16 sessions, measuring parental sensitivity and infant attachment security, including infant attachment disorganisation (Bakermans-Kranenburg 2003; Bakermans-Kranenburg 2005).

### **Evidence summary**

Three systematic reviews compared interventions to enhance sensitivity and/or attachment security with usual care and other controls (Bakermans-Kranenburg 2003; Bakermans-Kranenburg 2005; Doughty 2007). Bakermans-Kranenburg 2003 and 2005 did not report their search dates, while Doughty 2007 searched for studies between 1999 and 2007.

The inclusion criteria for these reviews varied as follows:

- Bakermans-Kranenburg 2003: studies of interventions that started before children's mean age of 53 months (excluding case studies and unpublished studies) using the classic Ainsworth sensitivity ratings scales or with post-tests based on the HOME Inventory, the NCATS or the Erickson rating scales for maternal sensitivity and supportiveness, or studies with other observational measures of parental behaviour clearly related to sensitivity, in low and high-risk populations, that aimed at enhancing positive parental behaviours (e.g. responsiveness, sensitive or involvement).
- Bakermans-Kranenburg 2005: studies of interventions that started before children's mean age of 54 months, in low and high-risk population (excluding case studies and unpublished studies), that assessed disorganised attachment with the Main and Solomon Coding System for disorganisation/disorientation or atypical attachment with Crittenden's PAA.
- Doughty 2007: systematic reviews, meta-analyses or RCTs (published between 1999 and 2006) investigating the effectiveness of an early intervention or strategy (involving infants and young children zero to four years and parents or primary caregivers) which aimed to promote the development of positive, trusting parent-child relationships (e.g. clinical and home-based interventions including group-based training programs, other types of training or education, home visiting with a clearly identified parent training component), reporting of key socio-emotional outcomes (for either parental sensitivity or responsiveness to infant needs and/or infant-parent attachment security).

Together, these three reviews included 93 relevant studies<sup>43</sup> with a total of 16,171 participants (ranging from 12 to 2,799 in the included studies), published between 1972 and 2006 (Bakermans-Kranenburg 2003; Bakermans-Kranenburg 2005; Doughty 2007).

In Bakermans-Kranenburg 2003 and 2005, the interventions ranged in their focuses (i.e. sensitivity alone, versus other), and who and where the interventions were delivered also varied. In Bakermans-Kranenburg 2003 the majority of interventions commenced before six months of age for the infants, with fewer commencing antenatally or after six months, while in Bakermans-Kranenburg 2005, there were similar numbers of interventions commencing before and after six months of age for the infants. Session numbers varied in both reviews with roughly even numbers of interventions delivering less than five, five to 16 and more than 16 sessions (Bakermans-Kranenburg 2003; Bakermans-Kranenburg 2005). In Doughty, all relevant studies used home visiting as the/a mode of delivery; the durations and intensities of interventions were not reported.

All three reviews were judged to be at high risk of bias (Bakermans-Kranenburg 2003; Bakermans-Kranenburg 2005; Doughty 2007) using ROBIS; two reviews were judged to be 'moderate' quality (Bakermans-Kranenburg 2003; Doughty 2007) and one review 'low' quality (Bakermans-Kranenburg 2005) using AMSTAR.

Two of three included systematic reviews provided pooled results:

- Bakermans-Kranenburg 2003 (high risk of bias; 'moderate' quality) included 70 studies assessing 88 interventions (51 in a 'core set' of RCTs), with a total of 9,957 participants (included study Ns not reported) published between 1972 and 2001.
- Bakermans-Kranenburg 2005 (high risk of bias; 'low' quality) included 10 studies assessing 15 interventions (11 assessed in RCTs), with a total of 842 participants (ranging from 30 to 172 in the included studies), published between 1988 and 2005.

For further details regarding the results from single studies from the other review (Doughty 2007), see the Technical Report.

### ***Primary outcome domain***

#### **Infant social and emotional wellbeing or development up to one year of age**

No pooled results were available.

### ***Secondary outcomes domains***

#### **Development for the infant, as a child, and up to 18 years**

No pooled results were available.

#### **Behaviour for the infant, as a child, and up to 18 years**

No pooled results were available.

#### **Physical wellbeing and safety for the infant, as a child, and up to 18 years**

No pooled results were available.

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<sup>43</sup>With some overlap (see Technical Report); Bakermans-Kranenburg 2003 included 70 studies assessing 88 interventions (51 interventions in 'core set' of RCTs); Bakermans-Kranenburg 2005 included 10 studies assessing 15 interventions (11 interventions assessed in RCTs); Doughty 2007 included 13 RCTs

**Parent-infant relationship**

Interventions to enhance sensitivity improved maternal sensitivity (measured using the Ainsworth/Erickson rating scales, HOME Inventory, NCATS or other observational tool) and also maternal attachment (measured using the Strange Situation Procedure (SSP) or other observational tool) in one review (time of outcome measures not reported) (both moderate quality evidence (assumed), downgraded due to inconsistency, with no information reported to determine risk of bias) (Bakermans-Kranenburg 2003). There was no clear impact seen however on disorganised attachment (measured using the Main and Solomon coding system, or Crittenden's Preschool Assessment of Attachment system) in a second review (high quality evidence (assumed), with no information reported to determine risk of bias) (Bakermans-Kranenburg 2005) (time of outcome measures not reported).

**Parent/caregiver psychosocial wellbeing**

No pooled results were available.

**Parent/caregiver knowledge, practices and behaviours**

No pooled results were available.

**Parent/caregiver views of the intervention**

No pooled results were available.

**Family relationships**

No pooled results were available.

**Systems outcomes**

No pooled results were available.

**Table 12: Interventions for enhancing sensitivity and/or attachment security evidence profile**

| <b>INTERVENTIONS FOR ENHANCING SENSITIVITY AND/OR ATTACHMENT SECURITY</b>   |   |  |  |                            |                   |
|---|---|--|--|----------------------------|-------------------|
| What is the effectiveness of interventions for enhancing sensitivity and/or attachment security for parents of infants in their first year of life for optimal social and emotional development for the infant, and later on as a child and adolescent? |   |  |  |                            |                   |
| <b>Comparison</b>   | Usual care and other controls   |  |  |                            |                   |
| <b>Outcome domain</b>   | <b>Outcome measure used in the review(s)</b>  | <b>Results reported in the review(s) and GRADE</b>   |  |                            | <b>Importance</b> |
|   |   | <b>Result</b> <sup>44,45</sup>   | <b>GRADE</b>   | <b>Quality of evidence</b> |                   |
| <b>Infant social and emotional wellbeing or development up to one year of age</b>   | No pooled results were available.   |  |  |                            | CRITICAL          |
| <b>Development for the infant, as a child, and up to 18 years</b>   | No pooled results were available.   |  |  |                            | CRITICAL          |
| <b>Behaviour for the infant, as a child, and up to 18 years</b>   | No pooled results were available.   |  |  |                            | CRITICAL          |
| <b>Physical wellbeing and safety for the infant, as a child, and up to 18 years</b>   | No pooled results were available.   |  |  |                            | CRITICAL          |
| <b>Parent-infant relationship</b>   | Maternal sensitivity (Ainsworth/Erickson; HOME Inventory; NCATS; other) (time of outcome measures NR)         | <b>ES: 0.33 (90% CI 0.25, 0.41); Q: 127.82 (P &lt; 0.001); P &lt; 0.001</b><br>(51 interventions from core set of RCTs, N=6,282) (Bakermans-Kranenburg 2003) | Risk of bias: 0 (assumed)<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Moderate (assumed)         | CRITICAL          |
|   | <i>GRADE reasons for downgrading: Risk of bias: NR; Inconsistency: substantial heterogeneity (P&lt;0.001)</i> |  |  |                            |                   |
|   | Attachment (SSP; other) (time of outcome measures NR)   | <b>ES: 0.20 (90% CI 0.04, 0.35); Q: 55.21 (P &lt; 0.001); P &lt; 0.05</b><br>(23 interventions from core set of RCTs, N=1,255) (Bakermans-Kranenburg 2003)   | Risk of bias: 0 (assumed)<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Moderate (assumed)         | CRITICAL          |

<sup>44</sup> All Ns reflect the total numbers (i.e. across both the intervention and control groups)

<sup>45</sup> Bolding indicates a statistically significant pooled result in favour of the intervention



|   |   |  |   |                |           |
|---|---|--|---|----------------|-----------|
|   | <i>GRADE reasons for downgrading: Risk of bias: NR; Inconsistency: substantial heterogeneity (P&lt;0.001)</i>   |  |   |                |           |
|   | Disorganised infant attachment (Main and Solomon coding system; Crittenden's PAA) (post-test; time of outcome measures largely NR)  | ES: 0.05 (90% CI - 0.07, 0.17); Q: 21.41 (P=NS); P=NS (10 studies, 11/15 interventions from RCTs, N=842) (Bakermans-Kranenburg 2005) | Risk of bias: 0 (assumed)<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | High (assumed) | CRITICAL  |
| <b>Parent/caregiver psychosocial wellbeing</b>              | No pooled results were available.   |  |   |                | IMPORTANT |
| <b>Parent/caregiver knowledge, practices and behaviours</b> | No pooled results were available.   |  |   |                | CRITICAL  |
| <b>Parent/caregiver views of the intervention</b>           | No pooled results were available.   |  |   |                | IMPORTANT |
| <b>Family relationships</b>                                 | No pooled results were available.   |  |   |                | CRITICAL  |
| <b>Systems outcomes</b>                                     | No pooled results were available.   |  |   |                | IMPORTANT |
| <b>Evidence statement</b>                                   |   |  |   |                |           |
| <b>Parent-infant relationship</b>                           | <u>Sensitivity and attachment</u> : Moderate quality evidence from two systematic reviews shows maternal sensitivity (measured using the Ainsworth/Erickson sensitivity rating scales, HOME Inventory, NCATS, or other tools) and attachment (measured using the SSP, or other tools) are improved with sensitivity interventions (51 interventions assessed in RCTs, N=6,282 and 23 interventions assessed in RCTs, N=1,255 respectively), and high quality evidence shows no clear impact on disorganised attachment (measured using the Main and Solomon coding system, or Crittenden's PAA) (time of outcome measures not reported) (10 studies (11/15 interventions assessed in RCTs), N=842). |  |   |                |           |

**Abbreviations:** CI: confidence interval; ES: effect size; GRADE: Grading of Recommendations Assessment, Development and Evaluation; HOME: Home Observation for Measurement of the Environment; N: number; NCATS: Nursing Child Assessment Teaching Scale; NR: not reported; P: P value; PAA: Preschool Assessment of Attachment System; Q: Cochran Q test of heterogeneity of the effect size; RCT: randomised controlled trial; SSP: Strange Situation Procedure

### **Characteristics that may have contributed to the effectiveness of interventions for enhancing sensitivity and/or attachment security for optimal social and emotional development of infants**

Bakermans-Kranenburg 2003 concluded that “the most effective interventions used a moderate number of sessions and a clear-cut behavioural focus [on maternal sensitivity] in families with, as well as without, multiple problems. Interventions that were more effective in enhancing parental sensitivity were also more effective in enhancing attachment security.” Bakermans-Kranenburg 2005 concluded that “interventions may be most effective in decreasing disorganization... when they start after six months of the infant’s age, when it is the infant who is primarily at-risk, and when a sensitivity-focused approach is used.”

***Who*** could<sup>46</sup> deliver the intervention, program or messages to optimise infant social and emotional wellbeing and development?

Bakermans-Kranenburg 2003 investigated whether the type of intervenor (non-professional, professional, or no intervenor) moderated the beneficial effect seen for maternal sensitivity, however found no clear impact (P=0.08). The impact of different types of intervenors on infant disorganised attachment was also assessed in Bakermans-Kranenburg 2005. While a statistical test could not be conducted, it was observed that interventions that used professional intervenors (as compared with those using lay persons or written materials) were the only interventions to show a significant effect size (Table 12b).

**Table 12b: Who delivered the interventions in Bakermans-Kranenburg 2003**

| Outcome                        | Moderator   | Significance |
|--------------------------------|---|--------------|
| Maternal sensitivity           | Intervenor (nonprofessional, professional, no intervenor) | NS           |
| Disorganised infant attachment | Intervenor (not in person, lay person, professional)      | NR           |

**Abbreviations:** NR: not reported; NS: non-significant; S: significant

***Where*** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?

Whether the intervention was delivered in the home (yes versus no), did not clearly moderate the effect of interventions for improving maternal sensitivity (P=0.12) (Bakermans-Kranenburg 2003), nor did interventions for improving infant disorganised attachment (statistical test not performed) (Bakermans-Kranenburg 2005) (Table 12c).

**Table 12c: Where the interventions were delivered in Bakermans-Kranenburg 2003**

| Outcome                        | Moderator         | Significance |
|--------------------------------|-------------------|--------------|
| Maternal sensitivity           | At home (yes, no) | NS           |
| Disorganised infant attachment | At home (yes, no) | NR           |

**Abbreviations:** NR: not reported; NS: non-significant; S: significant

***To whom*** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?

Bakermans-Kranenburg 2003 noted that sample socio-economic status (middle/high versus low) (P=0.58), adolescent motherhood (yes versus no) (P=0.88), preterm birth (yes versus no) (P=0.68), and the presence of multiple risk factors (yes versus no) (P=0.73), did not clearly moderate the effect the interventions on maternal sensitivity. However, interventions with clinically referred samples (e.g. referral for maternal depression, or an anxious-withdrawn child) were found to be more effective than interventions with other groups for improving maternal sensitivity (P=0.002). Interventions involving fathers were shown to be more effective than those without fathers (P=0.003) (Bakermans-Kranenburg 2003). Sample socio-economic status (middle/high versus low) (P=0.50), the presence of multiple risk factors (yes versus no) (P=0.83), and clinical risk (yes versus no) (P=0.82) did not clearly moderate the effect of the interventions on infant attachment security (Bakermans-Kranenburg 2003). However, interventions with a high proportion of insecurely

<sup>46</sup>We used could here and in the sentences that follow to acknowledge that studies conducted outside of Australia were not precluded. The MHPWC will therefore need to interpret what was found in the literature to the operational realities of the Australian context.

attached children in the control group (used as an indicator of the risk for attachment related problems in the sample) were shown to be associated with larger effect sizes ( $P < 0.001$ ) (Bakermans-Kranenburg 2003) (Table 12d).

The sample characteristics: socio-economic status (middle/high versus low) ( $P = 0.08$ ), the presence of multiple risk factors (yes versus no) ( $P = 0.91$ ), and clinical referrals (yes versus no) ( $P = 0.67$ ) were not associated with differences in effect sizes for infant disorganised attachment (Bakermans-Kranenburg 2005). However, interventions that were implemented in groups with the risk primarily located in the child (e.g. prematurity, irritability, or international adoption), were more effective than those with parents at risk (e.g. maternal of depression, maternal attachment insecurity, or poverty, social isolation and single parenthood) ( $P = 0.01$ ) (Bakermans-Kranenburg 2005). Further, studies with higher percentages of disorganised attachment in the control group were more effective (than those with lower percentages) ( $P < 0.001$ ) (Bakermans-Kranenburg 2005) (Table 12d).

**Table 12d: To whom the intervention were delivered in Bakermans-Kranenburg 2003**

| Outcome                        | Moderator                                      | Significance |
|--------------------------------|--|--------------|
| Maternal sensitivity           | Sample SES (middle/high, low)                  | NS           |
|                                | Adolescent motherhood (yes, no)                |              |
|                                | Preterm (yes, no)                              |              |
|                                | Multiple risk factors (yes, no)                |              |
|                                | Clinical risk (yes, no)                        | S            |
|                                | Fathers included (yes, no)                     |              |
| Attachment                     | Sample SES (middle/high, low)                  | NS           |
|                                | Multiple risk factors (yes, no)                |              |
|                                | Clinical risk (yes, no)                        |              |
|                                | Insecure % ( $\leq 33$ , $34-50$ , $\geq 51$ ) | S            |
| Disorganised infant attachment | Sample SES (middle/high, low)                  | NS           |
|                                | Multiple risk factors (yes, no)                |              |
|                                | Clinical risk (yes, no)                        |              |
|                                | Risk location (child, parent)                  | S            |
|                                | Disorganisation % ( $< 21$ , $\geq 21$ )       |              |

**Abbreviations:** NS: non-significant; S: significant; SES: socio-economic status

***When*** could be the best time for the intervention, program, or message delivery to occur? (In regards to caregiver preferences and accessibility; and in regards to improved outcomes for the infant, child and later on as the adolescent, and for the caregiver)

Interventions starting after six months of age for the infant were shown to be more effective in enhancing maternal sensitivity than those starting antenatally or at less than six months of age ( $P = 0.04$ ). In multiple regression analyses, the age of the infant at the start of the intervention was one of the two significant predictors of effect size (with a later start of the intervention predicting a higher effect size) (Bakermans-Kranenburg 2003). In regards to the number of sessions, interventions with less than five sessions were shown to be as effective as those with between five and 16 sessions for enhancing maternal sensitivity, however, interventions with more than 16 sessions were suggested to be less effective ( $P < 0.001$ ).

Interventions starting after six months of age for the infant were also shown to be more effective (than those starting antenatally or at less than six months of age) at enhancing infant attachment security ( $P = 0.04$ ) (Bakermans-Kranenburg 2003). No clear impact of the number of sessions (less than five, five to 16, more than 16) was observed for the outcome infant attachment ( $P = 0.22$ ) (Bakermans-Kranenburg 2003) (Table 12e).

Similarly, interventions starting later (after six months) were more effective than those starting antenatally or in the first six months of the infant's life for preventing disorganised infant attachment ( $P=0.02$ ) (Bakermans-Kranenburg 2005); no clear effect of the number of sessions was observed for this outcome ( $P=0.41$ ) (Table 12e).

**Table 12e: When the intervention were delivered in Bakermans-Kranenburg 2003**

| Outcome                        | Moderator                                       | Significance |
|--------------------------------|---|--------------|
| Maternal sensitivity           | Number of sessions (< 5, 5-16, > 16)            | S            |
|                                | Age at start (prenatal, < 6 months, > 6 months) | S            |
| Attachment                     | Number of sessions (< 5, 5-16, > 16)            | NS           |
|                                | Age at start (prenatal, < 6 months, > 6 months) | S            |
| Disorganised infant attachment | Number of sessions (< 5, 5-16, > 16)            | NS           |
|                                | Age at start (< 6 months, > 6 months)           | S            |

**Abbreviations:** NS: non-significant; S: significant

**How** could the intervention, program or messages regarding infant social and emotional wellbeing and development be delivered?

Bakermans-Kranenburg 2003 assessed the impact of the focus of the intervention on maternal sensitivity, and observed that interventions focused on sensitivity only were more effective than interventions with other focuses (including support only; representation only; and combinations of sensitivity, support and representation) ( $P=0.03$ ). In multiple regression analyses, the focus of the intervention was one of the two significant predictors of effect size (with sensitivity-focused interventions predicting a higher effect size) (Bakermans-Kranenburg 2003). Interventions with video feedback, compared with those without it, were shown to be more effective in enhancing maternal sensitivity ( $P=0.04$ ), as were short interventions (less than 16 sessions) focusing on sensitivity (compared with long interventions focusing on sensitivity, and short and long interventions with other focuses) ( $P<0.001$ ) (Table 12f).

Interventions focused on sensitivity only were also more effective than interventions with other focuses in enhancing infant attachment security ( $P<0.001$ ), however for this outcome, interventions with video feedback were suggested to be less effective ( $P=0.02$ ) (Bakermans-Kranenburg 2003). Bakermans-Kranenburg 2003 noted that the studies most effective (with the largest effect sizes) in enhancing maternal sensitivity were also most effective in enhancing attachment security ( $P=0.001$ ) (Table 12f).

Bakermans-Kranenburg 2005 also observed that interventions focused on sensitivity only were more effective than interventions with other focused for preventing disorganised infant attachment ( $P=0.03$ ); the use of video feedback, however did not clearly influence this outcome (Table 12f).

**Table 12f: How intervention were delivered in Bakermans-Kranenburg 2003**

| Outcome                        | Factor  | Significance |
|--------------------------------|---|--------------|
| Maternal sensitivity           | Focus of the intervention (sensitivity only, other)   | S            |
|                                | Video feedback (yes, no)  |              |
|                                | Focus of the intervention x N sessions (sensitivity x < 16 sessions, other x < 16 sessions, sensitivity x > 16 sessions, other > 16 sessions) |              |
| Attachment                     | Focus of the intervention (sensitivity only, other)   | S            |
|                                | Video feedback (yes, no)  |              |
|                                | Focus of the intervention x sessions (sensitivity x < 16 sessions, other x < 16 sessions, sensitivity x > 16 sessions, other > 16 sessions)   |              |
| Disorganised infant attachment | Focus of the intervention (sensitivity only, other)   | S            |
|                                | Video feedback (yes, no)  | NS           |

**Abbreviations:** N: number; NS: non-significant; S: significant; x: times

*How could the intervention, program or messages regarding infant social and emotional wellbeing and development be **framed**?*

Intervention framing was not covered in Bakermans-Kranenburg 2003 or Bakermans-Kranenburg 2005.

*What could **impede** or interfere with engagement with interventions or programs or caregivers enacting upon messages?*

Factors impeding engagement of caregivers with interventions or programs were not directly covered (Bakermans-Kranenburg 2003; Bakermans-Kranenburg 2005). Bakermans-Kranenburg 2003 discussed the obstacle for long-term interventions in families with multiple problems of differential attrition, whereby it may be challenging for control groups to remain motivated without experiencing some form of support. Bakermans-Kranenburg 2003 noted the potential benefits of involving fathers in preventive interventions which “may motivate their partners to continue participation and to practice new behaviours at home.” However they also discussed that such involvement could be counterproductive. In two of the three included studies involving fathers in the review, while the effects on paternal sensitivity were large, similar effects on maternal sensitivity were not seen, and in one study, the intervention effects were in fact negative for mothers (Bakermans-Kranenburg 2003). Possible explanations provided by Bakermans-Kranenburg 2003 included less attention paid to mothers’ needs and abilities in such interventions, or mothers underestimating the importance of their own practising of new skills and child-rearing insights with the involvement of fathers.

*What could **facilitate** or drive engagement with interventions or programs or caregivers enacting upon messages?*

Factors facilitating engagement of caregivers with interventions or programs were not covered in Bakermans-Kranenburg 2003 or Bakermans-Kranenburg 2005.

## Interventions for preventing later antisocial behaviour and delinquency

### Description of intervention based on the included evidence

Of the three systematic reviews included in this category only one presented pooled quantitative results (Piquero 2008). In this overview, interventions that aimed to prevent childhood behaviour problems were mostly home visiting programs, that had parental education and/or family support as a major component, delivered to families from both general and high risk populations, with infants one year of age or less (Piquero 2008).

### Evidence summary

Three systematic reviews assessed interventions to prevent later antisocial behaviour and delinquency (Bernazzani 2001; Piquero 2008; Yoshikawa 1995). Bernazzani 2001 searched for studies between 1967 and 2011, while Piquero 2008 searched up to 2009, and Yoshikawa 1995 did not report the review search dates.

Inclusion criteria for these reviews varied, and were as follows:

- Bernazzani 2001: randomised or quasi-experimental trials, assessing interventions involving the provision of parent training for families with a child under age three, (with a 5- or 4-star design according to the 'Threats to Trial Integrity Score') and outcome measures of children's delinquent behaviour or disruptive behaviour.
- Piquero 2008: RCTs investigating the effects of early family/parent training on child behaviour problems such as conduct problems, with families with a child under five (in the general or high-risk population), antisocial behaviour and delinquency, with before-and-after measures of delinquent behaviour or behaviour problems (with adequate data for calculating an effect size if not provided).
- Yoshikawa 1995: studies with 'adequate' research designs (conducted in the United States or Canada) assessing interventions that served populations which displayed the risk factors associated with later delinquent or antisocial behaviour, which provided services between the prenatal period and entry into primary school, and assessed effects on risk factors for chronic juvenile delinquency and/or antisocial behaviour or delinquency.

Together, these three reviews included 44 relevant studies<sup>47</sup> (including at least 16 RCTs) with a total of more than 9,395<sup>48</sup> participants in two systematic reviews (and not reported in one review) (ranging from 64 to more than 2,000 in the included studies), published between 1973 and 2008 (Bernazzani 2001; Piquero 2008; Yoshikawa 1995).

In Bernazzani 2011 interventions (predominately home visiting) ranged in their timing and durations (e.g. commencing in the prenatal period, continuing to two years; or beginning prior to 12 months of age for the infant and continuing beyond age two, up to three to six years). Piquero 2008 did not describe the characteristics of the relevant home visiting interventions in detail; however the majority commenced around the time of birth. In Yoshikawa 1995, the timing, intensity and durations of family support, and combined education and family support programs varied considerably, with many involving weekly or bi-weekly home visits, with total numbers of visits ranging from 10 to 110.

One review was judged to be at unclear risk of bias (Piquero 2008), and two reviews were judged to be at high risk of bias (Bernazzani 2001; Yoshikawa 1995) using ROBIS; two reviews were judged to

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<sup>47</sup>With some overlap (see Technical Report)

<sup>48</sup>Bernazzani 2001 reported 'final N' for each trial; for one included trial, the N reported was >2,000

be 'moderate' quality (Bernazzani 2001; Piquero 2008) and one review 'low' quality (Yoshikawa 1995) using AMSTAR.

Two of the three included systematic reviews provided pooled results:

- Piquero 2008 (unclear risk of bias; 'moderate' quality) included 10 relevant studies (RCTs) with a total of 5,070 participants (ranging from 64 to 1,139 in the included studies), published between 1979 and 2008.
- Yoshikawa 1995 (high risk of bias; 'low' quality) included 28 relevant studies (study designs and Ns not reported), published between 1973 and 1994.

As Yoshikawa 1995 did not provide pooled numerical results, we were unable to GRADE outcomes reported by this review.

For further details regarding the results from single studies from the other review (Bernazzani 2001), see the Technical Report.

### ***Primary outcome domain***

#### **Infant social and emotional wellbeing or development up to one year of age**

No pooled results were available.

### ***Secondary outcomes domains***

#### **Development for the infant, as a child, and up to 18 years**

The effects of family support programs on early cognitive ability (such as early IQ, school achievement, language development, verbal ability (measuring tools/tests not reported)) were unclear in one review, though combined early education and family support programs showed some benefits in the same review (family support programs: at four months, up to grade five; combined early education and family support interventions: 12 months, up to 10 years) (quality of the evidence not assessed) (Yoshikawa 1995).

#### **Behaviour for the infant, as a child, and up to 18 years**

Home visiting interventions reduced child disruptive behaviours (measured using the CBCL, ECBI, or by the number of children 'hitting others') (moderate quality evidence, downgraded due to high risk of bias) in one review (Piquero 2008). Family support programs had no clear impact on antisocial/delinquent behaviour (measured using teacher ratings) (at two years, up to grade four), although combined early education and family support interventions reduced aggressive behaviour (measured using teacher ratings, self-reported delinquency, or official criminal acts/arrests) at eight to 16 years of age, in a second review (quality of the evidence not assessed) (Yoshikawa 1995).

#### **Physical wellbeing and safety for the infant, as a child, and up to 18 years**

No pooled results were available.

#### **Parent-infant relationship**

Family support interventions and combined education and family support interventions showed some benefits on parenting (such as mother-child interaction, parenting behaviour, attachment, and child welfare (measuring tools not reported)) in one review (family support programs: at four to 54 months; combined education and family support interventions: four months to five years) (quality of the evidence not assessed) (Yoshikawa 1995).

**Parent/caregiver psychosocial wellbeing**

Family support programs and combined education and family support programs both improved aspects of the maternal life course (such as maternal education and employment, childbearing, family economic self-sufficiency) in one review (family support: one to four years; combined education and family support: one to 10 years) (quality of the evidence not assessed) (Yoshikawa 1995).

**Parent/caregiver knowledge, practices and behaviours**

No pooled results were available.

**Parent/caregiver views of the intervention**

No pooled results were available.

**Family relationships**

No pooled results were available.

**Systems outcomes**

No pooled results were available.

**Potential harms<sup>49</sup>**

In one review (Yoshikawa 1995), single study results show significantly poorer outcomes for antisocial/delinquent behaviour at school entry (within the outcome domain of behaviour for the infant, as a child, and up to 18 years) with early education programs. However, these results must be interpreted in context and with caution, as other single study results show positive results for the same outcome. For further details regarding potential harms from single studies see the pink shaded rows of the Evidence Tables in the Technical Report.

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<sup>49</sup>In this context, harm refers to a significantly poorer outcome in the intervention group relative to the control group within a pre-specified primary or secondary outcome domain.



**Table 13: Interventions for preventing later antisocial behaviour and delinquency evidence profile**

| <b>INTERVENTIONS FOR PREVENTING LATER ANTISOCIAL BEHAVIOUR AND DELINQUENCY</b>  |   |  |  |                            |                   |
|---|---|--|--|----------------------------|-------------------|
| What is the effectiveness of interventions for preventing later antisocial behaviour and delinquency, in the infant’s first year of life for optimal social and emotional development for the infant, and later on as a child and adolescent? |   |  |  |                            |                   |
| <b>Comparison</b>   | Non-intensive follow up or not reported   |  |  |                            |                   |
| <b>Outcome domain</b>   | <b>Outcome measure used in the review(s)</b>  | <b>Results reported in the review(s) and GRADE</b>   |  |                            | <b>Importance</b> |
|   |   | <b>Result</b> <sup>50,51</sup>   | <b>GRADE</b>   | <b>Quality of evidence</b> |                   |
| <b>Infant social and emotional wellbeing or development up to one year of age</b>   | No pooled results were available.   |  |  |                            | CRITICAL          |
| <b>Development for the infant, as a child, and up to 18 years</b>   | Early cognitive ability (early IQ; school achievement; language development; verbal ability (actual measuring tools/tests NR)): family support programs (4 months to grade 5 (~10-11 years))        | 11 studies (designs NR; N=NR) Significantly better in 4 studies; mixed results in 3 studies; and no clear differences seen in 4 studies (Yoshikawa 1995) | Insufficient information to GRADE  | Not assessed               | CRITICAL          |
|   | Early cognitive ability (early IQ; school achievement; language development; verbal ability (actual measuring tools/tests NR)): combined early education and family support (12 months to 10 years) | 9 studies (designs NR; N=NR) Significantly better in 7 studies; mixed results in 2 studies (Yoshikawa 1995)  | Insufficient information to GRADE  | Not assessed               | CRITICAL          |
| <b>Behaviour for the infant, as a child, and up to 18 years</b>   | Child disruptive behaviour outcomes (CBCL; ECBI; hitting others) (time of measure NR)   | <b>ES (weighted): 0.30 (95% CI 0.04, 0.56); Q: 11.73, P=NS; P &lt; 0.05</b> (8 RCTs, N=NR) (Piquero 2008)  | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Moderate                   | CRITICAL          |
|   | <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations</i>   |  |  |                            |                   |
|   | Antisocial/delinquent behaviour (teacher rated; self-reported delinquency; official criminality (e.g. criminal acts/arrests)): family support programs (2 years to grade 4 (~9-10 years))           | 3 studies (designs NR; N=NR) Significantly less avoidant and angry in 1 study; and no clear differences seen in 2 studies (Yoshikawa 1995)               | Insufficient information to GRADE  | Not assessed               | CRITICAL          |

<sup>50</sup> All Ns reflect the total numbers (i.e. across both the intervention and control groups)

<sup>51</sup> Bolding indicates a statistically significant pooled result in favour of the intervention

|   |   |  |                                   |              |           |
|---|---|--|-----------------------------------|--------------|-----------|
|   | Antisocial/delinquent behaviour (teacher rated; self-reported delinquency; official criminality (e.g. criminal acts/arrests)): combined early education and family support (8-16 years) | 3 studies (designs NR; N=NR)<br>Significantly less aggressive behaviour in 3 studies (Yoshikawa 1995)  | Insufficient information to GRADE | Not assessed | CRITICAL  |
| <b>Physical wellbeing and safety for the infant, as a child, and up to 18 years</b> | No pooled results were available.   |  |                                   |              | CRITICAL  |
| <b>Parent-infant relationship</b>   | Parenting (mother-child interaction; parenting behaviour; attachment; child welfare): family support (4-54 months)  | 16 studies (designs NR; N=NR)<br>10 studies showed significant improvements; 3 studies had mixed results; 3 studies showed no clear differences (Yoshikawa 1995) | Insufficient information to GRADE | Not assessed | CRITICAL  |
|   | Parenting (mother-child interaction; parenting behaviour; attachment; child welfare): combined education and family support (4 months to 5 years)                                       | 7 studies (designs NR; N=NR)<br>5 studies showed significant improvements; 1 study had mixed results; 1 study showed no clear differences (Yoshikawa 1995)       | Insufficient information to GRADE | Not assessed | CRITICAL  |
| <b>Parent/caregiver psychosocial wellbeing</b>                                      | Maternal life course (maternal education and employment; childbearing; family economic self-sufficiency): family support (1-4 years)  | 5 studies (designs NR; N=NR)<br>5 studies showed significant improvements (Yoshikawa 1995)   | Insufficient information to GRADE | Not assessed | IMPORTANT |
|   | Maternal life course (maternal education and employment; childbearing; family economic self-sufficiency): combined education and family support (1-10 years)                            | 4 studies (designs NR; N=NR)<br>4 studies showed significant improvements (Yoshikawa 1995)   | Insufficient information to GRADE | Not assessed | IMPORTANT |
| <b>Parent/caregiver knowledge, practices and behaviours</b>                         | No pooled results were available.   |  |                                   |              | CRITICAL  |
| <b>Parent/caregiver views of the intervention</b>                                   | No pooled results were available.   |  |                                   |              | IMPORTANT |
| <b>Family relationships</b>   | No pooled results were available.   |  |                                   |              | CRITICAL  |
| <b>Systems outcomes</b>   | No pooled results were available.   |  |                                   |              | IMPORTANT |

| Evidence statement  |   |
|---|---|
| <b>Behaviour for the infant, as a child, and up to 18 years</b> | <u>Child disruptive behaviour</u> : Moderate quality evidence from one systematic review shows that home visiting interventions to prevent later antisocial behaviour and delinquency can reduce child disruptive behaviour (measured using the CBCL, ECBI, or by the number of children 'hitting others') (time of outcome measure not reported) (eight RCTs, N=NR). |

**Abbreviations:** CBCL: Child Behaviour Checklist; CI: confidence interval; ECBI: Eyberg Child Behaviour Inventory; ES: effect size; GRADE: Grading of Recommendations Assessment, Development and Evaluation; IQ: Intelligence Quotient; N: number; NR: not reported; NS: not significant; P: P value; Q: Cochran Q test for heterogeneity of the effect size; RCT: randomised controlled trial

**Characteristics that may have contributed to the effectiveness of interventions for preventing later antisocial behaviour and delinquency for optimal social and emotional development of infants**

***Who** could<sup>52</sup> deliver the intervention, program or messages to optimise infant social and emotional wellbeing and development?*

In Piquero 2008, child disruptive behaviours were shown to be reduced with home visiting interventions. There was limited detail regarding who delivered the interventions in the eight included studies, though it was discussed that these interventions “typically involved health professionals such as nurses, doctors, or paraprofessionals.”

In Yoshikawa 1995, possible benefits were seen with family support programs (particularly for parenting and the maternal life course), and with combined family support and education programs (for early cognitive ability, antisocial/delinquent behaviour, parenting and the maternal life course). Limited detail was provided regarding who delivered the interventions in the included studies, except for the three programs which showed long-term reductions in antisocial behaviour or chronic delinquency (Johnson 1987; Lally 1988; Seitz 1994). In these studies Yoshikawa 1995 discussed that the home-visitor-to-family ratios were generally one to 10 or better, with staff-child ratios in infant/toddler educational child care in the range of one adult to three or four children, and one to six in preschool programs. In one of the programs, there was a four person team delivering the intervention: a paediatrician, a home visitor, a primary child care worker, and a developmental examiner.

***Where** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?*

The reduction in child disruptive behaviours observed in Piquero 2008 was with home visiting interventions. Six of the eight studies were conducted in the United States, with one conducted in Australia and one in New Zealand (Piquero 2008).

All studies in Yoshikawa 1995 were conducted in the United States or Canada (a review inclusion criterion). Though few specific details were provided in regards to where the interventions were delivered, all except for one of the studies assessing family support program were delivered in the home, and many of the combined family support and education programs were delivered in both the home and an educational day care setting (Yoshikawa 1995) (see Table 13b).

<sup>52</sup>We used could here and in the sentences that follow to acknowledge that studies conducted outside of Australia were not precluded. The MHPWC will therefore need to interpret what was found in the literature to the operational realities of the Australian context.

***To whom*** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?

Piquero 2008 provided limited detail regarding to whom the home visiting interventions (associated with a reduction in child disruptive behaviours) were delivered; it was discussed that in these intervenors “visited the mothers...”

Though Yoshikawa 1995 provided few specific details of the populations in the included studies, a review inclusion criterion was that the study assessed a program that “served populations which displayed the risk factors associated with later delinquent or antisocial behaviour (for example, low household income, single parent, low parental educational level, low birth weight, and/or preterm birth).” It was discussed that the three programs which showed long-term reductions in antisocial behaviour or chronic delinquency all targeted areas with the highest crime rates – urban, low-income communities (Yoshikawa 1995). Specifically they addressed low-income Mexican-American families and low-income African-American families from pregnancy or birth.

***When*** could be the best time for the intervention, program, or message delivery to occur? (In regards to caregiver preferences and accessibility; and in regards to improved outcomes for the infant, child and later on as the adolescent, and for the caregiver)

Limited detail was provided regarding when the home visiting interventions (associated with a reduction in child disruptive behaviours) in Piquero 2008 were delivered; it was discussed that in these interventions began “relatively early on in life (i.e., pre-birth and/or during infancy).” Seven of the eight included studies had a ‘targeted age’ of birth; one study targeted one year olds.

The age of the children at commencement and completion of the programs in Yoshikawa 1995, along with the ‘intensity’ of the programs delivered varied considerably, and no clear patterns were identified for family support programs, nor for combined family support and education programs (see Table 13b).

Yoshikawa 1995 discussed some common characteristics of the three ‘effective’ programs, which showed long-term reductions in antisocial behaviour or chronic delinquency. The individual components in each program were intensive, with home visits made weekly to monthly, with the total number ranging from 25 to 60, and the early educational component ranged from half-day to full-day sessions, usually four to five days a week; none of the programs were shorter than two years, but lengths varied from two to five years; two of the programs were implemented at or before birth, and one began at age one for the infant.

**Table 13b: When the interventions were delivered in Yoshikawa 1995**

| Type of program | Outcome           | Age of child at start and end of intervention (Intensity of the intervention)  | Results      |
|-----------------|-------------------|--|--------------|
| Family support  | Cognitive ability | 0-3 months (7 in hospital sessions and 4 home visits)  | 4 studies: S |
|                 |                   | 0-12 months (44 classes)   |              |
|                 |                   | 3 months to 3 years (from 3 months to 2 years: weekly home visits, from age 2 to 3: twice weekly part-day preschool)   |              |
|                 |                   | 0-12 months (15 home visits)   |              |
|                 |                   | 0-6 months (bi-weekly home visits)   | 3 studies: I |
|                 |                   | 7 <sup>th</sup> month pregnancy to 3 years (18 home visits in year 1, 12 in year 2, 8 in year 3)                       |              |
|                 |                   | 3, 7 or 11 months to 16 months later (weekly home visits)  |              |
|                 |                   | 0-12 months (home visits weekly for 1-4 months, bi-weekly for 5-8 months, monthly for 9-12 months (average 23 visits)) | 4 studies NS |
|                 |                   | Starting at 0-9 months to 18 months (approximately weekly home visits)   |              |

|                              |   |   |               |   |               |
|------------------------------|---|---|---------------|---|---------------|
|                              |   | Pregnancy to 24 months (1 home visit per week for 1 <sup>st</sup> 6 weeks postpartum gradually slowing to 1 visit every 6 weeks (average 31 visits))  |               |   |               |
|                              |   | 0-5 years (107 home visits)   |               |   |               |
|                              | Antisocial or delinquent behaviour                                  | 1-2 years (weekly home visits)  | 1 study: S    |   |               |
|                              |   | 7 <sup>th</sup> month pregnancy to 3 years (18 home visits in year 1, 12 in year 2, 8 in year 3)  | 2 studies: NS |   |               |
|                              |   | 3 months to 3 years (from 3 months to 2 years: weekly home visits, from age 2 to 3: twice weekly part-day preschool)  |               |   |               |
|                              | Parenting   | 0-12 months (home visits weekly for 1-4 months, bi-weekly for 5-8 months, monthly for 9-12 months (average 23 visits))  | 10 studies: S |   |               |
|                              |   | Pregnancy to 6 months (2 home visits per month for 6 months)  |               |   |               |
|                              |   | 0-2 years (weekly home visits, bi-weekly visits to paediatrician and bi-weekly calls to paediatrician)  |               |   |               |
|                              |   | 0-2 years (10 home visits)  |               |   |               |
|                              |   | Pregnancy to 1 year (30 home visits)  |               |   |               |
|                              |   | 3, 7 or 11 months to 16 months later (weekly home visits)   |               |   |               |
|                              |   | 7 <sup>th</sup> month of pregnancy to 15 months postpartum OR 6 weeks to 15 months postpartum (7 visits from 6 weeks to 6 months, 3 visits from 6-15 months)  |               |   |               |
|                              |   | 1-2 years (weekly home visits)  |               |   |               |
|                              |   | Pregnancy to 24 months (1 home visit per week for 1 <sup>st</sup> 6 weeks postpartum gradually slowing to 1 visit every 6 weeks (average 31 visits))  |               |   |               |
|                              |   | 0-12 months (15 home visits)  |               |   |               |
|                              |   | 0-6 months (bi-weekly home visits)  |               | 3 studies: I  |               |
|                              |   | 7 <sup>th</sup> month pregnancy to 3 years (18 home visits in year 1, 12 in year 2, 8 in year 3)  |               |   |               |
|                              |   | Starting at 0-9 months to 18 months (approximately weekly home visits)  |               |   |               |
|                              |   |   |               | 0-18 months (21 home visits)  | 3 studies: NS |
|                              |   |   |               | 0-3 months (3 home visits per month for 3 months after birth, with or without extended contact between mother and infant in hospital) |               |
|                              |   | 0-5 years (107 home visits)   |               |   |               |
|                              | Maternal life course  | 0-12 months (44 classes)  | 5 studies: S  |   |               |
|                              |   | 0-6 months (bi-weekly home visits)  |               |   |               |
|                              |   | 7 <sup>th</sup> month pregnancy to 3 years (18 home visits in year 1, 12 in year 2, 8 in year 3)  |               |   |               |
|                              |   | Pregnancy to 24 months (1 home visit per week for 1 <sup>st</sup> 6 weeks postpartum gradually slowing to 1 visit every 6 weeks (average 31 visits))  |               |   |               |
|                              |   | Beginning in pregnancy (daily classes for teen mothers (14-19 years), from 1-4 academic quarters)   |               |   |               |
| Education and family support | Cognitive ability   | 3-5 months to 3 years (year 1: 3-4 half days per week with mothers and infants together in centre, 15-36 months: 4 half days per week, mothers as understudies to teachers, fifth day in classes)   | 7 studies: S  |   |               |
|                              |   | 2 months to 3 years (2 half days per week in centre, child care and parenting groups)   |               |   |               |
|                              |   | From hospital to discharge to 3 years (home visits weekly in year 1, bi-weekly in years 2 and 3, at least 5 half days at preschool per week in 2 <sup>nd</sup> and 3 <sup>rd</sup> years, bi-monthly group meetings in 2 <sup>nd</sup> and 3 <sup>rd</sup> years) |               |   |               |
|                              |   | From 0-6 months (5 half days per week with mothers and children together at preschool, mothers employed as teachers' aides)   |               |   |               |
|                              |   | 0-5 years (full-day child care 5 days per week, job counselling and training for parents)   |               |   |               |
|                              |   | 0-5 years (weekly home visits, full-day child care from 6 months to 5 years)  |               |   |               |
|                              |   | Pregnancy to 30 months (average of 38 home visits, optional educational child care, well baby exams)  |               |   |               |
|                              |   | 1-3 years to 3-5 years (year 1: 25 home visits, year 2: 4 half days per week of educational child care plus classes for parents)  |               | 2 studies: I  |               |
|                              | 0-5 years (110 home visits and full-day child care 5 days per week) |   |               |   |               |
|                              | Antisocial/delinquent behaviour                                     | 1-3 years to 3-5 years (year 1: 25 home visits, year 2: 4 half days per week of educational child care plus classes for parents)  | 3 studies: S  |   |               |
|                              |   | 0-5 years (weekly home visits, full-day child care from 6 months to 5 years)  |               |   |               |
|                              |   | Pregnancy to 30 months (average of 38 home visits, optional educational child care, well baby exams)  |               |   |               |

|  |                      |   |              |
|--|----------------------|---|--------------|
|  | Parenting            | 3-5 months to 3 years (year 1: 3-4 half days per week with mothers and infants together in centre, 15-36 months: 4 half days per week, mothers as understudies to teachers, fifth day in classes)   | 5 studies: S |
|  |                      | 2 months to 3 years (2 half days per week in centre, child care and parenting groups)   |              |
|  |                      | From hospital to discharge to 3 years (home visits weekly in year 1, bi-weekly in years 2 and 3, at least 5 half days at preschool per week in 2 <sup>nd</sup> and 3 <sup>rd</sup> years, bi-monthly group meetings in 2 <sup>nd</sup> and 3 <sup>rd</sup> years) |              |
|  |                      | 0-5 years (full-day child care 5 days per week, job counselling and training for parents)   |              |
|  |                      | 1-3 years to 3-5 years (year 1: 25 home visits, year 2: 4 half days per week of educational child care plus classes for parents)  |              |
|  | Maternal life course | From 0-6 months (5 half days per week with mothers and children together at preschool, mothers employed as teachers' aides)   | 1 study: I   |
|  |                      | 0-5 years (110 home visits and full-day child care 5 days per week)   | 1 study: NS  |
|  |                      | 3-5 months to 3 years (year 1: 3-4 half days per week with mothers and infants together in centre, 15-36 months: 4 half days per week, mothers as understudies to teachers, fifth day in classes)   | 4 studies: S |
|  |                      | From hospital to discharge to 3 years (home visits weekly in year 1, bi-weekly in years 2 and 3, at least 5 half days at preschool per week in 2 <sup>nd</sup> and 3 <sup>rd</sup> years, bi-monthly group meetings in 2 <sup>nd</sup> and 3 <sup>rd</sup> years) |              |
|  |                      | From 0-6 months (5 half days per week with mothers and children together at preschool, mothers employed as teachers' aides)   |              |
| Pregnancy to 30 months (average of 38 home visits, optional educational child care, well baby exams) |                      |   |              |

**Abbreviations:** I: inconsistent results; NS: not significant results; S: significant results in favour of the intervention

***How*** could the intervention, program or messages regarding infant social and emotional wellbeing and development be delivered?

Piquero 2008 provided limited detail regarding how the home visiting interventions (associated with a reduction in child disruptive behaviours) were delivered; it was discussed that the intervenors “visited the mothers and gave them advice about how to effectively manage their child’s behavior.”

Yoshikawa 1995 noted that programs with “long-term effects on crime and antisocial behaviour tended to be those that combined early childhood education and family support services.” Little detail was provided regarding the characteristics of these programs, however it was discussed that all provided quality educational child care and/or preschool as well as support to adults in peer groups and family settings, and each had strong theoretical bases for their centre-based and home visiting curricula (though further detail regarding these theoretical bases were not provided) (Yoshikawa 1995).

***How*** could the intervention, program or messages regarding infant social and emotional wellbeing and development be ***framed***?

Piquero 2008 and Yoshikawa 1995 did not address intervention framing.

***What*** could ***impede*** or interfere with engagement with interventions or programs or caregivers enacting upon messages?

Piquero 2008 and Yoshikawa 1995 did not address factors impeding intervention engagement.

What could **facilitate** or drive engagement with interventions or programs or caregivers enacting upon messages?

Piquero 2008 and Yoshikawa 1995 did not address factors facilitating intervention engagement.

## Day care interventions

### Description of intervention based on the included evidence

Day care interventions include the provision of non-parental, out-of-home care, including for preschool education, and may have various aims including the promotion of mothers' participation in paid work and the socialisation of children (Zoritch 2000). Of the two systematic reviews included in this category one presented pooled quantitative results (Zoritch 2000). In this overview, day care interventions generally commenced when the child was less than one year of age, in families of lower socioeconomic status and most often mixed an element of out-of-home educational centre-based day care with some home visiting and targeted parental training, with intensities and durations of day care varying up to eight hours per day, for five years (Zoritch 2000).

### Evidence summary

Two systematic reviews assessed day care interventions (including educational day care and early education interventions) (Yoshikawa 1995; Zoritch 2000). Both Yoshikawa 1995 and Zoritch 2000 did not report the review search dates.

The inclusion criteria for the two reviews varied and were as follows:

- Yoshikawa 1995 included only studies with 'adequate' research designs (conducted in the United States of Canada) assessing interventions that served population which displayed the risk factors associated with later delinquent or antisocial behaviour, which provided services between the prenatal period and entry into primary school, and assessed effects on risk factors for chronic juvenile delinquency and/or antisocial behaviour or delinquency.
- Zoritch 2000 included only RCTs or qRCTs assessing interventions which involved the provision on non-parental day care for children under the age of five years.

Together, these two reviews included 32 relevant studies<sup>53</sup> (including at least three RCTs and one q-RCT) with a total of 1,201 participants in one review (and not reported in one review) (ranging from 40 to 985 in the included studies), published between 1982 and 1994 (Yoshikawa 1995; Zoritch 2000).

In Yoshikawa 1995, the timing, intensity and durations of family support, and combined education and family support programs varied considerably, with many involving weekly or bi-weekly home visits, with total numbers of visits ranging from 10 to 110. In Zoritch 2000, all but one of the relevant trials mixed out-of-home day care with some home visiting (parental training), with intensity/durations of day care ranging, up to eight hours per day for five years.

Both reviews were judged to be at high risk of bias (Yoshikawa 1995; Zoritch 2000) using ROBIS; one review were judged to be 'moderate' quality (Zoritch 2000) and one review 'low' quality (Yoshikawa 1995) using AMSTAR.

Both included systematic reviews provided some pooled results (Yoshikawa 1995; Zoritch 2000). As Yoshikawa 1995 did not provide pooled numerical results, we did not assess the quality of the evidence (using the GRADE system) for the outcomes reported by this review.

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<sup>53</sup>With some overlap (see Technical Report)



### **Primary outcome domain**

#### **Infant social and emotional wellbeing or development up to one year of age**

No pooled results were available.

### **Secondary outcomes domains**

#### **Development for the infant, as a child, and up to 18 years**

Educational day care and early education interventions increased IQ (measuring tools/tests not reported) at 36 months of age in one review (very low quality evidence, downgraded due to high risk of bias and inconsistency) (Zoritch 2000). In a second review, however, the effects of family support programs or combined early education and family support interventions on early cognitive ability (such as early IQ, school achievement, language development, verbal ability (actual measuring tools/tests not reported)) were unclear (family support programs: at four months, up to grade five; combined early education and family support interventions: 12 months, up to 10 years) (quality of the evidence not assessed) (Yoshikawa 1995).

#### **Behaviour for the infant, as a child, and up to 18 years**

Family support programs had no clear impact on antisocial/delinquent behaviour (measured using teacher ratings) in one review (at two years, up to grade four), although combined early education and family support interventions reduced aggressive behaviour (measured using teacher ratings, self-reported delinquency, or official criminal acts/arrests) at eight to 16 years of age in the same review (quality of the evidence not assessed) (Yoshikawa 1995).

#### **Physical wellbeing and safety for the infant, as a child, and up to 18 years**

No pooled results were available.

#### **Parent-infant relationship**

The effect of family support interventions or combined education and family support interventions had on parenting (such as mother-child interaction, parenting behaviour, attachment, and child welfare (measuring tools not reported)) was unclear in one review (family support programs: at four to 54 months; combined education and family support interventions: four months to five years) (quality of the evidence not assessed) (Yoshikawa 1995).

#### **Parent/caregiver psychosocial wellbeing**

Family support, and combined education and family support programs both improved aspects of the maternal life course (such as maternal education and employment, childbearing, family economic self-sufficiency) in one review (family support: one to four years; combined education and family support: one to 10 years) (quality of the evidence not assessed) (Yoshikawa 1995).

#### **Parent/caregiver knowledge, practices and behaviours**

No pooled results were available.

#### **Parent/caregiver views of the intervention**

No pooled results were available.

#### **Family relationships**

No pooled results were available.

#### **Systems outcomes**

No pooled results were available.

**Table 14: Day care interventions evidence profile**

| <b>DAY CARE INTERVENTIONS</b>  |  |   |   |                            |                                |
|--|--|---|---|----------------------------|--------------------------------|
| What is the effectiveness of day care interventions for infants in their first year of life for optimal social and emotional development for the infant, and later on as a child and adolescent? |  |   |   |                            |                                |
| <b>Comparison</b>  | Varied or not reported   |   |   |                            |                                |
| <b>Outcome domain</b>  | <b>Outcome measure used in the review(s)</b>   | <b>Results reported in the review(s) and GRADE</b>  |   |                            | <b>Importance<sup>54</sup></b> |
|  |  | <b>Result<sup>55,56</sup></b>   | <b>GRADE</b>  | <b>Quality of evidence</b> |                                |
| <b>Infant social and emotional wellbeing or development up to one year of age</b>  | No pooled results were available.  |   |   |                            | CRITICAL                       |
| <b>Development for the infant, as a child, and up to 18 years</b>  | Intelligence (IQ) (measuring tools/tests NR) (at 36 months)  | <b>MD (F): 14.37 (95% CI 12.30, 16.44); I<sup>2</sup> 94%; P &lt; 0.0001</b><br>(3 RCTs, 1 qRCT, N=1,109) (Zoritch 2000)                                    | Risk of bias: -1<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Very low                   | IMPORTANT                      |
|  | <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Inconsistency: very substantial heterogeneity (I<sup>2</sup> &gt; 80%); random effects model not used</i> |   |   |                            |                                |
|  | Early cognitive ability (early IQ; school achievement; language development; verbal ability (actual measuring tools/tests NR)): family support programs (4 months to grade 5 (~10-11 years))       | 11 studies (designs NR; N=NR)<br>Significantly better in 4 studies; mixed results in 3 studies; and no clear differences seen in 4 studies (Yoshikawa 1995) | Insufficient information to GRADE   | Not assessed               | CRITICAL                       |
| Early cognitive ability (IQ; school achievement; language development; verbal ability (actual measuring tools/tests NR)): combined early education and family support (12 months to 10 years)    | 9 studies (designs NR; N=NR)<br>Significantly better in 7 studies; mixed results in 2 studies (Yoshikawa 1995)   | Insufficient information to GRADE   | Not assessed  | CRITICAL                   |                                |

<sup>54</sup> The ratings in this column reflect the MHPWC preliminary assessment of the importance of outcome domains prior to the completion of the overview. They were not reassessed by the MHPWC once the overview was complete, as the MHPWC determined that they did not have sufficient evidence on the intervention to draw a conclusion on its effect on social and emotional development of the infant, the child and later on as an adolescent. Therefore the MHPWC did not undertake the GRADE process for assessing the quality of the overall body of evidence or formulate a Working Committee conclusion.

<sup>55</sup> All Ns reflect the total numbers (i.e. across both the intervention and control groups)

<sup>56</sup> Bolding indicates a statistically significant pooled result in favour of the intervention

|   |   |  |                                   |              |          |
|---|---|--|-----------------------------------|--------------|----------|
| <b>Behaviour for the infant, as a child and up to 18 years</b>                      | Antisocial/delinquent behaviour (teacher rated): family support programs (2 years to grade 4 (~9-10 years))   | 3 studies (designs NR; N=NR)<br>Significantly less avoidant and angry in 1 study; and no clear differences seen in 2 studies (Yoshikawa 1995)                    | Insufficient information to GRADE | Not assessed | CRITICAL |
|   | Antisocial/delinquent behaviour (teacher rated; self-reported delinquency; official criminality (e.g. criminal acts/arrests)): combined early education and family support (8-16 years) | 3 studies (designs NR; N=NR)<br>Significantly less aggressive behaviour in 3 studies (Yoshikawa 1995)  | Insufficient information to GRADE | Not assessed | CRITICAL |
| <b>Physical wellbeing and safety for the infant, as a child, and up to 18 years</b> | No pooled results were available.   |  |                                   |              | CRITICAL |
| <b>Parent-infant relationship</b>   | Parenting (mother-child interaction; parenting behaviour; attachment; child welfare (measuring tools NR)): family support (4-54 months)   | 16 studies (designs NR; N=NR)<br>10 studies showed significant improvements; 3 studies had mixed results; 3 studies showed no clear differences (Yoshikawa 1995) | Insufficient information to GRADE | Not assessed | CRITICAL |
|   | Parenting (mother-child interaction; parenting behaviour; attachment; child welfare (measuring tools NR)): combined education and family support (4 months to 5 years)                  | 7 studies (designs NR; N=NR)<br>5 studies showed significant improvements; 1 study had mixed results; 1 study showed no clear differences (Yoshikawa 1995)       | Insufficient information to GRADE | Not assessed | CRITICAL |
| <b>Parent/caregiver psychosocial wellbeing</b>                                      | Maternal life course (maternal education and employment; childbearing; family economic self-sufficiency): family support (1-4 years)  | 5 studies (designs NR; N=NR)<br>5 studies showed significant improvements (Yoshikawa 1995)   | Insufficient information to GRADE | Not assessed | CRITICAL |
|   | Maternal life course (maternal education and employment; childbearing; family economic self-sufficiency): combined education and family support (1-10 years)                            | 4 studies (designs NR; N=NR)<br>4 studies showed significant improvements (Yoshikawa 1995)   | Insufficient information to GRADE | Not assessed | CRITICAL |
| <b>Parent/caregiver knowledge, practices and behaviours</b>                         | No pooled results were available.   |  |                                   |              | CRITICAL |

|   |   |           |
|---|---|-----------|
| <b>Parent/caregiver views of the intervention</b>                 | No pooled results were available.   | IMPORTANT |
| <b>Family relationships</b>                                       | No pooled results were available.   | CRITICAL  |
| <b>Systems outcomes</b>   | No pooled results were available.   | IMPORTANT |
| <b>Evidence statement</b>   |   |           |
| <b>Development for the infant, as a child, and up to 18 years</b> | <u>Intelligence</u> : Very low quality evidence from one systematic review shows that early education or day care interventions can improve IQ (measuring tools/tests NR) at 36 months (three RCTs, one qRCT, N=1,109). |           |

**Abbreviations:** CI: confidence intervals; (F): fixed effect; GRADE: Grading of Recommendations Assessment, Development and Evaluation; IQ: intelligence quotient; MD: mean difference; N: number; NR: not reported; P: P value; qRCT: quasi-randomised controlled trial; RCT: randomised controlled trial

## **Skin-to-skin care interventions**

### **Description of intervention based on the included evidence**

Early skin-to-skin care is the placing of the naked baby prone on the mother's bare chest at birth or soon afterwards, with aims including the promotion of mother-infant interactions, and general infant health (Moore 2012). Only one systematic review was included in this category and it provided pooled results (Moore 2012). In this overview, skin-to-skin care interventions include the promotion of exposed skin-to-skin contact in healthy term or late preterm infants assigned to the normal newborn nursery, and often the opportunity to suckle during contact, beginning soon after birth, with durations of contact varying from 15 minutes to a mean of 27 to 48 hours of continuous skin-to-skin care (Moore 2012).

### **Evidence summary**

One systematic review compared skin-to-skin care compared with no skin-to-skin care in term and late preterm newborns (Moore 2012). Moore 2012 searched for studies up to 2011, and included RCTs with mothers and their healthy full-term or late preterm newborns, assessing the active encouragement of early skin-to-skin contact (starting less than 24 hours before birth) was compared to usual hospital care.

This review included 34 relevant studies (RCTs) with 2,177 participants (ranging from eight to 204 in the included studies), published between 1977 and 2010 (Moore 2012).

In Moore 2012, the duration of skin-to-skin varied from 15 minutes to a mean of 37 of 48 hours of continuous skin-to-skin care.

This review was judged to be at low risk of bias using ROBIS, and was judged to be 'high' quality using AMSTAR (Moore 2012)

Moore 2012 provided pooled results.

### ***Primary outcome domain***

#### **Infant social and emotional wellbeing or development up to one year of age**

No pooled results were available.

### ***Secondary outcomes domains***

#### **Development for the infant, as a child, and up to 18 years**

No clear impact of skin-to-skin care for healthy newborns was seen on infant body weight at 14 days of age in one review (moderate quality evidence, downgraded due to imprecision) (Moore 2012).

#### **Behaviour for the infant, as a child, and up to 18 years**

No pooled results were available.

#### **Physical wellbeing and safety for the infant, as a child, and up to 18 years**

No pooled results were available.

#### **Parent-infant relationship**

No pooled results were available.

### Parent/caregiver psychosocial wellbeing

No pooled results were available.

### Parent/caregiver knowledge, practices and behaviours

Skin-to-skin care for healthy newborns was shown to increase breastfeeding at one to four months post birth (very low quality evidence, downgraded due to high risk of bias, inconsistency and risk of publication bias), however no clear impacts of this intervention on duration of breastfeeding (very low quality evidence, downgraded due to high risk of bias, inconsistency and imprecision) or on breastfeeding at one month post birth (low quality evidence, downgraded due to high risk of bias and inconsistency) were seen (Moore 2012).

### Parent/caregiver views of the interventions

No pooled results were available.

### Family relationships

No pooled results were available.

### Systems outcomes

No pooled results were available.

**Table 15: Skin-to-skin care interventions evidence profile**

| <b>SKIN-TO-SKIN CARE INTERVENTIONS</b>  |   |   |  |                            |                                |
|---|---|---|--|----------------------------|--------------------------------|
| What is the effectiveness of skin-to-skin care interventions in the first year of an infant's life for optimal social and emotional development for the infant, child and adolescent? |   |   |  |                            |                                |
| <b>Comparison</b>   | Usual hospital care                               |   |  |                            |                                |
| <b>Outcome domain</b>   | <b>Outcome measured used in the review(s)</b>     | <b>Results reported in the review(s)</b>  |  |                            | <b>Importance<sup>57</sup></b> |
|   |   | <b>Result<sup>58,59</sup></b>   | <b>GRADE</b>   | <b>Quality of evidence</b> |                                |
| <b>Infant social and emotional wellbeing or development up to one year of age</b>   | No pooled results were available.                 |   |  |                            | CRITICAL                       |
| <b>Development for the infant, as a child, and up to 18 years</b>   | Infant body weight change (g) (day 14 post-birth) | MD (F): -8.00 (95% CI -175.60, 159.61); I <sup>2</sup> 0%; P=0.93 (2 RCTs, N=43) (Moore 2012) | Risk of bias: 0<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Moderate                   | CRITICAL                       |
| <i>GRADE reasons for downgrading: <b>Imprecision</b>: studies with small sample sizes; wide CIs</i>   |   |   |  |                            |                                |

<sup>57</sup> The ratings in this column reflect the MHPWC preliminary assessment of the importance of outcome domains prior to the completion of the overview. They were not reassessed by the MHPWC once the overview was complete, as the MHPWC determined that they did not have sufficient evidence on the intervention to draw a conclusion on its effect on social and emotional development of the infant, the child and later on as an adolescent. Therefore the MHPWC did not undertake the GRADE process for assessing the quality of the overall body of evidence or formulate a Working Committee conclusion.

<sup>58</sup> All Ns reflect the total numbers (i.e. across both the intervention and control groups)

<sup>59</sup> Bolding indicates a statistically significant pooled result in favour of the intervention

|   |   |  |  |          |           |
|---|---|--|--|----------|-----------|
| Behaviour for the infant, as a child, and up to 18 years  | No pooled results were available.   |  |  |          | CRITICAL  |
| Physical wellbeing and safety for the infant, as a child, and up to 18 years  | No pooled results were available.   |  |  |          | CRITICAL  |
| Parent-infant relationship  | No pooled results were available.   |  |  |          | CRITICAL  |
| Parent/caregiver psychosocial wellbeing   | No pooled results were available.   |  |  |          | CRITICAL  |
| Parent/caregiver knowledge, practices and behaviours  | Breastfeeding (1 to 4 months post-birth)  | <b>RR (R): 1.27 (95% CI 1.06, 1.53); I<sup>2</sup> 47%; P=0.0093</b><br>(13 RCTs, N=702)<br>(Moore 2012) | Risk of bias: -1<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: -1 | Very low | CRITICAL  |
|   | <i>GRADE reasons for downgrading: Risk of bias: 7/13 RCTs rated overall unclear/high risk of bias; Inconsistency: substantial heterogeneity; Publication bias: funnel plot asymmetry</i>  |  |  |          |           |
|   | Duration of breastfeeding (days)  | MD (R): 42.55 (95% CI -1.69, 86.79); I <sup>2</sup> 66%; P=0.059<br>(7 RCTs, N=324)<br>(Moore 2012)      | Risk of bias: -1<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Very low | CRITICAL  |
|   | <i>GRADE reasons for downgrading: Risk of bias: 5/7 RCTs rated overall unclear/high risk of bias; Inconsistency: substantial heterogeneity; Imprecision: wide CIs</i>   |  |  |          |           |
|   | Breastfeeding (1 year post-birth)   | RR (F): 6.19 (95% CI 0.82, 46.78); I <sup>2</sup> 0%; P=0.077<br>(2 RCTs, N=62)<br>(Moore 2012)          | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0  | Low      | CRITICAL  |
| <i>GRADE reasons for downgrading: Risk of bias: 1 RCT rated overall high risk of bias; Imprecision: studies with small sample sizes; wide CIs</i> |   |  |  |          |           |
| Parent/caregiver views of the intervention  | No pooled results were available.   |  |  |          | IMPORTANT |
| Family relationships  | No pooled results were available.   |  |  |          | CRITICAL  |
| Systems outcomes  | No pooled results were available.   |  |  |          | IMPORTANT |
| <b>Evidence statements</b>  |   |  |  |          |           |
| Development for the infant, as a child, and up to 18 years  | <u>Weight</u> : Moderate quality evidence from one systematic review suggests no clear impact of skin-to-skin care interventions for healthy newborns on infant body weight at 14 days of age (two RCTs, N=43).   |  |  |          |           |
| Parent/caregiver knowledge, practices and behaviours  | <u>Breastfeeding</u> : Very low quality evidence from one systematic review shows that skin-to-skin care interventions for healthy newborns can increase breastfeeding at one to four months post birth (13 RCTs, N=702), though low and very low quality evidence suggests no clear impact at one month post birth (2 RCTs, N=62) or on duration of breastfeeding (7 RCTs, N=304). |  |  |          |           |

**Abbreviations:** CI: confidence interval; (F): fixed effect; g: grams; GRADE: Grading of Recommendations Assessment, Development and Evaluation; MD: mean difference; P: P value RCT: randomised controlled trial; (R): random effects; RR: risk ratio

## Behavioural sleep interventions

### Description of intervention based on the included evidence

Behavioural interventions for infant sleep are parental practices or infant-care methods aiming to modify the infant's neurobiological characteristics so that nocturnal self-settling episodes are more common (Douglas 2013). Only one systematic review was included in this category and it did not provide pooled results (Douglas 2013). In this overview, behavioural sleep interventions include those assessed in parents and their typically developing infants (inclusion criteria specified an upper age limit of six months, however the review authors noted some studies included infants up to 12 months) that incorporate one or more of the following: delayed responses to infant signals or cues; regulation of feed times; algorithms for sleep durations and bedtimes; and other strategies aiming to condition in the infant to fall asleep in the absence of feeding or bodily contact with the carer (Douglas 2013).

### Evidence summary

One systematic review assessed behavioural sleep interventions (Douglas 2013). Douglas 2013 searched for studies between 1993 and 2013 and included meta-analyses, systematic reviews, RCTs and cohort studies if they considered the effects of a behavioural intervention on infant sleep, were published in a peer-reviewed publication, and if participants were parents and their typically development infants (with an upper age limit of six months).

This review included at least seven relevant studies (three RCTs, one controlled study, two cohort studies, and one pre/post intervention study) with a total of over 1,410 participants (ranging from 111 to 364), published between 2006 and 2013 (Douglas 2013). The characteristics of the interventions in Douglas 2013 were poorly reported.

This review was judged to be at high risk of bias using ROBIS, and was judged to be 'low' quality using AMSTAR (Douglas 2013).

Douglas 2013 provided no pooled results. For further details regarding the results from single studies in Douglas 2013, see the Technical Report.

### Potential harms<sup>60</sup>

In one review (Douglas 2013), single study results show significantly poorer outcomes for crying at five weeks (within the outcome domain of behaviour for the infant, as a child, and up to 18 years) with behavioural sleep interventions. However, these results must be interpreted in context and with caution, as other single study results show positive results for the same outcome. For further details regarding potential harms from single studies see the pink shaded rows of the Evidence Tables in the Technical Report.

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<sup>60</sup>In this context, harm refers to a significantly poorer outcome in the intervention group relative to the control group within a pre-specified primary or secondary outcome domain.



**Table 16: Behavioural sleep interventions evidence profile**

| <b>BEHAVIOURAL SLEEP INTERVENTIONS</b>  |  |  |                                |
|---|--|--|--------------------------------|
| What is the effectiveness of behavioural sleep interventions for infants in their first year of life for optimal social and emotional development for the infant, and later on as a child and adolescent? |  |  |                                |
| <b>Comparison</b>   | NR   |  |                                |
| <b>Outcome domain</b>   | <b>Outcome measure used in the review(s)</b>   | <b>Results reported in the review(s) and GRADE</b> | <b>Importance<sup>61</sup></b> |
| <b>Infant social and emotional wellbeing or development up to one year of age</b>   | No pooled results were available.  |  | CRITICAL                       |
| <b>Development for the infant, as a child, and up to 18 years</b>   | No pooled results were available.  |  | CRITICAL                       |
| <b>Behaviour for the infant, as a child, and up to 18 years</b>   | No pooled results were available.  |  | CRITICAL                       |
| <b>Physical wellbeing and safety for the infant, as a child, and up to 18 years</b>   | No pooled results were available.  |  | CRITICAL                       |
| <b>Parent-infant relationship</b>   | No pooled results were available.  |  | CRITICAL                       |
| <b>Parent/caregiver psychosocial wellbeing</b>  | No pooled results were available.  |  | CRITICAL                       |
| <b>Parent/caregiver knowledge, practices and behaviours</b>   | No pooled results were available.  |  | CRITICAL                       |
| <b>Parent/caregiver views of the intervention</b>   | No pooled results were available.  |  | IMPORTANT                      |
| <b>Family relationships</b>   | No pooled results were available.  |  | CRITICAL                       |
| <b>Systems outcomes</b>   | No pooled results were available.  |  | IMPORTANT                      |
| <b>Evidence statement</b>   | The effects of behavioural sleep interventions on infants' social and emotional development and wellbeing are uncertain. |  |                                |

**Abbreviations:** GRADE: Grading of Recommendations Assessment, Development and Evaluation; NR: not reported

<sup>61</sup> The ratings in this column reflect the MHPWC preliminary assessment of the importance of outcome domains prior to the completion of the overview. They were not reassessed by the MHPWC once the overview was complete, as the MHPWC determined that they did not have sufficient evidence on the intervention to draw a conclusion on its effect on social and emotional development of the infant, the child and later on as an adolescent. Therefore the MHPWC did not undertake the GRADE process for assessing the quality of the overall body of evidence or formulate a Working Committee conclusion.

## **Anticipatory guidance interventions**

### **Description of intervention based on the included evidence**

Anticipatory guidance for development is education provided to parents/caregivers in order to promote optimal developmental outcomes for children (Regalado 2001). Of the two systematic reviews included in this category neither presented pooled results (Regalado 2001; Piotrowski 2009). In this overview, anticipatory guidance interventions include those providing preventive advice such as regarding infant development, the mother-infant relationship, infant temperament, and sleep habits, by physicians/other health care workers. These interventions were assessed in the general population, specifically infants and their parents in health care settings during the perinatal period and early infancy (Regalado 2001; Piotrowski 2009).

### **Evidence summary**

Two systematic reviews compared anticipatory guidance with varied controls (Regalado 2001; Piotrowski 2009). Regalado 2001 searched for studies between 1979 and 1999, while Piotrowski 2009 searched between 1966 and 2007.

Regalado 2001 included studies published between 1979 and 1999, evaluating efficacy or effectiveness of education, intervention and care coordination services or assessment approaches, with services applicable to an office practice setting, targeting children from birth to three years. Piotrowski 2009 however included published empirical evaluation of the Healthy Steps for Young Children Program, with subjective or objective outcomes.

Together, these reviews included 31 studies (13 RCTs, nine nRCTs (designs not further described) and nine evaluations (with some randomised sites)) with a total of 8,204 participants (ranging from 20 to 5,565 in the included studies), published between 1979 and 2007.

The interventions in Regalado 2001 involved various forms of anticipatory guidance for promoting child development (addressing: child development, the mother-infant relationship, infant temperament, sleep habits, book sharing, group child well-care) or problem-focused developmental interventions (counselling, addressing: excessive crying or night waking); intervention characteristics were poorly reported. Piotrowski 2009 however included evaluations of the Healthy Steps for Young Children Program, a three year program involving a wide variety of services to parents during the first three years of life, extending beyond typical paediatric care (nine well-child office visits; seven home visits; availability of an information line; monthly parent group sessions).

Both reviews were judged to be at high risk of bias using ROBIS, and were judged to be 'low' quality using AMSTAR (Regalado 2001; Piotrowski 2009).

No pooled results were available from the two systematic reviews (Regalado 2001; Piotrowski 2009). For further details regarding the results from single studies from the two reviews (Regalado 2001; Piotrowski 2009), see the Technical Report.

**Table 17: Anticipatory guidance interventions evidence profile**

| <b>ANTICIPATORY GUIDANCE INTERVENTIONS</b>   |  |  |                                |
|--|--|--|--------------------------------|
| What is the effectiveness of anticipatory guidance interventions for parents of infants in their first year of life for optimal social and emotional development for the infant, and later on as a child and adolescent? |  |  |                                |
| <b>Comparison</b>  | Variable (including usual care)  |  |                                |
| <b>Outcome domain</b>  | <b>Outcome measure used in the review(s)</b>   | <b>Results reported in the review(s) and GRADE</b> | <b>Importance<sup>62</sup></b> |
| Infant social and emotional wellbeing or development up to one year of age   | No pooled results were available.  |  | CRITICAL                       |
| Development for the infant, as a child, and up to 18 years   | No pooled results were available.  |  | CRITICAL                       |
| Behaviour for the infant, as a child, and up to 18 years   | No pooled results were available.  |  | CRITICAL                       |
| Physical wellbeing and safety for the infant, as a child, and up to 18 years   | No pooled results were available.  |  | CRITICAL                       |
| Parent-infant relationship   | No pooled results were available.  |  | CRITICAL                       |
| Parent/caregiver psychosocial wellbeing  | No pooled results were available.  |  | CRITICAL                       |
| Parent/caregiver knowledge, practices and behaviours   | No pooled results were available.  |  | CRITICAL                       |
| Parent/caregiver views of the intervention   | No pooled results were available.  |  | IMPORTANT                      |
| Family relationships   | No pooled results were available.  |  | CRITICAL                       |
| Systems outcomes   | No pooled results were available.  |  | IMPORTANT                      |
| <b>Evidence statement</b>  | The effects of anticipatory guidance interventions on infants' social and emotional development and wellbeing are uncertain. |  |                                |

**Abbreviations:** GRADE: Grading of Recommendations Assessment, Development and Evaluation

<sup>62</sup> The ratings in this column reflect the MHPWC preliminary assessment of the importance of outcome domains prior to the completion of the overview. They were not reassessed by the MHPWC once the overview was complete, as the MHPWC determined that they did not have sufficient evidence on the intervention to draw a conclusion on its effect on social and emotional development of the infant, the child and later on as an adolescent. Therefore the MHPWC did not undertake the GRADE process for assessing the quality of the overall body of evidence or formulate a Working Committee conclusion.

## **Interventions for promoting effective parenting**

### **Description of intervention based on the included evidence**

Of the two systematic reviews included in this category, both presented pooled results (Mercer 2006; Gardner 2006). Interventions in both of the included systematic reviews were assessed in the general population, specifically pregnant women or mothers with infants. They included individual and group education and support programs, home visiting and parent-infant attachment and relationship interventions, focused on facilitating or strengthening the mothering processes or behaviours such as infant caregiving, awareness of and responsiveness to infant interactive capabilities, maternal-infant attachment, maternal/social role preparation and therapeutic nurse-client relationships. One of the reviews (Mercer 2006) described interventions provided by nurses.

### **Evidence summary**

Two systematic reviews compared effective parenting interventions predominately with usual care (Mercer 2006; Gardner 2006). Gardner 2006 did not report the review search dates, however they only included studies published between 1994 and 2004, while Mercer 2006 searched up to 2005.

Gardner 2006 included studies published between 1994 and 2004 describing interventions designed to facilitate or strengthen mothering processes and behaviours in adult women with newborns or infants less than 24 months of age; Mercer 2006 included published reports of experimental studies, with random assignment, of nursing interventions that focused on a facet of maternal behaviour in the process of becoming a mother during pregnancy or the first four months following birth, or both, which measured a maternal outcome (e.g. preparing for the infant, or developing attachment to the infant).

Together, these two reviews included 50 studies (40 RCTs, seven quasi-experimental studies, two 'self-selection' studies and one pre/post study) with 1,622 participants in one review (ranging from 20 to 221 in the included studies) (Mercer 2006) (Ns not reported in one review (Gardner 2006)), published between 1980 and 2006.

Interventions in Gardner 2006 included individual education/counselling and support, group programs, mother-infant contact, home visiting, and multi-component programs; the durations/intensities of interventions were not reported. Mercer 2006 included interventions focused on: instructions for infant caregiving; building awareness of and responsiveness to infant interactive capabilities; fostering maternal-infant attachment; maternal/social role preparation; and interactive therapeutic nurse-client relationships; (while durations/intensities were largely not reported) interventions ranged in duration from one hour after birth to during pregnancy and the first year post-birth.

Both reviews were judged to be at high risk of bias using ROBIS, and were judged to be 'low' quality using AMSTAR (Mercer 2006; Gardner 2006).

Both included systematic reviews provided pooled results (Mercer 2006; Gardner 2006). As Mercer 2006 and Gardner 2006 did not provide pooled numerical results, we did not assess the quality of the evidence (using the GRADE system) for the outcomes reported by these reviews.

### ***Primary outcome domain***

#### **Infant social and emotional wellbeing or development up to one year of age**

No pooled results were available.

### ***Secondary outcomes domains***

#### **Development for the infant, as a child, and up to 18 years**

No pooled results were available.

#### **Behaviour for the infant, as a child, and up to 18 years**

No pooled results were available.

#### **Physical wellbeing and safety for the infant, as a child, and up to 18 years**

No pooled results were available.

#### **Parent-infant relationship**

Nursing interventions to build awareness of, and responsiveness to, infant interactive capabilities improved mother-infant interaction skills (measuring tool(s) not reported) in the first two weeks after birth in one review (quality of the evidence not assessed) (Mercer 2006). These interventions also increased sensitive, reciprocal mother-infant interactions (measuring tool(s) not reported) during or following infant feeding in 'at risk' population in the same review (quality of the evidence not assessed) (Mercer 2006). In a second review, general mother-infant interaction (measuring tool(s) not reported) also improved from one day, up to three months postpartum (quality of the evidence not assessed) (Gardner 2006).

#### **Parent/caregiver psychosocial wellbeing**

No pooled results were available.

#### **Parent/caregiver knowledge, practices and behaviours**

Nursing interventions focused on instructions for infant caregiving, or on building awareness of and responsiveness to infant interactive capabilities had no clear effect on maternal knowledge (measuring tool(s) not reported) (up to six weeks) or confidence (measuring tool(s) not reported) (up to one month) in one review (quality of the evidence not assessed) (Mercer 2006).

#### **Parent/caregiver views of the intervention**

No pooled results were available.

#### **Family relationships**

No pooled results were available.

#### **Systems outcomes**

No pooled results were available.

#### **Potential harms<sup>63</sup>**

In one review (Mercer 2006), single study results show significantly poorer outcomes for maternal anxiety (within the outcome domain of parent/caregiver psychosocial wellbeing) with nursing

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<sup>63</sup>In this context, harm refers to a significantly poorer outcome in the intervention group relative to the control group within a pre-specified primary or secondary outcome domain.

interventions compared with usual care. For further details regarding potential harms from single studies see the pink shaded rows of the Evidence Tables in the Technical Report.

**Table 18: Interventions for promoting effective parenting evidence profile**

| <b>INTERVENTIONS FOR PROMOTING EFFECTIVE PARENTING</b>   |  |   |                                   |                     |                          |
|--|--|---|-----------------------------------|---------------------|--------------------------|
| What is the effectiveness of interventions for promoting effective parenting of infants in their first year of life for optimal social and emotional development for the infant, and later on as a child and adolescent? |  |   |                                   |                     |                          |
| Comparison   | Predominately usual care   |   |                                   |                     |                          |
| Outcome domain   | Outcome measure used in the review(s)                              | Results reported in the review(s) and GRADE   |                                   |                     | Importance <sup>64</sup> |
|  |  | Result <sup>65</sup>  | GRADE                             | Quality of evidence |                          |
| Infant social and emotional wellbeing or development up to one year of age   | No pooled results were available.                                  |   |                                   |                     | CRITICAL                 |
| Development for the infant, as a child, and up to 18 years   | No pooled results were available.                                  |   |                                   |                     | CRITICAL                 |
| Behaviour for the infant, as a child, and up to 18 years   | No pooled results were available.                                  |   |                                   |                     | CRITICAL                 |
| Physical wellbeing and safety for the infant, as a child, and up to 18 years   | No pooled results were available.                                  |   |                                   |                     | CRITICAL                 |
| Parent-infant relationship   | Mother-infant interaction (measuring tools NR) (1 day to 3 months) | Significantly improved in 3 RCTs (only during infancy: day 1 to 3 months postpartum, N=NR) (Gardner 2006) | Insufficient information to GRADE | Not assessed        | CRITICAL                 |

<sup>64</sup> The ratings in this column reflect the MHPWC preliminary assessment of the importance of outcome domains prior to the completion of the overview. They were not reassessed by the MHPWC once the overview was complete, as the MHPWC determined that they did not have sufficient evidence on the intervention to draw a conclusion on its effect on social and emotional development of the infant, the child and later on as an adolescent. Therefore the MHPWC did not undertake the GRADE process for assessing the quality of the overall body of evidence or formulate a Working Committee conclusion.

<sup>65</sup> All Ns reflect the total numbers (i.e. across both the intervention and control groups)

|   |  |  |                                   |              |           |
|---|--|--|-----------------------------------|--------------|-----------|
|   | Sensitive, reciprocal mother-infant infections (measuring tools NR) (during or following infant feeding)                                 | Positive effect for 'at risk' populations (3 RCTs, N=158) Nursing interventions focused on building awareness of and responsiveness to infant interactive capabilities (Mercer 2006) | Insufficient information to GRADE | Not assessed | CRITICAL  |
|   | Mother-infant interactive skills (measuring tools NR) (during first 2 weeks)   | Increased (3 RCTs, N=80) Nursing interventions focused on building awareness of and responsiveness to infant interactive capabilities (Mercer 2006)                                  | Insufficient information to GRADE | Not assessed | CRITICAL  |
| <b>Parent/caregiver psychosocial wellbeing</b>              | No pooled results were available.  |  |                                   |              | CRITICAL  |
| <b>Parent/caregiver knowledge, practices and behaviours</b> | Maternal knowledge of infant care (measuring tools NR) (up to 6 weeks)   | No difference (3 RCTs, N=286) Nursing interventions focused on instructions for infant caregiving (Mercer 2006)  | Insufficient information to GRADE | Not assessed | CRITICAL  |
|   | Maternal confidence (measuring tools NR) (up to 1 month)   | No increase (2 RCTs, N=66) Nursing interventions focused on building awareness of and responsiveness to infant interactive capabilities (Mercer 2006)                                | Insufficient information to GRADE | Not assessed | CRITICAL  |
| <b>Parent/caregiver views of the intervention</b>           | No pooled results were available.  |  |                                   |              | IMPORTANT |
| <b>Family relationships</b>                                 | No pooled results were available.  |  |                                   |              | CRITICAL  |
| <b>Systems outcomes</b>                                     | No pooled results were available.  |  |                                   |              | IMPORTANT |
| <b>Evidence statement</b>                                   | The effects of interventions for promoting effective parenting on infants' social and emotional development and wellbeing are uncertain. |  |                                   |              |           |

**Abbreviations:** GRADE: Grading of Recommendations Assessment, Development and Evaluation; N: number; NR; not reported; RCT: randomised controlled trial

## Interventions for parents of infants at risk of developmental delays

### Description of intervention based on the included evidence

Of the three systematic reviews included in this category one presented pooled quantitative results (Wallace 2010). Interventions in Wallace 2010 were targeted towards infants at risk for autism spectrum disorder and included infants/toddlers with developmental impairments or at risk of such impairments (prematurity; developmental delay including Down syndrome; and risk of intellectual disability. Most interventions in the included studies in Wallace 2010 were delivered in homes, hospitals, centres in the community and day care centres and sometimes as combinations, and were of long duration and high intensity.

### Evidence summary

Three systematic reviews assessed interventions to improve developmental outcomes for infants 'at risk of developmental delay' (Kemp 2014; Kong 2013; Wallace 2010). Kong 2013 searched for studies between 1990 and 2010, and Kemp 2014 searched from 2000 to 2013; while Wallace 2010 did not report the review search dates.

The review inclusion criteria varied across the three reviews, and were as follows:

- Kemp 2014: first level: studies published after 2000 in a peer-reviewed journal, using the term "coaching", involving parents/caregivers of infants and toddlers with disabilities, developmental delay, or at high risk for developmental delay, with a majority of participants between birth and three years, with sessions delivered at least partially in the context of home visits, reflecting at least one of a variety of early intervention disciplines; second level: reporting on empirical research, and reporting child and/or family outcomes; third level: only studies published between 2011 and 2013.
- Kong 2013: studies published in peer-reviewed journals, focused on responsive interaction interventions, including responsiveness components as the primary features of the intervention, employing a quasi-experimental or experimental group design, including a measure of children's outcomes, with child participants between birth and six years, with disabilities or delays, or at risk for delays.
- Wallace 2010: well-designed, controlled intervention efficacy studies published in peer-reviewed journals, involving infants or toddlers with developmental impairments or significant risk of such impairments, from birth to three years, with sufficient data to calculate effect sizes.

Together, these three reviews included 39 relevant studies<sup>66</sup> (25 RCTs, and 14 (quasi)experimental studies) with a total of approximately 5,671 participants<sup>67</sup> (ranging from 16 to 985 in the included studies), published between 1976 and 2012 (Kemp 2014; Kong 2013; Wallace 2010).

In Kemp 2014, the coaching sessions varied from 11 weekly 1.5 hour home visits, to one hour sessions, two times per week for three to six months. The responsive interaction interventions in Kong 2013 varied in length of sessions from 20 to 120 minutes, total number of sessions ranging from six to 108, frequency of sessions from monthly to five times per week, and durations from six to 27 weeks. Where reported, the durations of the variety of interventions to improve developmental outcomes in Wallace 2010 range from three sessions in the neonatal intensive care, to five days per week of day care up to age five.

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<sup>66</sup>With some overlap (see Technical Report)

<sup>67</sup>Kong 2013 did not report sample sizes, however reported a mean of approximately N=60 per study; therefore, the estimated N for the five studies of relevance was 300



All three reviews were judged to be at high risk of bias (Kemp 2014; Kong 2013; Wallace 2010) using ROBIS; one review was judged to be 'moderate' quality (Wallace 2010) and two reviews 'low' quality (Kemp 2014; Kong 2013) using AMSTAR.

Two of three included systematic reviews provided pooled results:

- Kong 2013 (high risk of bias; 'low' quality) included five relevant studies (three experimental, and two quasi-experimental studies) with an estimated total of 600 participants, published between 1991 and 2010.
- Wallace 2010 (high risk of bias; 'moderate' quality) included 32 studies (23 RCTs, three quasi-RCTs<sup>68</sup>, and six nRCTs) with approximately 5,168 participants<sup>69</sup> (ranging from 16 to 985 in the included studies) published between 1973 and 2009.

As Kong 2013 did not provide pooled numerical results, we did not assess the quality of the evidence (using the GRADE system) for the outcomes reported by this review.

For further details regarding the results from single studies from the other review (Kemp 2014), see the Technical Report.

### ***Primary outcome domain***

#### **Infant social and emotional wellbeing or development up to one year of age**

No pooled results were available.

### ***Secondary outcomes domains***

#### **Development for the infant, as a child, and up to 18 years**

Interventions to improve developmental outcomes improved overall developmental ability (using standardised measures of overall developmental ability, including BSID, BAS, GMDS, MSCA, SB, and WPPSI) in infants with developmental delays (low to very low quality evidence, downgraded due to high risk of bias and imprecision, with no information reported to determine inconsistency, in preterm infants (low to very low quality evidence, downgraded due to high risk of bias and imprecision, with no information reported to determine inconsistency<sup>70</sup>, and in infants at risk for intellectual disability in one review (low quality evidence, downgraded due to high risk of bias and suspected inconsistency) (Wallace 2010).

#### **Behaviour for the infant, as a child, and up to 18 years**

Interventions to improve developmental outcomes improved social-communication (e.g. vocalisation, gestures, eye contact, turn-taking, intentional communication, utterance, target words, vocabulary words, different word roots, mean length of utterance, language development, cooperation, non-compliant/aggressive behaviours (measuring tools not reported)), emotional (e.g. positive affect and negative affect (measuring tools not reported)) and cognitive behaviours (e.g. complex play skills (measuring tools not reported)) in one review (quality of the evidence not assessed) (Kong 2013).

#### **Physical wellbeing and safety for the infant, as a child, and up to 18 years**

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<sup>68</sup>Described as 'partial' RCTs in Wallace 2010

<sup>69</sup>In Wallace 2010, some articles were 'follow up studies'; therefore, some participants were included in more than one study

<sup>70</sup>Substantial heterogeneity was assumed for preterm infants at 3-60 months

No pooled results were available.

### Parent-infant relationship

Interventions to improve developmental outcomes improved parental responsive behaviours (measured using observation systems (tools not reported)) in one review (quality of the evidence not assessed) (Kong 2013).

### Parent/caregiver psychosocial wellbeing

No pooled results were available.

### Parent/caregiver knowledge, practices and behaviours

Interventions to improve developmental outcomes improved parental emotional and social/verbal behaviours (measured using observation systems (tools not reported)) in one review (quality of the evidence not assessed) (Kong 2013).

### Family relationships

No pooled results were available.

### Family relationships

No pooled results were available.

### Systems outcomes

No pooled results were available.

**Table 19: Interventions for parents of infants at risk of developmental delays evidence profile**

| <b>INTERVENTIONS FOR PARENT OF INFANTS AT RISK OF DEVELOPMENTAL DELAYS</b>   |   |   |  |                            |                   |
|--|---|---|--|----------------------------|-------------------|
| What is the effectiveness of interventions for parents of infants at risk of developmental delays in their first year of life for optimal social and emotional development for the infant, and later on as a child and adolescent? |   |   |  |                            |                   |
| <b>Comparison</b>  | Usual care  |   |  |                            |                   |
| <b>Outcome domain</b>  | <b>Outcome measure used in the review(s)</b>  | <b>Results reported in the review(s) and GRADE</b>                                |  |                            | <b>Importance</b> |
|  |   | <b>Result</b> <sup>71,72</sup>  | <b>GRADE</b>   | <b>Quality of evidence</b> |                   |
| <b>Infant social and emotional wellbeing or development up to one year of age</b>  | No pooled results were available.   |   |  |                            | CRITICAL          |
| <b>Development for the infant, as a child, and up to 18 years</b>  | Overall developmental ability (BSID; GMDS; SB); Infants with developmental delays (at 15 months to 16 years)  | <b>Mean ES: 0.44` (range -0.11 to 0.93)</b><br>(5 nRCTs, N=194)<br>(Wallace 2010) | Risk of bias: -1<br>Inconsistency: NR<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Low to very low            | CRITICAL          |
|  | <i>GRADE reasons for downgrading: <b>Risk of bias:</b> studies with methodological limitations; <b>Inconsistency:</b> NR; <b>Imprecision:</b> studies with small sample sizes</i> |   |  |                            |                   |

<sup>71</sup>All Ns reflect the total numbers (i.e. across both the intervention and control groups)

<sup>72</sup>Bolding indicates a statistically significant pooled result in favour of the intervention

|   |  |  |   |                 |           |
|---|--|--|---|-----------------|-----------|
|   | Overall developmental ability (BSID; MSCA; SB); Infants at risk for intellectual disability (at 18-54 months)  | <b>Mean ES: 1.26` (range 0.24 to 1.38)</b><br>(3 RCT, N=234)<br>(Wallace 2010)               | Risk of bias: -1<br>Inconsistency: NR<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0          | Low to very low | CRITICAL  |
| <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Inconsistency: NR; Imprecision: studies with small sample sizes</i>      |  |  |   |                 |           |
|   | Overall developmental ability (BSID; BAS; GMDS; MSCA; SB; WPPSI); Preterm infants (at 3-60 months)   | <b>Mean ES: 0.44` (range -0.65 to 1.39)</b><br>(11 RCTs, 2 qRCTs, N=2,508)<br>(Wallace 2010) | Risk of bias: -1<br>Inconsistency: -1 (assumed)<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Low (assumed)   | CRITICAL  |
| <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Inconsistency (assumed): wide ranges indicate probable heterogeneity</i> |  |  |   |                 |           |
| <b>Behaviour for the infant, as a child, and up to 18 years</b>   | Social-communication behaviours (e.g. vocalisation, gestures, eye contact, turn-taking, intentional communication, utterance, target words, vocabulary words, different word roots, mean length of utterance, language development, cooperation, non-compliant/aggressive behaviours (tools NR)) (time of measures NR) | 1 experimental study and 1 quasi-experimental study showed improvements (Kong 2013)          | Insufficient information to GRADE   | Not assessed    | CRITICAL  |
|   | Emotional behaviours (e.g. positive affect and negative affect (tools NR)) (time of measures NR)   | 2 experimental studies and 1 quasi-experimental study showed improvements (Kong 2013)        | Insufficient information to GRADE   | Not assessed    | CRITICAL  |
|   | Cognitive behaviours (e.g. complex play skills (tools NR)) (time of measures NR)   | 2 experimental and 2 quasi-experimental studies showed improvements (Kong 2013)              | Insufficient information to GRADE   | Not assessed    | CRITICAL  |
| <b>Physical wellbeing and safety for the infant, as a child, and up to 18 years</b>   | No pooled results were available.  |  |   |                 | CRITICAL  |
| <b>Parent-infant relationship</b>   | Parental responsive behaviours (measured using observation systems (tools NR)) (time of measures NR)   | 3 experimental and 2 quasi-experimental studies showed improvements (Kong 2013)              | Insufficient information to GRADE   | Not assessed    | CRITICAL  |
| <b>Parent/caregiver psychosocial wellbeing</b>  | No pooled results were available.  |  |   |                 | IMPORTANT |
| <b>Parent/caregiver knowledge, practices and behaviours</b>   | Parental emotional behaviours (measured using observation systems (tools NR)) (time of measures NR)  | 2 experimental studies showed improvements (Kong 2013)                                       | Insufficient information to GRADE   | Not assessed    | CRITICAL  |

|   |  |   |                                   |              |           |
|---|--|---|-----------------------------------|--------------|-----------|
|   | Parental social/verbal behaviours (measured using observation systems (tools NR)) (time of measures NR)  | 2 experimental studies and 1 quasi-experimental study showed improvements (Kong 2013) | Insufficient information to GRADE | Not assessed | CRITICAL  |
| <b>Parent/caregiver views of the intervention</b>                 | No pooled results were available.  |   |                                   |              | IMPORTANT |
| <b>Family relationships</b>                                       | No pooled results were available.  |   |                                   |              | CRITICAL  |
| <b>Systems outcomes</b>   | No pooled results were available.  |   |                                   |              | IMPORTANT |
| <b>Evidence statement</b>   |  |   |                                   |              |           |
| <b>Development for the infant, as a child, and up to 18 years</b> | <u>Overall developmental ability:</u> Low, and low to very low quality evidence from one systematic review shows improved overall developmental ability (using standardised measures such as BSID, BAS, GMDS, MSCA, SB, and WPPSI) with interventions for infants with developmental delays at 15 months to 18 years (five nRCTs, N=194), infants at risk of intellectual disability at 18 to 54 months (three RCTs, N=234) and preterm infants at three to 60 months (11 RCTs, 2 qRCTs, N=2,508). |   |                                   |              |           |

<sup>73</sup>Statistical significance not reported but assumed to be significantly in favour of the intervention

**Abbreviations:** BAS: British Abilities Scales; BSID: Bayley Scales of Infant Development; ES: effect size; GMDS: Griffiths Mental Development Scales; GRADE: Grading of Recommendations Assessment, Development and Evaluation; MSCA: McCarthy Scales of Children's Abilities; N: number; NR: not reported; nRCT: non-randomised controlled trial; qRCT: quasi-randomised controlled trial; RCT: randomised controlled trial; SB: Stanford-Binet (Intelligence Scale); WPPSI: Wechsler Preschool and Primary Scale of Intelligence

### **Characteristics that may have contributed to the effectiveness of interventions for parents of infants at risk of developmental delays for optimal social and emotional development of infants**

In Wallace 2010, 30 out of the 32 included studies showed significant improvements in at least one aspect of developmental abilities in infants at risk for autism spectrum disorders (and so it was not feasible to present characteristics by the significance of intervention outcomes).

On the basis of effect analyses, the authors claimed characteristics of successful intervention to be

- 1) Parent involvement;
- 2) Individualisation;
- 3) Broad range of learning targets;
- 4) Providing early intense interventions for a long duration.

However there was insufficient detail provided in the review to be able to replicate or extend these analyses.

***Who could<sup>73</sup> deliver the intervention, program or messages to optimise infant social and emotional wellbeing and development?***

In Wallace 2010, nurses (including neonatal intensive care unit and public health nurses), intensive care unit staff, occupational therapists and developmental specialists delivered interventions in the studies of preterm infants. For about half the studies involving preterm infants and all of the studies including infants at risk of intellectual disability or with developmental delay, it was not reported who delivered the intervention.

<sup>73</sup>We used could here and in the sentences that follow to acknowledge that studies conducted outside of Australia were not precluded. The MHPWC will therefore need to interpret what was found in the literature to the operational realities of the Australian context.

***Where*** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?

Most interventions in the included studies in Wallace 2010 were delivered in homes, hospitals, centres in the community and day care centres and sometimes as combinations (e.g. day care centres and homes).

***To whom*** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?

In Wallace 2010, the included studies involved infants at risk for autism, which were categorised as studies including preterm infants (24 studies), infants with developmental delay (five studies), and infants at risk of intellectual disability (three studies). In regards to whom the interventions were delivered, generally this was described to be parents of infants, mostly mothers, with some studies targeting low income or specific minority groups (Wallace 2010). One study included parents of children diagnosed with Down syndrome (Connolly 1980). The studies included in the 'at risk for intellectual disability' category delivered the intervention directly to the infant/child as day care (Wallace 2010).

***When*** could be the best time for the intervention, program, or message delivery to occur? (In regards to caregiver preferences and accessibility; and in regards to improved outcomes for the infant, child and later on as the adolescent, and for the caregiver)

Duration and intensity of interventions varied considerably in Wallace 2010 – from three sessions in the intensive care unit to intensive day care five days a week up to the age of five. However, most interventions were of long duration and high intensity (Wallace 2010).

***How*** could the intervention, program or messages regarding infant social and emotional wellbeing and development be delivered?

How interventions, programs or messages were delivered was not well described in Wallace 2010. Many programs were individualised and some emphasised communication and language and parent-infant relationships, with one intervention built around the transactional nature of child development (Wallace 2010). As mentioned above several were intensive day care programs (Wallace 2010).

***How*** could the intervention, program or messages regarding infant social and emotional wellbeing and development be ***framed***?

Wallace 2010 did not report on intervention framing. However in one of the other included reviews without pooled results (Kemp 2014), comment was made that parent education has been regarded by many as being too directive and that coaching may be a more appropriate approach as it aligns better with adult learning principles and preferences.

***What*** could ***impede*** or interfere with engagement with interventions or programs or caregivers enacting upon messages?

In the Wallace 2010 review, the lack of effect seen in one included study may have been due in part to cultural differences, namely the practice of providing community support for infant development. Kemp 2014 discussed the lack of a standard definition for coaching and cites work where this absence has been a barrier for providers in understanding which components are most important in

achieving practice change; as well as the need to clarify the distinctions between coaching and parent education. Kemp 2014 also alluded to the burden for parents of having weekly home visits over extended periods.

Kong 2013 did not address factors impeding engagement.

*What could **facilitate** or drive engagement with interventions or programs or caregivers enacting upon messages?*

None of the three included reviews addressed factors enabling engagement (Wallace 2010 with pooled and graded results; Kemp 2014 and Kong 2013 with no pooled and/or graded results).

## Interventions for parents of preterm and low birthweight infants

### Description of intervention based on the included evidence

Of the five systematic reviews included in this category four presented pooled results (Evans 2014; Goyal 2013; Spittle 2012; Vanderveen 2009). Interventions for parents of preterm (generally < 37 weeks) or low birthweight infants varied considerably and included, inter alia, parent-infant interaction, home visiting alone or in combination with other interventions (e.g. centre-based meetings), and early education and support interventions focused on improving infant development or enhancing parent's skills. These interventions were delivered by a range of providers including nurses, specialists, trained paraprofessionals and social workers. The frequency and duration of the intervention programs ranged considerably from the length of in-hospital stay to weekly sessions for three years.

### Evidence summary

Five systematic reviews compared interventions for parents of preterm infants compared with predominately usual care (Brett 2011; Evans 2014; Goyal 2013; Spittle 2012; Vanderveen 2009). Vanderveen 2009 searched for studies from 1966 to 2008; Brett 2011 from 1980 to 2009; Spittle from 1966 to 2012; Goyal 2013 from 1980 to 2012; and Evans 2014, up to 2013.

The inclusion criteria of these five reviews varied and were as follows:

- Brett 2011: RCTs, quasi-experimental, cohort, case-control, cross-sectional, case series, case reports or qualitative studies, with parent-reported outcomes from interventions related to information provision, communication, or support at the neonatal unit and after discharge, involving parents who have had a preterm infant, that were relevant to developed countries, passed quality assessment, and were published between 1980 and 2009.
- Evans 2014: RCTs or qRCTs, involving preterm infants with no major congenital abnormalities and the mothers of these infants, assessing parenting interventions, that measured mother to infant and/or infant to mother attachment and/or relationship outcomes, with standardised mother-preterm infant relationship outcome measures.
- Goyal 2013: published experimental or quasi-experimental studies of home visiting programs (home-based, preventive, health promotion services, involving professionals as well as trained paraprofessionals) initiated in pregnancy or early infancy, published in 1980 or later, conducted in Canada or the United States, reporting on early childhood and/or parenting outcomes for preterm and/or low birthweight infants.
- Spittle 2012: RCTs or qRCTs of early developmental intervention programs that began within the first 12 months of life for preterm infants with no major congenital abnormalities (interventions could commence in hospital, however a post-discharge component was necessary), reporting on cognitive ability, motor ability or both.
- Vanderveen 2009: RCTs or qRCTs, in preterm infants or infants less than 2500 g at birth, assessing interventions aimed to improve development measured by standardised scales of infant development (compared with routine care/no intervention), involving parents, with an onset in the first 12 months of life.

Together, these five reviews included 115 relevant studies<sup>74</sup> (85 RCTs, 12 qRCTs, 16 cohort studies, and two quasi-experimental studies), with over 15,677 participants<sup>75</sup> (ranging from 16 to 985), published between 1979 and 2013.

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<sup>74</sup>With some overlap (see Technical Report

<sup>75</sup>N was NR for one study in Brett 2011

The durations/intensities of interventions for communicating with, supporting and providing information to parents of preterm infants in Brett 2011 were not reported. In Evans 2014, the interventions focusing on parent-infant relationships ranged in duration (from hospital stay only, e.g. six, 45 minute weekly sessions; to 12 months, e.g. one session at one week prior to discharge, and five sessions at one, three, and five, nine and 12 months). The home-visiting interventions in Goyal 2013 varied in durations from eight weeks to three years, with visits mostly weekly/bi-weekly in early infancy. In Spittle 2013, the interventions addresses development and milestones; understanding behavioural cues, infant stimulation; physiotherapy; occupational therapy; early educational intervention; and enhancement of the parent-infant relationship; intervention ranged from four sessions over approximately one month to weekly sessions for 12 months, followed by bi-weekly sessions for a further two years. In Vanderveen 2009, the interventions involving teaching/enhancing parent's skills and/or involving parents in aspects of care for their infant, range in length (from the duration of hospital stay (i.e. ending at neonatal intensive care unit discharge), to three years) and intensity (from daily to monthly).

All five reviews were judged to be at low risk of bias (Brett 2011; Evans 2014; Goyal 2013; Spittle 2012; Vanderveen 2009) using ROBIS; two reviews were judged to be 'high' quality (Spittle 2012; Vanderveen 2009) and three reviews 'moderate' quality (Brett 2011; Evans 2014; Goyal 2013) using AMSTAR.

Four of the five included systematic reviews provided pooled results:

- Evans 2014 (low risk of bias; 'moderate' quality) included 17 relevant studies (11 RCTs and six qRCTs) with 1,940 participants (ranging from 16 to 327 in the included studies), published between 1984 and 2013.
- Goyal 2013 (low risk of bias; 'moderate' quality) included 17 relevant studies (14 RCTs, one qRCT, one quasi-experimental design, and one cohort study) with 2,859 participants (ranging from 45 to 985 in the included studies), published between 1980 and 2010.
- Spittle 2012 (low risk of bias; 'high' quality) included 21 relevant studies (17 RCTs, four qRCTs) with 3,100 participants (ranging from 24 to 985), published between 1979 and 2011.
- Vanderveen 2009 (low risk of bias; 'high' quality) included 25 relevant studies (24 RCTs, one qRCT) with 3,509 participants (ranging from 24 to 985), published between 1980 and 2006.

For further details regarding the results from single studies from the other review (Brett 2011), see the Technical Report.

### ***Primary outcome domain***

#### **Infant social and emotional wellbeing or development up to one year of age**

No pooled results were available.

### ***Secondary outcomes domains***

#### **Development for the infant, as a child, and up to 18 years**

Interventions enhancing parental skills did not have a clear impact on cognitive development (measured using the BSID MDI or GMDS) in infants at six months (low quality evidence, downgraded due to high risk of bias and imprecision but improvements were seen at 12 months and 24 months in one review (both low quality evidence, downgraded due to risk of bias) and inconsistency (Vanderveen 2009). In a second review, home visiting interventions improved infant cognitive development at eight to 13 months (measured using the BSID MDI) (very low quality evidence, downgraded due to high risk of bias, inconsistency and risk of publication bias) (Goyal 2013), as did interventions addressing development (measured using the BSID or GMDS) at zero to two years in a



third review (low quality evidence, downgraded due to inconsistency and risk of publication bias) (Spittle 2012).

Interventions enhancing parental skills improved cognitive development (measured using the SB or MSCA) at preschool age (three years) in one review, but no clear impact was seen for such studies assessing cognitive development (measured using the WPPSI or BAS) at school age (five years) in the same review (both moderate quality evidence, downgraded due to high risk of bias) (Vanderveen 2009). In a second review, interventions addressing development improved cognitive development (measured using the SB, MSCA or BSID-MDI) at preschool age (three to less than five years) (moderate quality evidence, downgraded due to high risk of bias), but did not persist through to school age (measured using the WISC or KBIT) (five to 17 years) in the same review (very low quality evidence, downgraded due to inconsistency and imprecision) (Spittle 2012).

Interventions enhancing parental skills improved motor development in infancy (measured using the BSID PDI) (at 12 months of age) in one review (moderate quality evidence, downgraded due to high risk of bias, but this was not apparent at six months, and did not persist up to 24 months in the same review (both low quality evidence, downgraded due to high risk of bias and imprecision) (Vanderveen 2009). In a second review, interventions addressing development improved motor development from zero to two years of age (measured using the BSID-PDI, GMDS locomotor subscale) (low quality evidence, downgraded due to high risk of bias, and risk of publication bias), but this effect was not apparent at preschool age (three to less than five years) (measured using the GMDS locomotor subscale or PEDI) (low quality evidence, downgraded due to high risk of bias and imprecision) (Spittle 2012).

Interventions addressing development did not have a clear impact on cerebral palsy up to six years of age in one review (low quality evidence, downgraded due to high risk of bias) and imprecision (Spittle 2012).

#### **Behaviour for the infant, as a child, and up to 18 years**

No pooled results were available.

#### **Physical wellbeing and safety for the infant, as a child, and up to 18 years**

No pooled results were available.

#### **Parent-infant relationship**

Demonstration and Interaction, State Modulation and Parent Baby Interaction Program interventions did not have a clear impact on mother-infant interaction (measured using the NCAFS or the NCATS up to three months) in one review (very low quality evidence, downgraded due to high risk of bias, inconsistency and imprecision) (Evans 2014). In a second review, home visiting interventions improved parenting quality and interaction (measured using the HOME Inventory) for infants at eight to 12 months of age (very low quality evidence, downgraded due to high risk of bias, imprecision and risk of publication bias) (Goyal 2013).

#### **Parent/caregiver psychosocial wellbeing**

No pooled results were available.

#### **Parent/caregiver knowledge, practices and behaviours**

No pooled results were available.

**Parent/caregiver views of the intervention**

No pooled results were available.

**Family relationships**

No pooled results were available.

**Systems outcomes**

No pooled results were available.

**Potential harms<sup>76</sup>**

In one review (Brett 2011), single study results show significantly poorer outcomes for support from health professionals (within the outcome domain of parent/caregiver views of intervention). In another review (Evans 2014), single study results show significantly poorer outcomes for mother infant interaction (within the outcome domain of parent infant relationship); and in a third review (Goyal 2013) aspects of child health (within the outcome domain of physical wellbeing and safety for the infant, as a child, and up to 18 years) for intervention compared with control. However, these results must be interpreted in context and with caution, as other single study results show positive results for the same outcome. For further details regarding potential harms from single studies see the pink shaded rows of the Evidence Tables in the Technical Report.

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<sup>76</sup>In this context, harm refers to a significantly poorer outcome in the intervention group relative to the control group within a pre-specified primary or secondary outcome domain.

Table 20: Interventions for parents of preterm and low birthweight infants evidence profile

| <b>INTERVENTIONS FOR PARENTS OF PRETERM AND LOW BIRTHWEIGHT INFANTS</b>  |   |   |  |                            |                   |
|--|---|---|--|----------------------------|-------------------|
| What is the effectiveness of interventions targeted at parents of preterm and low birthweight infants in their first year of life for optimal social and emotional development for the infant, and later on as a child and adolescent? |   |   |  |                            |                   |
| <b>Comparison</b>  | Predominately standard care or usual practice   |   |  |                            |                   |
| <b>Outcome domain</b>  | <b>Outcome measure used in the review(s)</b>  | <b>Results reported in the review(s) and GRADE</b>  |  |                            | <b>Importance</b> |
|  |   | <b>Result<sup>77,78</sup></b>   | <b>GRADE</b>   | <b>Quality of evidence</b> |                   |
| <b>Infant social and emotional wellbeing or development up to one year of age</b>  | No pooled results were available.   |   |  |                            | CRITICAL          |
| <b>Development for the infant, as a child, and up to 18 years</b>  | Cognitive development in infancy (BSID MDI; GMDS) (at 6 months)   | MD (R): 3.55 (95% CI -0.05, 7.16); heterogeneity P=NS; P=0.05 (6 RCTs, N=964)<br>Interventions enhancing parental skills (Vanderveen 2009)                  | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0  | Low                        | CRITICAL          |
|  | <i>GRADE reasons for downgrading: <b>Risk of bias</b>: most RCTs had unclear methods for allocation concealment; <b>Imprecision</b>: wide CIs</i>   |   |  |                            |                   |
|  | Cognitive development in infancy (BSID MDI) (at 8-13 months)  | <b>SMD (R): 0.50 (95% CI 0.18 to 0.83); I<sup>2</sup> 68%; P=0.002</b><br>(7 RCTs, 1 qRCT, 1 cohort study, N=516)<br>Home visiting (Goyal 2013)             | Risk of bias: -1<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: -1 | Very low                   | CRITICAL          |
|  | <i>GRADE reasons for downgrading: <b>Risk of bias</b>: mostly RCTs but some concerns about attrition bias; <b>Inconsistency</b>: substantial heterogeneity; <b>Publication bias</b>: systematic review only included studies from North America</i> |   |  |                            |                   |
| <b>Development for the infant, as a child, and up to 18 years</b>  | Cognitive development in infancy (BSID MDI; GMDS) (0-2 years)   | <b>SMD (R): 0.31 (95% CI 0.13, 0.50); I<sup>2</sup> 69%; P=0.0008</b><br>(10 RCTs, 3 qRCTs, N=2,147)<br>Interventions addressing development (Spittle 2012) | Risk of bias: 0<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: -1  | Low                        | CRITICAL          |
|  | <i>GRADE reasons for downgrading: <b>Inconsistency</b>: substantial heterogeneity; <b>Publication bias</b>: some funnel plot asymmetry<sup>79</sup></i>   |   |  |                            |                   |

<sup>77</sup> All Ns reflect the total numbers (i.e. across both the intervention and control groups)

<sup>78</sup> Bolding indicates a statistically significant pooled result in favour of the intervention

<sup>79</sup> Assessed by the Evidence Reviewer

|   |  |   |          |          |
|---|--|---|----------|----------|
| Cognitive development in infancy (BSID MDI; GMDS) (at 12 months)  | <b>MD (R): 5.57 (95% CI 2.29, 8.86); heterogeneity P&lt;0.001; P=0.009</b><br>(11 RCTs, 1 qRCT, N=2,198)<br>Interventions enhancing parental skills<br>(Vanderveen 2009) | Risk of bias: -1<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Low      | CRITICAL |
| <i>GRADE reasons for downgrading: Risk of bias: most RCTs had unclear methods for allocation concealment; Inconsistency: substantial heterogeneity (P&lt;0.001)</i> |  |   |          |          |
| Cognitive development in infancy (BSID MDI; GMDS) (at 24 months)  | <b>MD (R): 7.59 (95% CI 3.31, 11.67); heterogeneity P=0.0009; P=0.0003</b><br>(7 RCTs, N=1,490)<br>Interventions enhancing parental skills<br>(Vanderveen 2009)          | Risk of bias: -1<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Low      | CRITICAL |
| <i>GRADE reasons for downgrading: Risk of bias: most RCTs had unclear methods for allocation concealment; Inconsistency: substantial heterogeneity (P=0.0009)</i>   |  |   |          |          |
| Cognitive development at preschool age (SB; MSCA) (at 36 months)  | <b>MD (R): 9.66 (95% CI 5.01, 14.31); heterogeneity P=NS; P&lt;0.0001</b><br>(2 RCTs, N=961)<br>Interventions enhancing parental skills<br>(Vanderveen 2009)             | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | Moderate | CRITICAL |
| <i>GRADE reasons for downgrading: Risk of bias: most RCTs had unclear methods for allocation concealment</i>  |  |   |          |          |
| Cognitive development at preschool age (SB; MSCA; BSID MDI) (at 3 to < 5 years)   | <b>SMD (F): 0.45 (95% CI 0.34, 0.57); I<sup>2</sup> 0%; P&lt;0.00001</b><br>(6 RCTs, N=1,276)<br>Interventions addressing development<br>(Spittle 2012)                  | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | Moderate | CRITICAL |
| <i>GRADE reasons for downgrading: Risk of bias: 3 RCTs had unclear allocation concealment</i>   |  |   |          |          |
| Cognitive development at school age (WPPSI-R; BAS) (at 5 years)   | <b>MD (R): -1.36 (95% CI -3.64, 0.92); heterogeneity P=NS; p=0.24</b><br>(3 RCTs, N=1,017)<br>Interventions enhancing parental skills<br>(Vanderveen 2009)               | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | Low      | CRITICAL |
| <i>GRADE reasons for downgrading: Risk of bias: most RCTs had unclear methods for allocation concealment; Imprecision: wide CIs</i>                                 |  |   |          |          |

|   |   |   |          |           |
|---|---|---|----------|-----------|
| Cognitive development at school age (WISC; KBIT) (5 to < 17 years)  | SMD (R): 0.25 (95% CI -0.10, 0.61); $I^2$ 82%; P=0.16<br>(4 RCTs, N=1,242)<br>Interventions addressing development (Spittle 2012)                                       | Risk of bias: 0<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Very low | CRITICAL  |
| <i>GRADE reasons for downgrading: Inconsistency: very substantial heterogeneity (<math>I^2 &gt; 80%</math>); Imprecision: wide CIs</i>                              |   |   |          |           |
| Motor development in infancy (BSID PDI) (at 6 months)   | MD (R): 3.47 (95% CI -3.92, 10.86); heterogeneity P=NS; P=0.36 (4 RCTs, N=176)<br>Interventions enhancing parental skills (Vanderveen 2009)                             | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Low      | IMPORTANT |
| <i>GRADE reasons for downgrading: Risk of bias: most RCTs had unclear methods for allocation concealment; Imprecision: wide CIs</i>                                 |   |   |          |           |
| Motor development in infancy (BSID PDI) (at 12 months)  | <b>MD (R): 5.10 (95% CI 1.44 to 8.75); heterogeneity P=NS; P=0.006</b> (9 RCTs, N=1,319)<br>Interventions enhancing parental skills (Vanderveen 2009)                   | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0  | Moderate | IMPORTANT |
| <i>GRADE reasons for downgrading: Risk of bias: most RCTs had unclear methods for allocation concealment</i>  |   |   |          |           |
| Motor development in infancy (BSID PDI) (at 24 months)  | MD (R): 2.47 (95% CI -2.01 to 6.94); heterogeneity P=NS; P=0.28<br>(4 RCTs, N=1,025)<br>Interventions enhancing parental skills (Vanderveen 2009)                       | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Low      | IMPORTANT |
| <i>GRADE reasons for downgrading: Risk of bias: most RCTs had unclear methods for allocation concealment; Imprecision: wide CIs</i>                                 |   |   |          |           |
| Motor development in infancy (BSID PDI; GMDS locomotor subscale) (at 0-2 years)   | <b>SMD (F): 0.10 (95% CI 0.00, 0.19); <math>I^2</math> 0%; P=0.04</b><br>(8 RCTs, 2 qRCTs, N=1,745) <sup>#</sup><br>Interventions addressing development (Spittle 2012) | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: -1 | Low      | IMPORTANT |
| <i>GRADE reasons for downgrading: Risk of bias: 1 crossover RCT and 2 qRCTs had inadequate allocation concealment; Publication bias: some funnel plot asymmetry</i> |   |   |          |           |
| Motor development at preschool age (GMDS locomotor subscale; PEDI) (at 3 to < 5 years)  | SMD (F): 0.14 (95% CI -0.16, 0.44); $I^2$ 0%; P=0.36<br>(2 RCTs, N=168)<br>Interventions addressing development (Spittle 2012)  | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Low      | IMPORTANT |

|   |  |   |  |          |           |
|---|--|---|--|----------|-----------|
|   | <i>GRADE reasons for downgrading: Risk of bias: 1 RCT with unclear allocation concealment; Imprecision: studies with small sample sizes</i>  |   |  |          |           |
|   | Cerebral palsy: (infancy to 6 years)   | RR (F): 0.89 (95% CI 0.55, 1.44); I <sup>2</sup> 0%; P=0.64 (4 RCTs, 1 qRCT, N=737)<br>Interventions addressing development (Spittle 2012)  | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0  | Low      | IMPORTANT |
|   | <i>GRADE reasons for downgrading: Risk of bias: 1 RCT with unclear allocation concealment and 1 qRCT; Imprecision: wide CIs</i>  |   |  |          |           |
| <b>Behaviour for the infant, as a child, and up to 18 years</b>                     | No pooled results were available.  |   |  |          | CRITICAL  |
| <b>Physical wellbeing and safety for the infant, as a child, and up to 18 years</b> | No pooled results were available.  |   |  |          | CRITICAL  |
| <b>Parent-infant relationship</b>   | Mother-infant interaction (NCAFS or NCATS effect on mother) (1 NCAFS prior to discharge, 1 NCAFS at 1.5 months ca and 1 NCATS at 3 months ca)  | SMD (R): 0.04 (95% CI -0.34, 0.41); I <sup>2</sup> 76%; P=0.85 (3 qRCTs, N=508)<br>Interventions: Demonstration and Interaction, State Modulation, Parent Baby Interaction Program (Evans 2014) | Risk of bias: -1<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Very low | CRITICAL  |
|   | <i>GRADE reasons for downgrading: Risk of bias: qRCTs scored 6 or 7 (out of 11) on PEDro scale; Inconsistency: substantial heterogeneity; Imprecision: wide CIs</i>  |   |  |          |           |
|   | Parenting quality and interaction (HOME Inventory) (at 8-12 months)  | <b>SMD (R): 0.79 (95% CI 0.57 to 1.02); I<sup>2</sup> 0%; P&lt;0.001</b> (4 RCTs, 1 cohort, 1 quasi-experimental study, N=336)<br>Home visiting (Goyal 2013)                                    | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: -1 | Very low | CRITICAL  |
|   | <i>GRADE reasons for downgrading: Risk of bias: mostly RCTs but some concerns about attrition bias; Imprecision: studies with small sample sizes; wide CIs; Publication bias: systematic review only included studies from North America</i> |   |  |          |           |
| <b>Parent/caregiver psychosocial wellbeing</b>                                      | No pooled results were available.  |   |  |          | IMPORTANT |
| <b>Parent/caregiver knowledge, practices and behaviours</b>                         | No pooled results were available.  |   |  |          | CRITICAL  |
| <b>Parent/caregiver views of the intervention</b>                                   | No pooled results were available.  |   |  |          | IMPORTANT |
| <b>Family relationships</b>   | No pooled results were available.  |   |  |          | CRITICAL  |
| <b>Systems outcomes</b>   | No pooled results were available.  |   |  |          | IMPORTANT |

| Evidence statements   |  |
|---|--|
| <b>Development for the infant, as a child, and up to 18 years</b> | <p><u>Cognitive development in infancy</u>: Mostly low quality evidence from three systematic reviews shows that home visiting, parenting skills and developmental interventions each improve cognitive development (measured using the BSID or GMDS) from six months, up to two years of age in infants born preterm (41 RCTs, five qRCTs, one cohort study, N=7,315).</p> <p><u>Cognitive development at preschool age</u>: Moderate quality evidence from two systematic reviews shows that parenting skills and developmental interventions each improve cognitive development (measured using the SB Intelligence Scales, MSCA, WPPSI or BAS) at three to five years of age in children born preterm (eight RCTs, N=2,237).</p> <p><u>Cognitive development at school age</u>: Low to very low quality evidence from two systematic reviews suggests no clear effect of parenting skills and developmental interventions on cognitive development (measured using the WISC or KBIT) from five to 17 years of age in children born preterm (seven RCTs, N=2,259).</p> <p><u>Motor development in infancy</u>: Moderate to low quality evidence from two systematic reviews shows that parenting skills and developmental interventions each improve motor development (measured using the BSID PDI or GMDS locomotor subscale) from six months, up to two years of age in infants born preterm (25 RCTs, two qRCTs, N=4,265).</p> <p><u>Motor development at preschool age</u>: Low quality evidence from one systematic review suggests no clear effect of developmental interventions on motor development (measured using the GMDS locomotor subscale or PEDI) at three to five years of age in children born preterm (two RCTs, N=168).</p> <p><u>Cerebral palsy</u>: Low quality evidence from one systematic review suggests no clear effect of developmental interventions on the rate of cerebral palsy up to six years of age in children born preterm (four RCTs and one qRCT, N=737).</p> |
| <b>Parent-infant relationship</b>                                 | <p><u>Mother-infant interaction</u>: Very low quality evidence from one systematic review suggests no clear effect of relationship interventions on mother-infant interaction (measured using the NCAFS or NCATS) up to three months corrected age for infants born preterm (three qRCTs, N=508).</p> <p><u>Parenting quality and interaction</u>: Very low quality evidence from one systematic review shows an improvement in parenting quality and interaction (measured using the HOME Inventory) with home visiting interventions at eight to 12 months of age for infants born preterm (four RCTs, one cohort and one quasi-experimental study, N=336).</p>  |

#5 of these 10 studies were also included in Vanderveen 2009

**Abbreviations:** BAS: British Abilities Scales; BSID: Bayley Scale of Infant Development; CI: confidence interval; (F): fixed effect; GMDS: Griffiths Mental Development Scales; GRADE: Grading of Recommendations Assessment, Development and Evaluation;; HOME: Home Observation for Measurement of the Environment; KBIT: Kaufman Brief Intelligence Test; MSCA: McCarthy Scales of Children's Abilities; MD: mean difference; MDI: Mental Development Index; N: number; NCAFS: Nursing Child Assessment Feeding Scale; NCATS: Nursing Child Assessment Teaching Scale; NS: non-significant; PDI: Psychomotor Development Index; P: P value; PEDI: Paediatric Evaluation of Disability Inventory; qRCT: quasi-randomised trial; (R): random effects; RCT: randomised controlled trial; RR: risk ratio; SMD: standardised mean difference; SB: Stanford-Binet (Intelligence Scale); WISC: Wechsler Intelligence Scale for Children; WPPSI: Wechsler Preschool and Primary Scale of Intelligence

### Characteristics that may have contributed to the effectiveness of interventions for parents of preterm and low birthweight infants for optimal social and emotional development of infants

While four reviews contributed pooled data in this category, very few characteristics contributing to the effectiveness of interventions for parents of preterm infants were identified. Spittle 2012

concluded that although “Early intervention programmes for preterm infants have a positive influence on cognitive and motor outcomes during infancy, with the cognitive benefits persisting into pre-school age. There is a great deal of heterogeneity between studies due to the variety of early developmental intervention programmes trialled and gestational ages of the preterm infants included, which limits the comparisons of intervention programmes.” While Vanderveen 2009 also found “positive clinically meaningful effects” on mental and performance scores with early interventions to improve neurodevelopmental outcomes of preterm infants, it was noted that “The intervention programs were diverse and varied in regards to period of application, intensity, setting and parental involvement.”

***Who*** could<sup>80</sup> deliver the intervention, program or messages to optimise infant social and emotional wellbeing and development?

Benefits for development (cognitive and motor) were seen in both Spittle 2012 and Vanderveen 2009. Spittle 2012 reported that the interventions in the included studies were commonly implemented by nurses or physiotherapists, and less often by psychologists, occupational therapists, doctors and speech pathologists. Vanderveen 2009 reported that the intervention programs varied in regards to parental involvement; studies were most often categorised as having ‘moderate’ or ‘substantial’ parental involvement (with very few having ‘minimal’ involvement).

Both Evans 2014 and Goyal 2013 reported on outcomes relating to the parent-infant relationship. In Evans 2014, no clear benefit (measured using the NCAFS or NCATS) was seen in three studies, where interventions were delivered by “examiners”, neonatal nurses and public health nurses (Evans 2014). A benefit was shown in Goyal 2013 (measured using the HOME Inventory); in the six included studies, intervenors varied, e.g. an infant development specialist, a nurse, a graduate student with a teenage work/study student, and a team of a registered nurse and occupational therapist.

***Where*** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?

Vanderveen 2009 reported that the interventions varied in regards to the setting, with eight of the relevant studies conducted in the neonatal intensive care unit/hospital, eight at home and/or a centre, and eight at both a neonatal intensive care unit in combination with home or centre. For cognitive and motor development outcomes, Spittle 2012 conducted subgroup analyses based on whether the intervention commenced in hospital (as an inpatient), or post-hospital discharge. Subgroup interaction tests suggested no clear differences for cognitive or motor development in infancy or pre-school, however suggested a possible subgroup effect for cognitive development at school age ( $P=0.03$ ). A significant benefit was shown in two studies which commenced in hospital which was not clearly seen in two studies which commenced post-discharge (Spittle 2012).

In Evans 2014 two of the studies reporting on the parent-infant relationship were conducted in the hospital and at home, with one conducted in the hospital only. The interventions in each the six studies reporting on the parent-infant relationship in Goyal 2013 were delivered in the home.

***To whom*** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?

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<sup>80</sup>We used could here and in the sentences that follow to acknowledge that studies conducted outside of Australia were not precluded. The MHPWC will therefore need to interpret what was found in the literature to the operational realities of the Australian context.



In Spittle 2012 the majority of studies reporting on cognitive and motor development included the spectrum of gestational ages from less than 37 weeks or birthweights less than 2500 g, with a smaller number of studies having lower thresholds for inclusion e.g. infants born at less than 34 weeks' gestational age or born at less than 1000 g. In addition some studies also focussed on families at increased social risk e.g. teenage mothers, parents of low socioeconomic status. Spittle 2012 conducted subgroup analyses based on gestational age and birthweight, and showed no clear impact of gestational age on cognitive development in infancy, or birthweight on cognitive development at preschool. The subgroup interaction test suggested a possible subgroup effect for cognitive development in infancy with varying birthweights; a significant benefit was seen in one study which included infants 1500 to less than 2500 g, which was not seen in another study including infants less than 1000 g (Spittle 2012).

Vanderveen 2009 reported that participants ranged in degree of prematurity (means ranged from 25.45 to 35.6 weeks gestation) and birthweight (means ranged from 785 to 2606 g). While Vanderveen 2009 discussed subgroup analyses according to 'low' and 'high' risk infants, no interactions effects were reported, and rather it was noted that intervention effects were generally greater for cognitive development than psychomotor development.

In Evans 2014, the gestational ages of infants in the three included studies which reported on the parent-infant relationship varied: 24 to 36 weeks, less than 32 weeks and less than 36 weeks. Similarly, study populations varied in Goyal 2013 in the six included studies which reporting on the parent-infant relationship (e.g. neonatal intensive care unit graduates with low birthweight, prematurity or other complications of parents with low socio-economic status, and preterm and term infants).

***When*** could be the best time for the intervention, program, or message delivery to occur? (In regards to caregiver preferences and accessibility; and in regards to improved outcomes for the infant, child and later on as the adolescent, and for the caregiver)

Spittle 2012 reported that the frequency and duration of the intervention programmes ranged from four sessions over approximately one month to weekly sessions for 12 months, followed by bi-weekly sessions for a further two years. The majority of interventions began post-discharge from hospital, with a few commencing while the infant was an inpatient (Spittle 2012). Spittle 2012 commented that higher participation was related to improved outcomes, stating that "subjective measurement of compliance by the study investigators may be biased and should be assessed more objectively." The observation that long term effects were limited by small numbers of studies as well as low rates of follow up was also made in Spittle 2012. In Vanderveen 2009, interventions also varied in regards to "period of application [and] intensity", with the length of interventions ranging from the duration of hospital stay (i.e. ending at neonatal intensive care unit discharge), to three years, and intensity ranging from daily to monthly.

In Evans 2014 and Goyal 2013, timing of enrolment, durations and intensities of interventions varied, and no clear patterns of effectiveness according to these characteristics were identified.

***How*** could the intervention, program or messages regarding infant social and emotional wellbeing and development be delivered?

For cognitive and motor development outcomes, Spittle 2012 conducted subgroup interaction tests of various intervention foci, finding no clear differences between interventions focused on the parent-infant relationship, on infant development or on both of these.

The theoretical constructs of intervention programs in Spittle 2012 included: teaching parents about infant development and milestones, understanding behavioural cues, infant stimulation, physiotherapy, occupational therapy, early educational intervention, enhancement of the parent-infant relationship, interaction effect of prematurity and maternal attributes, and responsiveness to infant cues important to development.

In Vanderveen 2009, the intervention programs were diverse; five of the relevant programs involved the NIDCAP, one involved kangaroo care, and the remainder included a variety of developmental interventions. While Vanderveen 2009 discussed the conduct of subgroup analyses based of the type of developmental intervention, no interaction test were performed/reported.

Goyal 2013 included only home visiting programs, but these employed differing theories of change, including: the transactional model focusing on parent-infant interactions, the interaction effect of prematurity and maternal attributes, and responsiveness to infant cues being important to development.

*How could the intervention, program or messages regarding infant social and emotional wellbeing and development be **framed**?*

Parents perceived the most effective communication to be when nurses asked questions and encouraged parents to ask questions, and when caring and reassuring communication was provided, allowing parents to be equal partners in the care of the infant. 'Chat' or 'social talk' between nurses and parents had a positive influence on mothers' confidence, their sense of control and their feelings of connection with their babies (Brett 2011).

*What could **impede** or interfere with engagement with interventions or programs or caregivers enacting upon messages?*

Parents perceived communication to be ineffective when the information given was inconsistent, when the staff did not check if parents understood the information and when questions were not allowed (Brett 2011).

*What could **facilitate** or drive engagement with interventions or programs or caregivers enacting upon messages?*

Brett 2011 documented factors which might help parents or caregivers more fully engage with programs. Parents reported feeling supported through individualised development and behavioural care programs, through being taught behavioural assessment scales, and through breastfeeding, kangaroo care and baby massage programs. The touch involved in kangaroo care was said by mothers to induce feelings of well-being and fulfilment (Brett 2011). Parents also felt supported through organised support groups and through provision of an environment where parents could meet and support each other. It was discussed that parental stress may be reduced through individual developmental care programs, psychotherapy, interventions that teach emotional coping skills, and active problem solving, and journal writing (Brett 2011). It was noted that a tour of the neonatal unit prior to the preterm birth may help to alleviate parents' fears (although some parents may find the appearance of the babies and the technology overwhelming) (Brett 2011).

Websites enabling individualised information were reported to help communication of complex issues and to humanise the experience of the neonatal intensive care unit (Brett 2011). Tape-recordings of consultations with doctors were also seen to be helpful by parents, as was a binder of information about medical and practical information related to the neonatal intensive care

unit (Brett 2011). Mothers reported less anxiety with early neonatal intensive care unit discharge accompanied by an individualised discharge plan, followed by home nursing care (Brett 2011). Discharge planning in general with education engendered a feeling of overall increased support. Parents valued continuity of care e.g. care continuing at home (Brett 2011).

## Interventions for teenage parents

### Description of intervention based on the included evidence

Interventions for teenage parents may be varied, with aims including improving the psychosocial health of the teenage parents, and the developmental health of their children (Barlow 2011). Of the two systematic reviews included in this category one presented pooled results (Barlow 2011). In this overview, interventions for teenage parents include individual or group-based parenting programs focused on improving parenting attitudes, practices, skills/knowledge or wellbeing (excluding programs where the parenting program was combined with a home visiting intervention) (Barlow 2011). Programs were delivered to mothers aged 20 or under from clinical or population samples and their infants, in community or outpatient settings, and in teenage parents' homes (Barlow 2011). The interventions commenced during pregnancy or in the postnatal period, with varied durations and frequencies including standard group based parenting programs delivered over four to six weeks, and brief interventions (mostly observation of videotape interactions focusing on improving mother-infant interaction) ranging from one session to 12 weeks (Barlow 2011).

### Evidence summary

Two systematic reviews assessed individual and group-based parenting interventions for teenage parents (Barlow 2011; Coren 2003). Coren 2003 did not report the review search dates, while Barlow 2011 searched up to 2010.

Coren 2003 included studies of parenting programs that were individual or group-based in format, offered antenatally or postnatally to pregnant or parenting teenagers (less than 20 years), based on a structured format, focused on improving parenting attitudes, practices, skills or knowledge. While Barlow 2011 also included studies assessing parenting interventions (individual or group-based; antenatally and postnatally, or only postnatally administered; with a structured format) aimed specifically at teenage parents, only RCTs or qRCTs (comparing the intervention with no treatment/treatment as usual/a waiting list control) were included.

Together, these two reviews included 22 relevant studies<sup>81</sup> (13 RCTs, three two-group pre and post-test non-equivalent control group studies, one pre/post-test matched control group study, and five one-group pre/post-test studies) with a total of 2,044 participants (ranging from 24 to 535 in the included studies), published between 1977 and 2002 (Barlow 2011; Coren 2003).

In Coren 2003, the intervention durations/intensities (where reported) ranged from a one 15-minute video session, to one year of 1.5 hour weekly group parenting sessions. In Barlow 2011, interventions varied in duration from one visit, to 10 to 12 weeks.

Both of the reviews were judged to be at low risk of bias (Barlow 2011; Coren 2003) using ROBIS; one review was judged to be 'high' quality (Barlow 2011) and one review 'moderate' quality (Coren 2003) using AMSTAR.

One of two included systematic reviews provided pooled results (Barlow 2011). Barlow 2011 (low risk of bias; 'high' quality) included eight studies (RCTs) with 513 participants (ranging from 20 to 164 in the included studies), published between 1977 and 2002.

For further details regarding the results from single studies from the other review (Coren 2003), see the Technical Report.

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<sup>81</sup>With some overlap (see Technical Report)

### ***Primary outcome domain***

#### **Infant social and emotional wellbeing or development up to one year of age**

No pooled results were available.

### ***Secondary outcomes domains***

#### **Development for the infant, as a child, and up to 18 years**

No pooled results were available.

#### **Behaviour for the infant, as a child, and up to 18 years**

No pooled results were available.

#### **Physical wellbeing and safety for the infant, as a child, and up to 18 years**

No pooled results were available.

#### **Parent-infant relationship**

Parenting interventions improved post-intervention (up to six weeks) parent-child interactions (measured using the NCATS parent subscale) (low quality evidence, downgraded due to risk of bias and imprecision) in one review, but this was not sustained at three month follow up in the same review (very low quality evidence, downgraded due to risk of bias, inconsistency and imprecision) (Barlow 2011). There were also improvements in child-parent interaction (measured using the NCATS baby subscale) at three month follow up, and combined parent-child interaction (measured using the NCATS total score) post-intervention and at three month follow up in this review (all low quality evidence, downgraded due to risk of bias and imprecision) (Barlow 2011).

#### **Parent/caregiver psychosocial wellbeing**

No pooled results were available.

#### **Parent/caregiver knowledge, practices and behaviours**

Parenting interventions did not have a clear impact on any of four components of parents' sense of competence in their parenting role post-intervention (four to seven weeks) in one review (measured using the measured using the AAPI): appropriate developmental expectation of children; empathic awareness) (very low quality evidence, downgraded due to risk of bias, inconsistency and imprecision) (and measured using the AAPI: non-belief in corporal punishment; lack of parent child role reversal) (low quality evidence, downgraded due to risk of bias and imprecision) (Barlow 2011).

#### **Parent/caregiver views of the intervention**

No pooled results were available.

#### **Family relationships**

No pooled results were available.

#### **Systems outcomes**

No pooled results were available.

**Table 21: Interventions for teenage parents evidence profile**

| <b>INTERVENTIONS FOR TEENAGE PARENTS</b>   |   |   |  |                            |                   |           |
|--|---|---|--|----------------------------|-------------------|-----------|
| What is the effectiveness of interventions for teenage parents in the infant's first year of life for optimal social and emotional development for the infant, and later on as a child and adolescent? |   |   |  |                            |                   |           |
| <b>Comparison</b>  | Predominately usual care  |   |  |                            |                   |           |
| <b>Outcome domain</b>  | <b>Outcome measure used in the review(s)</b>  | <b>Results reported in the review(s) and GRADE</b>  |  |                            | <b>Importance</b> |           |
|  |   | <b>Result<sup>82,83</sup></b>   | <b>GRADE</b>   | <b>Quality of evidence</b> |                   |           |
| <b>Infant social and emotional wellbeing or development up to one year of age</b>  | No pooled results were available.   |   |  |                            | CRITICAL          |           |
| <b>Development for the infant, as a child, and up to 18 years</b>  | No pooled results were available.   |   |  |                            | CRITICAL          |           |
| <b>Behaviour for the infant, as a child, and up to 18 years</b>  | No pooled results were available.   |   |  |                            | CRITICAL          |           |
| <b>Physical wellbeing and safety for the infant, as a child, and up to 18 years</b>  | No pooled results were available.   |   |  |                            | CRITICAL          |           |
| <b>Parent-infant relationship</b>  | Parent interaction with child (NCATS parent subscale) (post-intervention, up to 6 weeks)  | <b>SMD (F): -0.91 (95% CI -1.52, -0.30); I<sup>2</sup> 0%; P=0.0036</b><br>(2 RCTs, N=46) (Barlow 2011) | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0  | Low                        | IMPORTANT         |           |
|  | <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Imprecision: studies with small sample sizes</i>   |   |  |                            |                   |           |
|  | Parent interaction with child (NCATS parent subscale) (at 3 month follow up)  | SMD (R): -6.11 (95% CI -16.99, 4.77); I <sup>2</sup> 95%; P=0.27<br>(2 RCTs, N=47) (Barlow 2011)        | Risk of bias: -1<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Very low                   |                   | IMPORTANT |
|  | <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Inconsistency: very substantial heterogeneity (I<sup>2</sup>&gt;80%); Imprecision: studies with small sample sizes</i> |   |  |                            |                   |           |
|  | Child interaction with parent (NCATS baby subscale) (at 3 month follow up)  | <b>SMD (F): -0.65 (95% CI -1.25, -0.06); I<sup>2</sup> 0%; P=0.031</b><br>(2 RCTs, N=47) (Barlow 2011)  | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0  | Low                        |                   | IMPORTANT |
| <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Imprecision: studies with small sample sizes</i>  |   |   |  |                            |                   |           |

<sup>82</sup>All Ns reflect the total numbers (i.e. across both the intervention and control groups)

<sup>83</sup>Bolding indicates a statistically significant pooled result in favour of the intervention

|   |   |   |  |          |           |  |
|---|---|---|--|----------|-----------|--|
|   | Combined parent-child interaction (NCAFS total score) (post-intervention, up to 6 weeks)  | <b>SMD (F): -0.71 (95% CI -1.31, -0.11); I<sup>2</sup> 0%: P=0.021</b><br>(2 RCTs, N=46) (Barlow 2011)  | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0  | Low      | IMPORTANT |  |
| <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Imprecision: studies with small sample sizes</i> |   |   |  |          |           |  |
|   | Combined parent-child interaction (NCAFS total score) (at 3 month follow up)  | <b>SMD (F): -0.90 (95% CI -1.51, -0.30); I<sup>2</sup> 0%: P=0.0036</b><br>(2 RCTs, N=47) (Barlow 2011) | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0  | Low      | IMPORTANT |  |
| <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Imprecision: studies with small sample sizes</i> |   |   |  |          |           |  |
| <b>Parent/caregiver knowledge, practices and behaviours</b>   | Sense of competence in parenting role (AAPI, appropriate developmental expectation of children) (post-intervention) (4-7 weeks)   | SMD (R): 0.17 (95% CI -0.96, 1.30); I <sup>2</sup> 81%; P=0.77<br>(2 RCTs, N=70) (Barlow 2011)          | Risk of bias: -1<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Very low | CRITICAL  |  |
|   | <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Inconsistency: very substantial heterogeneity (I<sup>2</sup>&gt;80%); Imprecision: studies with small sample sizes</i> |   |  |          |           |  |
|   | Sense of competence in parenting role (AAPI, empathic awareness) (post-intervention, 4-7 weeks)   | SMD (R): 0.02 (95% CI -1.46, 1.50); I <sup>2</sup> 89%; P=0.98<br>(2 RCTs, N=69) (Barlow 2011)          | Risk of bias: -1<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Very low | CRITICAL  |  |
|   | <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Inconsistency: very substantial heterogeneity (I<sup>2</sup>&gt;80%); Imprecision: studies with small sample sizes</i> |   |  |          |           |  |
|   | Sense of competence in parenting role (AAPI, nonbelief in corporal punishment) (post-intervention, 4-7 weeks)   | SMD (F): 0.26 (95% CI -0.22, 0.73); I <sup>2</sup> 0%; P=0.29<br>(2 RCTs, N=69) (Barlow 2011)           | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0  | Low      | CRITICAL  |  |
|   | <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Imprecision: studies with small sample sizes</i>   |   |  |          |           |  |
|   | Sense of competence in parenting role (AAPI, lack of parent child role reversal) (post-intervention, 4-7 weeks)   | SMD (F): 0.09 (95% CI -0.38, 0.56); I <sup>2</sup> 0%; P=0.71<br>(2 RCTs, N=70) (Barlow 2011)           | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0  | Low      | CRITICAL  |  |
| <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Imprecision: studies with small sample sizes</i> |   |   |  |          |           |  |
| <b>Parent/caregiver psychosocial wellbeing</b>  | No pooled results were available.   |   |  |          | IMPORTANT |  |
| <b>Parent/caregiver views of the intervention</b>   | No pooled results were available.   |   |  |          | IMPORTANT |  |
| <b>Family relationships</b>   | No pooled results were available.   |   |  |          | CRITICAL  |  |
| <b>Systems outcomes</b>   | No pooled results were available.   |   |  |          | CRITICAL  |  |

| Evidence statements   |  |
|---|--|
| <b>Parent-infant relationship</b>                           | <u>Parent-child interactions</u> : Low quality evidence from one systematic review shows that teenage parenting interventions can improve combined parent-child interactions post-intervention (up to six weeks) and at three month follow up, as well as children’s interactions with parents at three month follow up, and parents’ interactions with children post-intervention (up to six weeks); very low quality evidence shows no clear effect on parent’s interactions with children three month follow up (all measured using the NCATS total score, parent or baby subscale) (two RCTs, N=47). |
| <b>Parent/caregiver knowledge, practices and behaviours</b> | <u>Sense of competence in parenting role</u> : Low to very low quality evidence from one systematic review indicates no clear impact of teenage parenting interventions on sense of parenting competence (measured using the AAPI) at four to seven weeks (two RCTs, N=70).  |

**Abbreviations:** AAPI: Adult Adolescent Parenting Inventory; BDI: Beck Depression Inventory; CI: confidence interval; (F): fixed effect; GRADE: Grading of Recommendations Assessment, Development and Evaluation; NCAFS: Nursing Child Assessment Feeding Scale; NCATS: Nursing Child Assessment Teaching Scale; N: number; P: P value; (R): random effects; RCT: randomised controlled trial; SMD: standardised mean difference

### Characteristics that may have contributed to the effectiveness of interventions for teenage parents for optimal social and emotional development of infants

Barlow 2011 discussed that while the included studies suggested some benefits of parenting programs for teenage parents and their children (particularly those focusing on improving the early parent-infant interaction) that the methodological quality of the studies was poor, and there was notable clinical heterogeneity particularly in terms of the different focuses and durations of the interventions. Barlow 2011 concluded “As such it is not possible at the current time to be clear what the necessary ingredients of successful parenting programmes for teenage parents comprise.”

***Who*** could<sup>84</sup> deliver the intervention, program or messages to optimise infant social and emotional wellbeing and development?

The two studies providing data for the outcomes parent interaction with child, child interaction with parent and combined parent-child interaction were delivered by nurses. Who delivered the intervention in the two studies providing data regarding sense of competence in the parenting role was not clear (Barlow 2011).

***Where*** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?

The two studies assessing parent-child interaction were conducted in the United States (with recruitment from a residential maternity home) and in Canada (with recruitment from a school-based program for teen parents). In both studies, the program was delivered in the participants’ homes (Barlow 2011).

The two studies assessing sense of competence in the parenting role were conducted in the United States; one study recruited women from a community setting, and the other recruited women from

<sup>84</sup>We used could here and in the sentences that follow to acknowledge that studies conducted outside of Australia were not precluded. The MHPWC will therefore need to interpret what was found in the literature to the operational realities of the Australian context.



a range of settings (high school, via a hospital community health nurse, healthy clinic and social service agency). One study delivered the intervention in community settings, and the other delivered the intervention in both community and outpatient settings.

***To whom*** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?

The two studies assessing parent-child interaction included adolescent mothers (less than 20 years) of infants, with one study recruiting single, predominately first-time black, Hispanic or white mothers following a normal birth (mean age 17 years) and the other recruiting first-time mothers, following a healthy birth (mean age 18 years) (Barlow 2011).

The two studies assessing sense of competence in the parenting role also included adolescent mothers, with one study recruiting single, predominately African-American mothers living with parents, following a normal birth (mean age of 17 years), and the other recruiting predominately white, first-time mothers of low socio-economic status (mean age of 18 years) (Barlow 2011).

***When*** could be the best time for the intervention, program, or message delivery to occur? (In regards to caregiver preferences and accessibility; and in regards to improved outcomes for the infant, child and later on as the adolescent, and for the caregiver)

In the two studies assessing parent-child interaction the duration and length of follow-up of the intervention varied, from a one visit intervention (“likely that duration was a few hours”) with follow up four weeks later, to six weeks duration, with follow up four to five weeks later (Barlow 2011).

The two studies assessing sense of competence in the parenting role had durations of four weeks and six to seven weeks, with no follow up (Barlow 2011).

***How*** could the intervention, program or messages regarding infant social and emotional wellbeing and development be delivered?

In one of the studies assessing parent-child interaction an individual-based educational video-tape modelling parent program was assessed, with the use of two structured teaching tasks during the session; instruction and feedback were provided, with discussion on infant cues, maternal response to infant distress and the use of language. In the second study, the ‘Keys to Caregiving’ program was assessed – a manualised program designed to improve interaction and responsiveness, with an information pamphlet provided before each home visit (Barlow 2011).

Both studies assessing sense of competence in the parenting role were provided in the group-format (Barlow 2011). In one study a group-based educational active learning parent program (with demonstration and practice of parenting skills), was compared with a group-based passive learning program (with audio-visual-only education), and a no-treatment control. Parenting skills covered included: appropriate developmental expectations, empathy for children’s needs, alternatives to corporal punishment and family roles. In the second study, an audio-visual parent education program, was compared with booklet only education, an audio-visual and booklet program, and a treatment-as-usual control. The education programs included content on play activity and infant stimulation, stress and coping strategies, discipline strategies, nutrition and feeding tips, formal and informal support systems, and development in early childhood (Barlow 2011).

*How could the intervention, program or messages regarding infant social and emotional wellbeing and development be **framed**?*

Framing of the program/messages was not covered in Barlow 2011.

*What could **impede** or interfere with engagement with interventions or programs or caregivers enacting upon messages?*

Factors impeding engagement with the programs were not covered in Barlow 2011.

*What could **facilitate** or drive engagement with interventions or programs or caregivers enacting upon messages?*

Factors facilitating engagement with the programs were not covered in Barlow 2011.

## Interventions for parents from low and middle income countries

### Description of intervention based on the included evidence

Of the four systematic reviews included in this category only one presented pooled results. The interventions in this systematic review were structured interventions to improve the mental health of women in the perinatal period in low and middle income countries, delivered by non-specialist health and community workers (Rahman 2013). The studies were conducted in Chile, China, India, Mexico, Pakistan, South Africa, Taipei and Taiwan.

### Evidence summary

Four systematic reviews assessed interventions for parents from low and middle income settings (Grantham-McGregor 2014; Knerr 2013; Mejia 2012; Rahman 2013). Mejia 2012 did not report the review search dates, however included studies published from 1990 onwards; Knerr 2013 searched for studies up to 2010, and Rahman included studies published up to 2012; Grantham-McGregor 2014, searched for studies from 2000 to 2013.

While all reviews focused on interventions in low and middle-income countries, the inclusion criteria varied and were as follows:

- Grantham-McGregor 2014: studies in low or middle-income countries, involving children five years and under, or pregnant women, with at least two components to the intervention (nutrition: micronutrient and/or macronutrient supplementation, education, breastfeeding promotion, responsive feeding; and stimulation: centre-based preschool and day care, parent groups, individual parent counselling, home visiting), including a child development and a health or nutrition outcome, with a control group of similar background, rated of “moderate” or “good” quality.
- Knerr 2013: randomised trials with parents or primary carers of children aged zero to 18 years, in low or middle-income countries, assessing interventions designed to reduce child abuse or harsh parenting, teach positive child behaviour management strategies, or improve parent-child attachment relationships through specific parenting components or curricula aimed at changing general parenting knowledge, attitudes or skills, compared with no intervention/treatment as usual or an alternative intervention.
- Mejia 2013: peer-reviewed, quantitative or qualitative evaluations of parenting programs for preventing emotional or behavioural difficulties, designed to target parents of children up to 12 years old, published from 1990 onwards.
- Rahman 2013: controlled trials from low and middle-income countries, published up to 2012, involving structured mental health interventions targeting women during pregnancy and after giving birth, or that measured maternal mental health outcomes up to 36 months postpartum

Together, these two reviews included 26 relevant studies<sup>85</sup> (23 RCTs, one qRCT, one time-lag controlled study and one historical matched control study) with a total of 26,379 participants (ranging from 38 to 19,030), published between 1981 and 2012.

The interventions delivered across the four reviews varied considerably; in Grantham-McGregor, the nutrition and stimulation interventions had durations from three months to 30 months (until the child was three years); in Knerr 2013, parenting interventions (mostly involving home visiting) were delivered for a period of three to six months, in five to 15 sessions. The durations/intensities of the parenting interventions delivered in the home/community in Mejia 2012 were not reported. In

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<sup>85</sup>With some overlap (see Technical Report)

Rahman 2013, the interventions to improve the mental health of women in the perinatal period, ranged from one session to 20 visits.

Two of the reviews were judged to be at unclear risk of bias (Knerr 2013; Rahman 2013) and two reviews were judged to be at high risk of bias (Grantham-McGregor 2014; Mejia 2012) using ROBIS; two reviews were judged to be 'moderate' quality (Knerr 2013; Rahman 2013) and two reviews 'low' quality (Grantham-McGregor 2014; Mejia 2012) using AMSTAR.

One of four included systematic reviews provided pooled results (Rahman 2013). Rahman 2013 (unclear risk of bias; 'moderate' quality) included 11 relevant studies (nine RCTs, one qRCT and one historical matched control study) with a total of 22,441 participants (ranging from 72 to 19,030 in the included studies), published between 2002 and 2012.

For further details regarding the results from single studies from the other three reviews (Grantham-McGregor 2014; Knerr 2013; Mejia 2012), see the Technical Report.

### ***Primary outcome domain***

#### **Infant social and emotional wellbeing or development up to one year of age**

No pooled results were available.

### ***Secondary outcomes domains***

#### **Development for the infant, as a child, and up to 18 years**

Maternal mental health interventions improved infant growth (exact measure used not reported) and development (measured using the GMDS or DASII) in one review (time of measures unclear/not reported) (both unclear quality evidence, with no information reported to determine risk of bias or inconsistency) (Rahman 2013).

#### **Behaviour for the infant, as a child, and up to 18 years**

No pooled results were available.

#### **Physical wellbeing and safety for the infant, as a child, and up to 18 years**

No pooled results were available.

#### **Parent-infant relationship**

Maternal mental health interventions improved the mother-infant relationship (measured using rated observations of parent-child interactions and the Acholi adaptation of the HOME Inventory) in one review at six to 12 months (unclear quality evidence, with no information reported to determine risk of bias or inconsistency) (Rahman 2013).

#### **Parent/caregiver psychosocial wellbeing**

Maternal mental health interventions reduced maternal depression (measured using the, SCID, CES-D, EPDS, 20-item SRQ-20, HDRS, K10 or Kitgum Maternal Mood Scale) at follow up four weeks to 12 months postpartum (moderate to low quality evidence (assumed), downgraded due to inconsistency, with no information reported regarding risk of bias) in one review (Rahman 2013). In the same review, these interventions reduced maternal depression at follow up three to four months postpartum, six months postpartum and 12 months postpartum in one review (all unclear quality evidence, with no information reported to determine risk of bias or inconsistency)(Rahman 2013).

### Parent/caregiver knowledge, practices and behaviours

No pooled results were available.

### Parent/caregiver views of the intervention

No pooled results were available.

### Family relationships

No pooled results were available.

### Systems outcomes

No pooled results were available.

**Table 22: Interventions for parents from low and middle income countries evidence profile**

| <b>INTERVENTIONS FOR PARENTS FROM LOW AND MIDDLE INCOME COUNTRIES</b>  |  |  |   |                            |                   |
|--|--|--|---|----------------------------|-------------------|
| What is the effectiveness of interventions for parents from low and middle income countries in the first year of life for optimal social and emotional development for the infant, and later on as a child and adolescent? |  |  |   |                            |                   |
| <b>Comparison</b>  | Predominately usual care                                       |  |   |                            |                   |
| <b>Outcome domain</b>  | <b>Outcome measure used in the review(s)</b>                   | <b>Results reported in the review(s) and GRADE</b>   |   |                            | <b>Importance</b> |
|  |  | <b>Result<sup>86,87</sup></b>  | <b>GRADE</b>  | <b>Quality of evidence</b> |                   |
| <b>Infant social and emotional wellbeing or development up to one year of age</b>  | No pooled results were available.                              |  |   |                            | CRITICAL          |
| <b>Development for the infant, as a child and up to 18 years</b>   | Infant growth (exact measures NR/unclear) (time of measure NR) | <b>SMD: 0.19 (95% CI 0.07, 0.31)</b><br>(2 RCTs, 1 historical matched control study <sup>#</sup> , N=1,125)<br>(Rahman 2013)                                   | Risk of bias: NR<br>Inconsistency: NR<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Unclear                    | IMPORTANT         |
|  | Infant development (GMDS; DAS) (time of measure NR)            | <b>SMD : 1.57 (95% CI 0.28, 2.85)</b><br>(2 RCTs <sup>#</sup> , N=473)<br>[includes 1 study in infants > 1 year at intervention commencement]<br>(Rahman 2013) | Risk of bias: NR<br>Inconsistency: NR<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Unclear                    | CRITICAL          |
| <b>Behaviour for the infant, as a child, and up to 18 years</b>  | No pooled results were available.                              |  |   |                            | CRITICAL          |
| <b>Physical wellbeing and safety for the infant, as a child, and up to 18 years</b>  | No pooled results were available.                              |  |   |                            | CRITICAL          |

<sup>86</sup> All Ns reflect the total numbers (i.e. across both the intervention and control groups)

<sup>87</sup> Bolding indicates a statistically significant pooled result in favour of the intervention

|  |  |   |   |                           |           |
|--|--|---|---|---------------------------|-----------|
| <b>Parent-infant relationship</b>                                | Mother-infant relationship (rated observations of parent-child interactions; Acholi adaptation of the HOME Inventory) (6-12 months)  | <b>SMD: 0.36 (95% CI 0.22, 0.51)</b><br>(3 RCTs, 1 historical matched control study, N=1,123)<br>[includes 1 study in infants > 1 year at intervention commencement]<br>(Rahman 2013)                                   | Risk of bias: NR<br>Inconsistency: NR<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Unclear                   | CRITICAL  |
| <b>Parent/caregiver psychosocial wellbeing</b>                   | Maternal depression (SCID-1; CES-D; EPDS; SRQ-20; HDRS; K10; Kitgum Maternal Mood Scale) (4 weeks to 12 months)  | <b>SMD: -0.38 (95% CI -0.56, -0.21); I<sup>2</sup> 80%</b><br>(11 RCTs, 1 qRCT, 1 historical matched control study, N=15,429)<br>[includes 2 studies in infants > 1 year at intervention commencement]<br>(Rahman 2013) | Risk of bias: NR<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Moderate to low (assumed) | IMPORTANT |
|  | <i>GRADE reasons for downgrading: Risk of bias: NR; Inconsistency: substantial heterogeneity</i>   |   |   |                           |           |
|  | Maternal depression (EPDS; Kitgum Maternal Mood Scale) (at 3-4 months postpartum)  | <b>SMD: -0.59 (95% CI -0.95, -0.24)</b><br>(4 RCTs, 1 qRCT, N=943)<br>(Rahman 2013)   | Risk of bias: NR<br>Inconsistency: NR<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Unclear                   | IMPORTANT |
|  | Maternal depression (SCID-1; EPDS; SRQ-20; HDRS) (at 6 months postpartum)  | <b>SMD: -0.27 (95% CI -0.50, -0.05)</b><br>(6 RCTs, 1 historical matched control study, N=1,945)<br>(Rahman 2013)   | Risk of bias: NR<br>Inconsistency: NR<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Unclear                   | IMPORTANT |
|  | Maternal depression (CES-D; K10) (at 12 months postpartum)   | <b>SMD: -0.19 (95% CI -0.36, -0.04)</b><br>(2 RCTs, N=12,541)<br>(Rahman 2013)  | Risk of bias: NR<br>Inconsistency: NR<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Unclear                   | IMPORTANT |
| <b>Parent/caregiver knowledge, practices and behaviours</b>      | No pooled results were available.  |   |   |                           | CRITICAL  |
| <b>Parent/caregiver views of the intervention</b>                | No pooled results were available.  |   |   |                           | IMPORTANT |
| <b>Family relationships</b>                                      | No pooled results were available.  |   |   |                           | CRITICAL  |
| <b>Systems outcomes</b>  | No pooled results were available.  |   |   |                           | IMPORTANT |
| <b>Evidence statements</b>                                       |  |   |   |                           |           |
| <b>Development for the infant, as a child and up to 18 years</b> | <p><u>Infant growth:</u> Unclear quality evidence from one systematic review shows that interventions in low to middle income settings to address maternal mental health improve infant growth (time of outcome measure not reported) (two RCTs, 1 historical matched control study, N=1,125).</p> <p><u>Infant development:</u> Unclear quality evidence from one systematic review shows that interventions in low to middle income settings to address maternal mental health improve infant development (measured using the GMDS or DAS-II) (time of outcome measure unclear) (two RCTs, N=473).</p> |   |   |                           |           |

|  |  |
|--|--|
| <b>Parent-infant relationship</b>              | <u>Mother-infant relationship</u> : Unclear quality evidence from one systematic review shows that interventions in low to middle income settings to address maternal mental health improve mother-infant relationships (measured using rated observations of parent-child interactions and the Acholi adaptation of the HOME Inventory) at six to 12 months (three RCTs, one historical matched control study, N=1,123).  |
| <b>Parent/caregiver psychosocial wellbeing</b> | <u>Maternal depression</u> : Moderate to low quality evidence from one systematic review shows that interventions in low to middle income settings to address maternal mental health improve maternal depression at four weeks to 12 months postpartum (measured using the, SCID-1, CES-D, EPDS, SRQ-20, HDRS, K10 or Kitgum Maternal Mood Scale) (11 RCTs, one qRCT, one historical group control study, N=15,429), and unclear quality evidence shows these interventions improve maternal depression at three to four months (four RCTs, one qRCT, N=943), six months (six RCTs, one historical matched control study, N=1,945), and 12 months postpartum (two RCTs, N=12,541). |

#It was unclear/NR which studies contributed data to these pooled results; the Evidence Reviewer has assumed studies based on the manuscript Tables/results reported

**Abbreviations:** CES-D: Center for Epidemiologic Studies Depression Scale; CI: confidence interval; DASII: Developmental Assessment Scales for Indian Infants; EPDS: Edinburgh Postnatal Depression Scale; GRADE: Grading of Recommendations Assessment, Development and Evaluation; GMDS: Griffiths Mental Development Scale; HDRS: Hamilton Depression Rating Scale; HOME: Home Observation for Measurement of the Environment; K10: Kessler Psychological Distress Scale; N: number; NR: not reported; qRCT: quasi-randomised controlled trial; RCT: randomised controlled trial; SCID: Structured Clinical Interview for DSM Disorders; SMD: standardised mean difference; SRQ-20: 20-item Self-Reporting Questionnaire

### **Characteristics that may have contributed to the effectiveness of interventions for parents from low and middle income countries for optimal social and emotional development of infants**

One of the four included reviews (Rahman 2013) provided pooled results; Rahman 2013 concluded that in low and middle income countries, the burden of common perinatal mental disorders (primarily postpartum depression or anxiety) “can be reduced through mental health interventions delivered by supervised non-specialists.” In assessing the characteristics that may have contributed to the effectiveness of such interventions, we have focused on the outcome maternal depression as a measure of parent/caregiver psychosocial wellbeing (the few included studies contributing to pooled data for other relevant outcomes each reported on maternal depression, and thus discussion of their characteristics are included below).

***Who could<sup>88</sup> deliver the intervention, program or messages to optimise infant social and emotional wellbeing and development?***

In four of the 13 included studies in Rahman 2013, interventions were implemented by mental health professionals: in Chile, China and Mexico. In all other studies, the interventions were implemented by local trained community health workers under professional supervision (Rahman 2013).

<sup>88</sup>We used could here and in the sentences that follow to acknowledge that studies conducted outside of Australia were not precluded. The MHPWC will therefore need to interpret what was found in the literature to the operational realities of the Australian context

***Where*** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?

Three of the studies in Rahman 2013 were conducted in China, two each in India, Pakistan and South Africa, and one in each of Chile, Jamaica, Mexico and Uganda. About half the studies involved home visits and the other half involved group sessions (locations not specified), embedded in routine antenatal care or delivered in hospital (Rahman 2013). There were no clear patterns of success according to the settings where the interventions were delivered (Rahman 2013).

***To whom*** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?

All 13 studies except four (from China and one from Mexico) included participants of low socioeconomic status who experienced difficulties that could have contributed to their mental health problems.

Of the nine studies where the intervention commenced antenatally, six showed significant reductions in maternal depression, while the other three showed no clear differences (Rahman 2013).

***When*** could be the best time for the intervention, program, or message delivery to occur? (In regards to caregiver preferences and accessibility; and in regards to improved outcomes for the infant, child and later on as the adolescent, and for the caregiver)

Frequency and/or duration of the interventions in Rahman 2013 did not appear to be clearly related to intervention success (in terms of reducing maternal depression). For example, in one study demonstrating success, the intervention involved discussion with nurses on the second day after giving birth, while a further study which did not show a clear difference involved home visits twice antenatally, twice weekly during the first month after birth, weekly for eight weeks, fortnightly for the next month, and monthly for the following two months. Time-points of measurement of maternal depression in the main meta-analysis ranged from four weeks to 12 months (Rahman 2013).

***How*** could the intervention, program or messages regarding infant social and emotional wellbeing and development be delivered?

The 13 studies covered a broad range of approaches. Studies showing benefits for maternal depression involved: manualised interventions incorporating cognitive and behavioural techniques; incorporation of the WHO Improving the Psychosocial Development of Children Programme; discussion of a booklet about postpartum depression; psychotherapy classes embedded in antenatal child birth education; participatory action cycles; emotional self-management training; and culturally appropriate psychoeducation; while studies showing no clear benefits involved: incorporation of the WHO Improving the Psychosocial Development of Children Programme; interventions to improve mothers' knowledge of child-rearing practices and parenting self-esteem; structured psychoeducational groups; use of images and simple text to demonstrate infant development, parent-child play activities and skilled parenting practices; information sharing and positive thinking; and supportive empathic listening (Rahman 2013).



*How could the intervention, program or messages regarding infant social and emotional wellbeing and development be **framed**?*

Rahman 2013 did not report on intervention framing.

*What could **impede** or interfere with engagement with interventions or programs or caregivers enacting upon messages?*

Rahman 2013 did not report on factors impeding intervention engagement.

*What could **facilitate** or drive engagement with interventions or programs or caregivers enacting upon messages?*

Rahman 2013 concluded that involvement of the family can help mitigate important risk factors for depression in women. Qualitative findings from included studies in Rahman 2013 were also reported; one study suggested that recipients felt supported, felt they could trust the provider, said the provider understood how they felt, made them appreciate what the baby could do, helped solved problems they were having with the baby, helped them understand the child's needs and how to respond to what the child was doing. In another included study, there was strong support from the local community for health workers and the project, and two further studies, trained lay health workers considered the intervention to be relevant and easy to integrate into their routine tasks.

## Interventions for low income/socially disadvantaged parents

### Description of intervention based on the included evidence

Interventions for low income/socially disadvantaged parents may be varied, but commonly aim to overcome the greater risk for infants from a variety of disadvantaged backgrounds of developmental problems and poorer health, such as through promoting the quality of parenting and the home environment. Of the three systematic reviews included in this category, only one presented pooled quantitative results (Mortensen 2014). Specific interventions in this overview include home-based programs designed to improve child development and relationship-based programs (particularly antenatal or postnatal home visiting, providing education and support for maximising the quality of parent-infant interaction) (Mortensen 2014). The interventions were delivered by professional and paraprofessional providers with a range over three to 64 sessions over a range of 1.5 to 36 months. The participants included pregnant women and/or parents of infants who were socioeconomically disadvantaged with respect to poverty, low parental education, or teenage parents.

### Evidence summary

Three systematic reviews assessed interventions for low income/socially disadvantaged parents (Maulik 2009; Miller 2011; Mortensen 2014). Maulik 2009 searched for studies up to 2008, Miller 2011 to 2010, and Mortensen to 2012.

The review inclusion criteria for these reviews varied, as follows:

- Maulik 2009: systematic reviews, randomised trials, quasi-experimental, cohort, case-control and cross-sectional studies describing interventions related to reading, music, play, cognitive/tactile stimulation and the parent-child intervention, which could be applied in large-scale community-based projects aimed to optimise neurodevelopment, and started and measured outcomes any time before three years of age.
- Miller 2011: RCTs comparing home-based preschool child development interventions (delivered by a trained, lay or professional family visitors, designed to improve child intellectual and socio-emotional development through provision of relevant knowledge and skills) with a standard care control, where participants were parents and children up to the age of school entry who were
- Mortensen 2014: RCTs or pre/post studies, published in peer-reviewed journal between 2000 and 2011, investigating a relationship-based intervention for parents with children between zero and 48 months old (including prenatal interventions), specifically targeting parent-child relational interactions (stand-alone/embedded within a larger program), including an observational measure of parent-child interactions, with the majority of the sample characterised by low socioeconomic status, low parental education or teenage childbearing.

Together, these three reviews included 49 relevant studies (35 RCTs, one cross-over study, nine quasi-experimental or non-randomised studies, and four cohort studies) with a total of more than 42,454 participants<sup>89</sup> (ranging from 13 to 14,084), published between 1980 and 2011 (Maulik 2009; Miller 2011; Mortensen 2014).

The interventions delivered in Maulik 2009, Miller 2011 and Mortensen 2014 varied between and within reviews. In Maulik 2009, durations/intensities varied greatly, e.g. one hour parent training in the neonatal nursery through music therapy, compared with a five day per week centre-based education program until age three. Similarly, in Miller 2011, interventions varied, though all involved home visits (e.g. from three prenatal and five postnatal visits, to visits for the first 12 months of the

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<sup>89</sup>In Mortensen 2014, the N for one included study was reported as more than 4,000

infant's life). In Mortensen 2014, the intervention durations spanned 1.50 to 36.00 months (mean 13.93 months); with the number of intervention sessions ranging from 2.83 to 64.0 (mean 26.78).

One of the reviews was judged to be at low risk of bias (Miller 2011) and two reviews were judged to be at high risk of bias (Maulik 2009; Mortensen 2014) using ROBIS; one review was judged to be 'high' quality (Miller 2011) and two reviews 'moderate' quality (Maulik 2009; Mortensen 2014) using AMSTAR.

All three included systematic reviews provided pooled results:

- Maulik 2009 (high risk of bias; 'moderate' quality) included 29 relevant studies (19 RCTs, five qRCT and one cross-over study, and four cohort studies) with a total of more than 36,000 participants (ranging from 13 to 14,084 in the included studies), published between 1980 and 2007.
- Miller 2011 (low risk of bias; 'high' quality) included three relevant studies (RCTs) with a total of 415 participants (ranging from 80 to 262 in the included studies), published between 1982 and 1993.
- Mortensen 2014 (high risk of bias; 'moderate' quality) included 17 relevant studies (13 RCT and four non-randomised studies) with a total of 6,039 participants (ranging from 16 to 2,799 in the included studies), published between 2000 and 2012.

As Maulik 2009 and Miller 2011 did not provide pooled numerical results, we did not assess the quality of the evidence (using the GRADE system) for the outcomes reported by these reviews.

### ***Primary outcome domain***

#### **Infant social and emotional wellbeing or development up to one year of age**

No pooled results were available.

### ***Secondary outcomes domains***

#### **Development for the infant, as a child, and up to 18 years**

Interventions directed towards early child development that used play as an important component improved children's cognitive development (measured using the GMDS, Brunet-Lezine Development Test or WISC) from 15 months up to 14 years of age in one review (quality of the evidence not assessed) (Maulik 2009). Interventions directed towards early child development that used play with reading/maternal and child care as important components also improved cognitive and psychomotor development (measured by Child Development Center of China Scale or BSID MDI and PDI) up to two years of age in the same review (quality of the evidence not assessed) (Maulik 2009). However, in a second systematic review, the effects of home-based preschool child development interventions on psychomotor development (measured using the BSID PDI) from 7.5 months up to two years of age were unclear (Miller 2011) (quality of the evidence not assessed).

#### **Behaviour for the infant, as a child, and up to 18 years**

Interventions directed towards early child development that used play as an important component improved behaviour (measured using observation or the CBCL) up to three years in one review, but clear differences were no longer seen at five years of age in the same review (quality of the evidence not assessed) (Maulik 2009).

#### **Physical wellbeing and safety for the infant, as a child, and up to 18 years**

No pooled results were available.

**Parent-infant relationship**

Relationship-based interventions increased supportive parent-child interactions (using observational measures, e.g. EA Scale, HOME Inventory, MBRS, NCATS) from 1.5 to 30 months in one review (low quality evidence, downgraded due to risk of bias and inconsistency) (Mortensen 2014). In a second review, parent-child interactions ('qualitatively assessed', or using the HOME Inventory, or Caregiver-Child Interaction Rating Scale) were also improved with interventions directed towards early child development that used play with reading/maternal and child care as important components up to 21 months (quality of the evidence not assessed) (Maulik 2009).

**Parent/caregiver psychosocial wellbeing**

No pooled results were available.

**Parent/caregiver knowledge, practices and behaviours**

No pooled results were available.

**Parent/caregiver views of the intervention**

No pooled results were available.

**Family relationships**

No pooled results were available.

**Systems outcomes**

No pooled results were available.

**Potential harms<sup>90</sup>**

In one review (Maulik 2009), single study results show significantly poorer outcomes for maternal depression (within the outcome domain of parent/caregiver psychosocial wellbeing) in studies that used basic maternal and/or child care as an important component of the intervention. For further details regarding potential harms from single studies see the pink shaded rows of the Evidence Tables in the Technical Report.

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<sup>90</sup>In this context, harm refers to a significantly poorer outcome in the intervention group relative to the control group within a pre-specified primary or secondary outcome domain.

**Table 23: Interventions for low-income/socially disadvantaged parents evidence profile**

| <b>INTERVENTIONS FOR LOW-INCOME/SOCIALLY DISADVANTAGED PARENTS</b>   |   |  |                                   |                            |                   |
|--|---|--|-----------------------------------|----------------------------|-------------------|
| What is the effectiveness of interventions for low income/socially disadvantaged parents in the infant's first year of life for optimal social and emotional development for the infant, and later on as a child and adolescent? |   |  |                                   |                            |                   |
| <b>Comparison</b>  | Usual care or not reported  |  |                                   |                            |                   |
| <b>Outcome domain</b>  | <b>Outcome measure used in the review(s)</b>  | <b>Results reported in the review(s) and GRADE</b>   |                                   |                            | <b>Importance</b> |
|  |   | <b>Result<sup>91,92</sup></b>  | <b>GRADE</b>                      | <b>Quality of evidence</b> |                   |
| <b>Infant social and emotional wellbeing or development up to one year of age</b>  | No pooled results were available.   |  |                                   |                            | CRITICAL          |
| <b>Development for the infant, as a child, and up to 18 years</b>  | Cognitive development (GMDS; Brunet-Lezine Development Test; WISC) (15 months to 14 years)                          | 3 studies (1 RCT, 2 cohort studies; N=4,508) showed improvements (Maulik 2009)   | Insufficient information to GRADE | Not assessed               | CRITICAL          |
|  | Cognitive and psychomotor development (Child Development Center of China Scale; BSID MDI and PDI) (up to 24 months) | 2 RCTs (N=215) showed improvements (Maulik 2009)   | Insufficient information to GRADE | Not assessed               | CRITICAL          |
|  | Psychomotor development (BSID PDI) (7.5-24 months)  | 1 RCT (N=47) showed no clear differences up to 7.5 months, while another RCT (N=80) showed significant improvements up to 2 years of age (Miller 2011) | Insufficient information to GRADE | Not assessed               | IMPORTANT         |
| <b>Behaviour for the infant, as a child, and up to 18 years</b>  | Behaviour (observation; CBCL) (up to 5 years)   | 2 RCTs (N=1,125) showed improvements up to 3 years, but clear differences were no longer seen at 5 years of age (Maulik 2009)                          | Insufficient information to GRADE | Not assessed               | CRITICAL          |
| <b>Physical wellbeing and safety for the infant, as a child, and up to 18 years</b>  | No pooled results were available.   |  |                                   |                            | CRITICAL          |

<sup>91</sup>All Ns reflect the total numbers (i.e. across both the intervention and control groups)

<sup>92</sup>Bolding indicates a statistically significant pooled result in favour of the intervention

|   |   |  |   |              |           |
|---|---|--|---|--------------|-----------|
| <b>Parent-infant relationship</b>                           | Observed supportive parent-child interactions (observational measures, e.g. EA Scale; HOME; MBRS; NCATS) (1.5-30 months)  | <b>ES (d): 0.23 (95% CI 0.14, 0.33); I<sup>2</sup> 59%; P&lt;0.001</b><br>(19 interventions (mostly RCTs), N=6,807)<br>[2 interventions commenced > 12 months]<br>(Mortensen 2014) | Risk of bias: -1<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: 0<br>Publication bias: 0 | Low          | CRITICAL  |
|   | <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Inconsistency: substantial heterogeneity</i>   |  |   |              |           |
|   | Parent-child interaction (qualitatively assessed; HOME Inventory; Caregiver-Child Interaction Rating Scale) (up to 21 months)   | 3 RCTs (N=189 and unclear for 3 <sup>rd</sup> RCT) showed improvements (Maulik 2009)   | Insufficient information to GRADE   | Not assessed | CRITICAL  |
| <b>Parent/caregiver psychosocial wellbeing</b>              | No pooled results were available.   |  |   |              | IMPORTANT |
| <b>Parent/caregiver knowledge, practices and behaviours</b> | No pooled results were available.   |  |   |              | CRITICAL  |
| <b>Parent/caregiver views of the intervention</b>           | No pooled results were available.   |  |   |              | IMPORTANT |
| <b>Family relationships</b>                                 | No pooled results were available.   |  |   |              | CRITICAL  |
| <b>Systems outcomes</b>                                     | No pooled results were available.   |  |   |              | IMPORTANT |
| <b>Evidence statement</b>                                   |   |  |   |              |           |
| <b>Parent-infant relationship</b>                           | <u>Supportive parent-child interactions</u> : Low quality evidence from one systematic review shows that relationship-based interventions for low income/socially disadvantaged parents can improve parent-child interactions (using observational measures, e.g. EA Scale, HOME, MBRS, NCATS) at 1.5 to 30 months (19 interventions (mostly RCTs), N=6,807). |  |   |              |           |

**Abbreviations:** BSID: Bayley Scale of Infant Development; CBCL: Child Behavior Checklist; CI: confidence interval; EA Scale: Emotional Availability Scale; ES: effect size; GMDS: Griffiths Mental Development Scales; GRADE: Grading of Recommendations Assessment, Development and Evaluation; HOME: Home Observation for Measurement of the Environment; MDI: Mental Development Index; MBRS: Maternal Behavior Rating Scale; N: number; NCATS: Nursing Child Assessment Teaching Scale; NR: not reported; P: P value; PDI: Psychomotor Development Index; RCT: randomised controlled trial; WISC: Wechsler Intelligence Scale for Children

### **Characteristics that may have contributed to the effectiveness of interventions for low income/socially disadvantaged parents for optimal social and emotional development of infants**

Maulik 2009 assessed interventions related to reading, music, play, cognitive/tactile stimulation and the parent-child interaction that could be applied in large-scale community-based projects, and concluded that “Play and reading were effective interactions.”

In Miller 2011 home-based interventions specifically targeted at improving developmental outcome for preschool children from socially disadvantaged families were assessed; it was discussed that while the review does not provide evidence of effectiveness, the studies forming the basis of the review were small scale and likely to be underpowered.

Mortensen 2014 assessed relationship-based intervention programs serving socio-economically disadvantaged families with infants and toddlers, and concluded “significant, yet modest effectiveness across all interventions...” and noted that “programs that were shorter in duration, that provided direct services to the parent-child dyad, used intervenors with professional qualifications, and assessed parent-child interactions with free-play tasks were the most effective.”

***Who*** could<sup>93</sup> deliver the intervention, program or messages to optimise infant social and emotional wellbeing and development?

In Maulik 2009, some benefits were seen for development, behaviour and the parent-infant relationships. Where reported, intervenors included trained community health workers, nurses, therapists and lay workers (Maulik 2009); no clear patterns for who delivered the intervention were observed.

In Miller 2011, one study showed benefit of home based child development intervention for psychomotor development up to two years, while a second study failed to show benefits at 7.5 months. In the study showing benefit, the home visits were delivered by a psychology graduate student and a training aide, while in the study showing no clear difference, visits were by a public health nurse.

In Mortensen 2014, relationship-based interventions were shown to increase supportive parent-child interactions; across the 19 studies/interventions in the meta-analysis, 12 used a professional intervenor (had a bachelor degree, advanced degree, and/or professional licensure) and seven used a paraprofessional intervenor (trained in the intervention but did not hold a professional licensure (such as local mothers from the community). Results of mixed-effects moderator analyses for the 15 random interventions indicated that interventions that utilised professional intervenors had significantly larger effect sizes (Mortensen 2014).

***Where*** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?

Studies showing benefits for development, behaviour and parent-child interactions in Maulik 2009 were conducted across a range of countries including Canada, China, Israel, Jamaica, and the United States, and were predominately conducted in the home or community; Maulik 2009 had a particular focus on interventions “that may be transferable to developing countries.”

In the study showing benefit in Miller 2011 for psychomotor development, mothers were recruited from a large university hospital neonatal nursery; the country of the study was not reported. The study which did not show benefits was conducted in Canada. The interventions in both studies were delivered in the home (Miller 2011).

In Mortensen 2014, nine of the 17 relevant relationship-based interventions which demonstrated an increase in supportive parent-child interactions, were conducted in the United States, with two conducted in South Africa, two in the Netherlands, two in the United Kingdom, and one each in Canada and Australia. All but one of the interventions took place in the family home; one was conducted in a high school. In all except for two of the interventions parent-child interactions were

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<sup>93</sup>We used could here and in the sentences that follow to acknowledge that studies conducted outside of Australia were not precluded. The MHPWC will therefore need to interpret what was found in the literature to the operational realities of the Australian context.

assessed in the family home in all but two studies where this was done in the hospital or clinic (Mortensen 2014)

***To whom*** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?

Maulik 2009 had a particular focus on interventions “that may be transferable to developing countries and to children at risk of developing secondary impairments,” however excluded studies involving special populations (including children with Down syndrome, cerebral palsy, autism or other specific disabilities). Included studies had populations such as preterm infants, low birthweight preterm or term infants, infants with non-organic failure to thrive/malnutrition, and mother-infant dyads where mothers had less than high school education (Maulik 2009).

Low income or social disadvantage was an inclusion criterion for the Miller 2011 review. In the one study showing benefit for psychomotor development, Black teenage mothers of newborn babies, with low income and low socio-economic status were included (mean age of 16.3 years) ; while in the second study, not showing benefit, pregnant mothers with low maternal educational attainment, and/or living below the poverty line were included (mean age of 24.4 years).

An inclusion criterion for Mortensen 2014 was that the majority (more than 50%) of the sample had to be characterised by low socio-economic status, low parental education or teenage childbearing. All of the interventions targeted the mother-infant dyad; in one, 5% of the sample were fathers.

***When*** could be the best time for the intervention, program, or message delivery to occur? (In regards to caregiver preferences and accessibility; and in regards to improved outcomes for the infant, child and later on as the adolescent, and for the caregiver)

Interventions showing benefits for development, behaviour or parent-child interactions in Maulik 2009 varied in terms of their timing, durations and frequencies (and for many studies, limited detail was provided). In five of the eight relevant studies (contributing to the pooled data), home visits were reported to have been first provided weekly (for eight weeks, up to two years), and then bi-weekly (for up to two years) (Maulik 2009).

In the study showing benefit for psychomotor development in Miller 2011, women were recruited postnatally, and then received six months of bi-weekly home visits, while in the study not showing benefit, pregnant women were recruited, who received three prenatal visits, and five postnatal home visits.

Across the 19 interventions included in the meta-analysis in Mortensen 2014 (showing a benefit of relationship-based interventions for supportive parent-child interactions), length of interventions ranged from 1.50 to 36.00 months (mean: 13.93, standard deviation: 11.50), with number of sessions ranging from 2.83 to 64.00 (mean: 26.78, standard deviation: 19.75). Results of mixed-effects moderator analyses for the 15 random interventions indicated that those that were shorter in duration in both total months, and total number of sessions, had significantly larger effect sizes (Mortensen 2014).

***How*** could the intervention, program or messages regarding infant social and emotional wellbeing and development be delivered?

In Maulik 2009, a review inclusion criterion was that interventions “had to be such that they could be applied in large-scale community-based projects.” Interventions showing benefits for



development, behaviour and the parent-infant relationship were those directed towards early child development that used play as an important component, and/or those directed towards early child development that used play with reading or maternal and child care as important components. For example, in one study that used play as an important component the first phase of the intervention involved telling parents to converse and sing to their children, and the second phase involved telling mothers to play with the children using homemade toys, and to interact through conversation (Maulik 2009); in a second study, using play and reading as important components, parents were taught how to stimulate their infants using visual and auditory stimuli; interventions included age-appropriate toys, books and pictorials that were used by the mothers while interacting with their babies (Maulik 2009).

Miller 2011 included studies of home-based preschool child development interventions. The study showing benefit for psychomotor development trained mothers in infant stimulation using caretaking, sensorimotor and mother interaction exercises, adapted from developmental assessment scales (NBAS, BSID); the study showing no benefit aimed to provide mothers with simple tools (based of items from the HOME Inventory) to maximise the quality of the mother-child relationship.

An inclusion criterion in Mortensen 2014 was that the study assessed a relationship-based intervention, specifically targeting parent-child relational interactions. Considering 'breadth' of the interventions, 11 of the 19 interventions included in the meta-analysis were considered 'direct' (provided targeted support to the parent-child dyad, e.g. parent coaching, reinforcement, modelling, video feedback) and eight were considered 'comprehensive' (providing similar parent-child relational guidance, but as one component within a broader intervention, e.g. mental/physical health services for parents and children, parent educational/employment assistance, economic assistance, community source referrals) (Mortensen 2014). Results of mixed-effects moderator analyses for the 15 random interventions indicated that those that provided direct services had significantly larger effect sizes (Mortensen 2014). Mortensen 2014 also considered whether the interventions assessed play tasks in the context of structured play (strict direction and a specific goal, and/or performing a series of tasks in a certain order, e.g. some parents were instructed to teach their child something that was intentionally above the child's abilities) or free play (parents and children instructed to play together as they normally would). Moderator analyses for the 15 random interventions indicated that those that assessed supportive parent-child interactions in the context of free play showed significantly larger effect sizes than those assessing interactions in the context of structured play (Mortensen 2014).

*How could the intervention, program or messages regarding infant social and emotional wellbeing and development be **framed**?*

Maulik 2009, Miller 2011 and Mortensen 2014 did not address intervention framing.

*What could **impede** or interfere with engagement with interventions or programs or caregivers enacting upon messages?*

Maulik 2009, Miller 2011 and Mortensen 2014 did not address factors impeding intervention engagement.

*What could **facilitate** or drive engagement with interventions or programs or caregivers enacting upon messages?*

Maulik 2009 and Miller 2011 did not address factors facilitating intervention engagement.

Mortensen 2014 discussed the finding of increased effectiveness (for supportive parent-child interactions) with relationship-based interventions of shorter duration for socioeconomically disadvantaged families, “shorter interventions may be more suitable... the lives of high-risk families tend to be marked by unstable living arrangements and varied conditions... making compliance to lengthy intervention protocol more challenging.”

## Interventions for parents with alcohol or drug problems

### Description of intervention based on the included evidence

Interventions for parents with alcohol or drug problems may include home visiting, institution-based interventions (such as in inpatient drug rehabilitation facilities, schools or acute care settings) and outpatient interventions, with aims including improving general health of parents and their infants, including through promoting parent-infant attachment and responsiveness, enhancing caregiving skills, and facilitating linking in parents in with health care (Bowie 2005; Suchman 2006; Turnbull 2012). Of the four systematic reviews included in this category only one presented pooled quantitative results (Turnbull 2012). Specific interventions for parents with alcohol and/or drug problems in this overview include home visits for women (predominately commencing in the postpartum period, by midwives, nurses, paraprofessionals and 'lay' women) with the aim of educating, supporting and empowering women (and often encouraging women to enrol in drug treatment programs (Turnbull 2012). Duration and intensity of interventions were most commonly weekly, then biweekly or monthly for 20 minutes up to four hours, from eight weeks to three years postpartum.

### Evidence summary

Four systematic reviews assessed interventions (home visiting, outpatient clinic or residential programs) for parents with alcohol or drug problems (Bowie 2005; Niccols 2012; Suchman 2006; Turnbull 2012). Bowie 2005 searched for studies from 1980 to 2003; Suchman 2006 did not report the review search dates however only included studies "completed within the last 10 years"; Turnbull 2012 searched between 1966 and 2011, and Niccols 2012 from 1990 to 2011.

The inclusion criteria for these reviews varied and were as follows:

- Bowie 2005: studies that focused on implementing an intervention aimed at enhancing the mother-infant interactions of drug-abusing mother and their infants, published between 1980 and 2003.
- Suchman 2006: studies using quasi-experimental as well as experimental designs, completed within the past 10 years, assessing programs (outpatient and home-visiting parenting interventions with drug-abusing and dependent mothers) for parents of young children from birth to five years of age.
- Niccols 2012: RCTs, quasi-experimental or cohort studies, of women with substance abuse problems at baseline who were pregnant or parenting, assessing treatment programs that included at least one specific substance abuse treatment and at least one parenting or child treatment service, with quantitative data on child outcomes.
- Turnbull 2012: studies using random or quasi-random allocation of pregnant or postpartum women with an alcohol or drug problem to home visits or no home visits (by teams or individuals: doctors, nurses, social workers, counsellors or trained people), or a different type of home visiting intervention.

Together, these four reviews included 23 relevant studies<sup>94</sup> (13 RCTs, seven quasi-experimental or non-randomised studies, and three cohort studies), with a total of approximately 2,460 participants<sup>95</sup> (ranging from 19 to 227), published between 1994 and 2006 (Bowie 2005; Niccols 2012; Suchman 2006; Turnbull 2012).

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<sup>94</sup>With some overlap (see Technical Report); there were discrepancies classification of studies (designs) across the four systematic reviews (we have reported designs as per the individual reviews)

<sup>95</sup>Ns in Niccols 2012 not clearly reported

Bowie 2004 included home visitation interventions, institution based interventions, a residential treatment program and in hospital postnatal program, with varying durations/intensities e.g. from a short intervention within 48 hours of birth, to home visits for 18 months postpartum, or 36 months of paraprofessional support. Suchman 2006 similarly included both home visiting and outpatient interventions, which also varied in duration/intensity, e.g. from weekly two hour group sessions for eight weeks, to one home visit weekly from birth to six week, plus two home visit per week from six to 36 months. Niccols 2012 included only integrated outpatient, or integrated residential programs, reported to be of six to 12 months in duration; and Turnbull 2012 included only home visiting interventions, predominately in the postpartum period, with roughly half of the interventions involving home visits at least weekly for some of the period, and continuing beyond six months.

Two of the reviews were judged to be at low risk of bias (Niccols 2012; Turnbull 2012) and two reviews were judged to be at high risk of bias (Bowie 2005; Suchman 2006) using ROBIS; one review was judged to be 'high' quality (Turnbull 2012), one review 'moderate' quality (Niccols 2012), and two reviews 'moderate' quality (Bowie 2005; Suchman 2006) using AMSTAR.

Three of four included systematic review provided pooled results (Bowie 2005; Suchman 2006; Turnbull 2012). As Bowie 2005 and Suchman 2006 did not provide pooled numerical results, we did not assess the quality of the evidence (using the GRADE system) for the outcomes reported by these reviews.

- Bowie 2005 (high risk of bias; 'low' quality) included six relevant studies (five RCTs and two quasi-experimental or non-randomised studies) with a total of 648 participants (ranging from 60 to 171 in the included studies), published between 1994 and 2000.
- Suchman 2006 (high risk of bias; 'low' quality) included five relevant studies (three RCTs and two non-randomised studies) with a total of 578 participants (ranging from 60 to 200 in the included studies), published between 1994 and 2002.
- Turnbull 2012 (low risk of bias; 'high' quality) included seven relevant studies (six RCTs and one qRCT) with a total of 950 participants (ranging from 60 to 227 in the included studies), published between 1994 and 2006.

For further details regarding the results from single studies from the other review (Niccols 2012), see the Technical Report.

### ***Primary outcome domain***

#### **Infant social and emotional wellbeing or development up to one year of age**

No pooled results were available.

### ***Secondary outcomes domains***

#### **Development for the infant, as a child, and up to 18 years**

Home visiting interventions did not have a clear impact on infant cognitive development (measured using the BSID MDI) at 18 to 36 months in one review (low quality evidence, downgraded due to risk of bias and imprecision) (Turnbull 2012). In the same review, home visiting interventions did not have a clear impact on infant psychomotor delay (measured using the BSID PDI) at 18 to 36 months (low quality evidence, downgraded due to risk of bias and imprecision) (Turnbull 2012). In a second review, the effects on cognitive development (also measured using the BSID MDI) up to 18 months were unclear (quality of the evidence not assessed) (Bowie 2005); and in a third review the effects on development (measure using the BSID) at six to 36 months were also unclear (quality of the evidence not assessed) (Suchman 2006).

**Behaviour for the infant, as a child, and up to 18 years**

No pooled results were available.

**Physical wellbeing and safety for the infant, as a child, and up to 18 years**

Home visiting interventions did not have a clear impact on decreasing incomplete vaccination schedules at six months in one review (low quality evidence, downgraded due to risk of bias and imprecision) (Turnbull 2012). Nor did these interventions have a clear impact on infant death (up to six months) in the same review (low quality evidence, downgraded due to risk of bias and imprecision) (Turnbull 2012).

**Parent-infant relationship**

No pooled results were available.

**Parent/caregiver psychosocial wellbeing**

No pooled results were available.

**Parent/caregiver knowledge, practices and behaviours**

Home visiting interventions did not have a clear impact on continued illicit drug use at six to 36 months in one review (very low quality evidence, downgraded due to risk of bias, inconsistency and imprecision) (Turnbull 2012). In the same review, there was also no clear impact on continued alcohol use at six to 36 months (low quality evidence, downgraded due to risk of bias and imprecision), failure to enrol in a drug treatment program (time of measure not reported) and failure to remain in drug treatment program at latest time measured at three to 18 months (both very low quality evidence, downgraded due to risk of bias, inconsistency and imprecision) (Turnbull 2012). However in a second systematic review women in programs were more likely to be drug free at 12 to 18 months (quality of the evidence not assessed) (Bowie 2005). Home visiting interventions did not have a clear effect on not breastfeeding at six months (low quality evidence, downgraded due to risk of bias and imprecision) (Turnbull 2012).

**Parent/caregiver views of the intervention**

No pooled results were available.

**Family relationships**

No pooled results were available.

**Systems outcomes**

Home visiting interventions did not have a clear impact on infants being in the care of their biological mother (including non-voluntary foster care) at 12 to 36 months (very low quality evidence, downgraded due to risk of bias, inconsistency and imprecision) (Turnbull 2012).

**Table 24: Interventions for parents with alcohol or drug problems evidence profile**

| <b>INTERVENTIONS FOR PARENTS WITH ALCOHOL OR DRUG PROBLEMS</b>   |   |   |   |                            |                   |
|--|---|---|---|----------------------------|-------------------|
| What is the effectiveness of interventions for parents with alcohol or drug problems in the infant's first year of life for optimal social and emotional development for the infant, and later on as a child and adolescent? |   |   |   |                            |                   |
| <b>Comparison</b>  | Usual care or not reported  |   |   |                            |                   |
| <b>Outcome domain</b>  | <b>Outcome measure used in the review(s)</b>  | <b>Results reported in the review(s) and GRADE</b>  |   |                            | <b>Importance</b> |
|  |   | <b>Result<sup>96</sup></b>  | <b>GRADE</b>  | <b>Quality of evidence</b> |                   |
| <b>Infant social and emotional wellbeing or development up to one year of age</b>  | No pooled results were available.   |   |   |                            | CRITICAL          |
| <b>Development for the infant, as a child, and up to 18 years</b>  | Cognitive development (BSID MDI) at latest time measured (18-36 months)   | MD (F): 2.89 (95% CI -1.17, 6.95); I <sup>2</sup> 11%; P=0.29 (3 RCTs, N=199) (Turnbull 2012) | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Low                        | CRITICAL          |
|  | <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Imprecision: studies with small sample sizes; wide CIs</i> |   |   |                            |                   |
|  | Cognitive development (BSID MDI) (6-18 months)  | 2 RCTs (N=234) showed improvements, 1 RCT (N=60) showed no clear difference (Bowie 2005)      | Insufficient information to GRADE   | Not assessed               | CRITICAL          |
|  | Psychomotor delay (BSID PDI) at latest time measured (18-36 months)   | MD (F): 3.14 (95% CI -0.03, 6.32); I <sup>2</sup> 0%; P=0.053 (3 RCTs, N=199) (Turnbull 2012) | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Low                        | IMPORTANT         |
|  | <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Imprecision: studies with small sample sizes</i>           |   |   |                            |                   |
|  | Development (BSID) (6-36 months)  | 2 RCTs (N=124) showed no clear differences; 1 nRCT (N=126) showed improvements (Suchman 2006) | Insufficient information to GRADE   | Not assessed               | CRITICAL          |
| <b>Behaviour for the infant, as a child, and up to 18 years</b>  | No pooled results were available.   |   |   |                            | CRITICAL          |
| <b>Physical wellbeing and safety for the infant, as a child, and up to 18 years</b>  | Incomplete vaccination schedule (6 months)  | RR (F): 1.09 (95% CI 0.91, 1.32); I <sup>2</sup> 0%; P=0.36 (2 RCTs, N=260) (Turnbull 2012)   | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Low                        | CRITICAL          |
|  | <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Imprecision: studies with small sample sizes</i>           |   |   |                            |                   |
|  | Infant death (up to 6 months)   | RR (F): 0.70 (95% CI 0.12, 4.16); I <sup>2</sup> 0%; P=0.70 (2 RCTs, N=228) (Turnbull 2012)   | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Low                        | CRITICAL          |

<sup>96</sup> All Ns reflect the total numbers (i.e. across both the intervention and control groups)

|   |  |  |  |              |           |
|---|--|--|--|--------------|-----------|
|   | <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Imprecision: studies with small sample sizes; wide CIs</i>  |  |  |              |           |
| <b>Parent-infant relationship</b>   | No pooled results were available.  |  |  |              | CRITICAL  |
| <b>Parent/caregiver psychosocial wellbeing</b>  | No pooled results were available.  |  |  |              | CRITICAL  |
| <b>Parent/caregiver knowledge, practices and behaviours</b>   | Continued illicit drug use (6-36 months)   | RR (F): 1.05 (95% CI 0.89, 1.24); I <sup>2</sup> 64%; P=0.58 (3 RCTs, N=384) (Turnbull 2012) | Risk of bias: -1<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Very low     | CRITICAL  |
|   | <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Inconsistency; substantial heterogeneity; Imprecision: studies with small sample sizes</i>  |  |  |              |           |
|   | Continued alcohol use (6-36 months)  | RR (F): 1.18 (95% CI 0.96, 1.46); I <sup>2</sup> 0%; P=0.12 (3 RCTs, N=384) (Turnbull 2012)  | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0  | Low          | CRITICAL  |
|   | <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Imprecision: studies with small sample sizes; wide CIs</i>  |  |  |              |           |
|   | Failure to enrol in drug treatment program (time of measure NR)  | RR (R): 0.45 (95% CI 0.10, 1.94); I <sup>2</sup> 92%; P=0.28 (2 RCTs, N=211) (Turnbull 2012) | Risk of bias: -1<br>Inconsistency: -2<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Very low     | CRITICAL  |
|   | <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Inconsistency; very substantial heterogeneity (I<sup>2</sup>&gt;80%); Imprecision: studies with small sample sizes; wide CIs</i>    |  |  |              |           |
|   | Failure to remain in drug treatment program at latest time measured (3-18 months)  | RR (F): 0.92 (95% CI 0.69, 1.23); I <sup>2</sup> 62%; P=0.58 (3 RCTs, N=315) (Turnbull 2012) | Risk of bias: -1<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Very low     | CRITICAL  |
|   | <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Inconsistency; substantial heterogeneity; random effects model not used; Imprecision: studies with small sample sizes; wide CIs</i> |  |  |              |           |
|   | Women being drug free (12-18 months)   | More likely in 2 RCTs (N=186) (Bowie 2005)   | Insufficient information to GRADE  | Not assessed | CRITICAL  |
|   | Not breastfeeding (at 6 months)  | RR (F): 0.95 (95% CI 0.83, 1.10); I <sup>2</sup> 0%; P=0.51 (2 RCTs, N=260) (Turnbull 2012)  | Risk of bias: -1<br>Inconsistency: 0<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0  | Low          | IMPORTANT |
| <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Imprecision: studies with small sample sizes</i> |  |  |  |              |           |
| <b>Parent/caregiver views of the intervention</b>   | No pooled results were available.  |  |  |              | IMPORTANT |
| <b>Family relationships</b>   | No pooled results were available.  |  |  |              | CRITICAL  |
| <b>Systems outcomes</b>   | Infant not in care of biological mother (including non-voluntary foster care) (12-36 months)   | RR (F): 0.83 (95% CI 0.50, 1.39); I <sup>2</sup> 63%; P=0.48 (2 RCTs, N=253) (Turnbull 2012) | Risk of bias: -1<br>Inconsistency: -1<br>Indirectness: 0<br>Imprecision: -1<br>Publication bias: 0 | Very low     | IMPORTANT |
|   | <i>GRADE reasons for downgrading: Risk of bias: studies with methodological limitations; Inconsistency; substantial heterogeneity; random effects model not used; Imprecision: studies with small sample sizes; wide CIs</i> |  |  |              |           |

| Evidence statements   |  |
|---|--|
| <b>Development for the infant, as a child, and up to 18 years</b>                   | <p><u>Cognitive development</u>: Low quality evidence from one systematic review shows no clear differences in cognitive development (measured using the BSID MDI) at 18 to 36 months with home visiting interventions for parents with alcohol or drug problems (three RCTs, N=199).</p> <p><u>Psychomotor delay</u>: Low quality evidence from one systematic review shows no clear differences in psychomotor development (measured using the BSID-PDI) at 18 to 36 months with home visiting interventions for parents with alcohol or drug problems (three RCTs, N=199).</p>  |
| <b>Physical wellbeing and safety for the infant, as a child, and up to 18 years</b> | <p><u>Incomplete vaccination schedule</u>: Low quality evidence from one systematic review shows no clear difference in completing vaccinations at six months with home visiting interventions for parents with alcohol or drug problems (two RCTs, N=260).</p> <p><u>Infant death</u>: Low quality evidence from one systematic review shows no clear difference in infant death up to six months with home visiting interventions for parents with alcohol or drug problems (two RCTs, N=228).</p>   |
| <b>Parent/caregiver knowledge, practices and behaviours</b>                         | <p><u>Continued illicit drug use</u>: Very low quality evidence from one systematic review shows no clear difference in continuing to use illicit drugs at six to 36 months with home visiting interventions for parents with alcohol or drug problems (three RCTs, N=348).</p> <p><u>Continued alcohol use</u>: Low quality evidence from one systematic review shows no clear difference in continuing to use alcohol at six to 36 months with home visiting interventions for parents with alcohol or drug problems (three RCTs, N=348).</p> <p><u>Failure to enrol in drug treatment program</u>: Very low quality evidence from one systematic review shows no clear difference in failing to enrol in drug treatment programs (time of outcome measure not reported) with home visiting interventions for parents with alcohol or drug problems (two RCTs, N=211).</p> <p><u>Failure to remain in drug treatment program</u>: Very low quality evidence from one systematic review shows no clear differences in failing to remain in drug treatment programs at three to 18 months with home visiting interventions for parents with alcohol or drug problems (three RCTs, N=315).</p> <p><u>Breastfeeding</u>: Low quality evidence from one systematic review shows no clear differences in breastfeeding at six months with home visiting interventions for parents with alcohol or drug problems (two RCTs, N=260).</p> |
| <b>Systems outcomes</b>   | <p><u>Infant not in care of biological mother</u>: Very low quality evidence from one systematic review shows no clear differences in numbers not in the care of their biological mother (including non-voluntary foster care) at 12 to 36 months with home visiting interventions for parents with alcohol or drug problems (two RCTs, N=253).</p>  |

**Abbreviations:** BSID: Bayley Scales of Infant Development; CI: confidence interval; (F): fixed effect; GRADE: Grading of Recommendations Assessment, Development and Evaluation; MD: mean difference; MDI: Mental Development Index; N: number; NR: not reported; P: P value; PDI: Psychomotor Development Index; (R): random effects; RCT: randomised controlled trial; RR: risk ratio



## Interventions for fathers

### Description of intervention based on the included evidence

Only one systematic review was included in this category and it did not provide pooled results (Magill-Evans 2006). In this overview, interventions for fathers included those assessed in predominately middle class families, with fathers of healthy or premature newborns or infants ranging from one encounter to daily encounters for one month. Specific interventions included education, observation and modelling of infant behaviour (such as through demonstration, or participation in the NBAS or APIB) by an interventionist to fathers in hospital prior to discharge), massage interventions (with fathers taught to massage their infants, using written instructions, demonstrations or videotapes), and kangaroo care interventions (with fathers participating in kangaroo care for preterm infants) (Magill-Evans 2006).

### Evidence summary

One systematic review compared interventions involving fathers with interventions involving no specific paternal involvement (Magill-Evans 2006). Magill-Evans 2006 searched for studies between 1983 and 2003, and included studies interventions with father of young children (infants or children younger than five) with a control group or used a pre-test/post-test design, that measured an aspect of father-child interaction and analysed father outcomes separately from mother outcomes.

This review included eight relevant studies (four RCTs and four cohort studies), with 506 participants (ranging from 14 to 146 in the included studies), published between 1985 and 2002 (Magill-Evans 2006). Interventions in the relevant studies included those promoting awareness/sensitivity to infant behaviour, teaching specific skills (massage, kangaroo care), or addressing the social and physical environment for labour and birth; intervention intensities/durations ranged from one encounter, to daily for one month (Magill-Evans 2006).

This review was judged to be high risk of bias using ROBIS, and was judged to be 'moderate' quality using AMSTAR (Magill-Evans 2006).

Magill-Evans 2006 provided no pooled results. For further details regarding the results from single studies from Magill-Evans 2006, see the Technical Report.

**Table 25: Interventions for fathers evidence profile**

| <b>INTERVENTIONS FOR FATHERS</b>   |  |  |                                |
|--|--|--|--------------------------------|
| What is the effectiveness of interventions targeted at fathers prior to birth and in the first year of an infant's life for optimal social and emotional development for the infant, child and adolescent? |  |  |                                |
| <b>Comparison</b>  | No specific paternal involvement – usual care/no intervention/brief intervention (i.e. information only) |  |                                |
| <b>Outcome domain</b>  | <b>Outcome measure used in the review(s)</b>   | <b>Results reported in the review(s) and GRADE</b> | <b>Importance<sup>97</sup></b> |

<sup>97</sup> The ratings in this column reflect the MHPWC preliminary assessment of the importance of outcome domains prior to the completion of the overview. They were not reassessed by the MHPWC once the overview was complete, as the MHPWC determined that they did not have sufficient evidence on the effect of interventions for fathers on social and emotional development of the infant, the child and later on as an adolescent to draw a conclusion. Therefore the MHPWC did not undertake the GRADE process for assessing the quality of the overall body of evidence or formulate a Working Committee conclusion.

|   |  |           |
|---|--|-----------|
| <b>Infant social and emotional wellbeing or development up to one year of age</b>   | No pooled results were available.  | CRITICAL  |
| <b>Development for the infant, as a child, and up to 18 years</b>                   | No pooled results were available.  | CRITICAL  |
| <b>Behaviour for the infant, as a child, and up to 18 years</b>                     | No pooled results were available.  | CRITICAL  |
| <b>Physical wellbeing and safety for the infant, as a child, and up to 18 years</b> | No pooled results were available.  | CRITICAL  |
| <b>Parent-infant relationship</b>   | No pooled results were available.  | CRITICAL  |
| <b>Parent/caregiver psychosocial wellbeing</b>                                      | No pooled results were available.  | CRITICAL  |
| <b>Parent/caregiver knowledge, practices and behaviours</b>                         | No pooled results were available.  | CRITICAL  |
| <b>Parent/caregiver views of the intervention</b>                                   | No pooled results were available.  | IMPORTANT |
| <b>Family relationships</b>   | No pooled results were available.  | CRITICAL  |
| <b>Systems outcomes</b>   | No pooled results were available.  | IMPORTANT |
| <b>Evidence statement</b>   | The effects of interventions for fathers on infants' social and emotional development and wellbeing are uncertain. |           |

**Abbreviations:** GRADE: Grading of Recommendations Assessment, Development and Evaluation

## Discussion

### Summary of main results

We included 51 systematic reviews which were grouped into 21 intervention/population categories in this overview.

#### *Summary of the overview*

#### ***Effective intervention/population categories (14 categories)***

Of the 21 intervention/population categories, 14 were identified to be 'effective'.

With **home visiting interventions** no clear difference was seen for infant temperament at four to 16 months (primary outcome domain) (Elkan 2000). Infant cognitive development up to 24 months and intelligence quotient up to 48 months were improved, but no clear differences were seen for motor development up to 18 months, or weight/height up to 48 months (development domain) (Elkan 2000). Sleeping difficulties were reduced with home visiting at six to 12 months (behaviour domain), and there was higher uptake of immunisations at six months to five years, and uptake of acute health care services at nine to 46 months, and reduced unintentional injuries up to 48 months (physical wellbeing and safety domain) (Elkan 2000). The quality of the home environment was improved at six weeks to 36 months (parent-infant relationship domain) with home visiting interventions, though no clear impacts on family size at one to 10 years, mothers' use of public assistance at 12 to 48 months and maternal employment at 12 to 46 months were seen (parent/caregiver knowledge, practices and behaviours domain) (Elkan 2000). Home visiting interventions were shown to increase breastfeeding at three months (parent/caregiver knowledge, practices and behaviours domain) (Elkan 2000), and to reduce substantiated maltreatment at one to 17 years (systems outcomes domain) (Reynolds 2009.)

**Antenatal and postnatal education and/or support interventions** improved children's cognitive development, motor development, social development and mental health post-intervention (15 months) and at follow up (28.6 months later) (development domain) (Pinquart 2010). Infant sleep, but not crying at six and 12 weeks, was improved (behaviour domain) with these interventions (Bryanton 2013), and benefits were also seen for: parenting quality post-intervention (15 months) and at follow up (28.6 months later) (parent-infant relationship domain), parental stress post-intervention (15 months), and parental mental health post-intervention (15 months) and at follow up (28.6 months later) (parent/caregiver psychosocial wellbeing domain); health promoting behaviour post-intervention (15 months) (parent/caregiver knowledge, practices and behaviours domain); couple adjustment post-intervention (15 months) and at follow up (28.6 months later) (family relationships domain); and child maltreatment post-intervention (15 months) (systems outcomes domain) (Pinquart 2010).

**Kangaroo care interventions** were shown to increase weight, length and head circumference at latest follow up (at discharge or 40 weeks' postmenstrual age up to six months of age or six month follow up) (development domain), reduce mortality, severe/infection/sepsis and nosocomial infection/sepsis at discharge or 40 to 41 weeks' postmenstrual age and/or at latest follow up postmenstrual age (physical wellbeing and safety domain), and increase breastfeeding (at discharge or 40 weeks' postmenstrual age, up to three month follow up) (parent/caregiver knowledge, practices and behaviours domain) (Conde-Agudelo 2014).

With **massage interventions**, no clear impact on infant temperament at four weeks to three months was observed (primary outcome domain) however benefits were seen for weight, length and head circumference gains from four weeks to six months, psychomotor development at three to six months, and gross and fine motor development at one to three years (but not cognitive development at three to 24 months, or language development at one to three years) (development domain) (Bennett 2013). Crying or fussing up to 16 weeks, and sleep up to three months were also improved with massage interventions (behaviour domain), though benefits were not seen for maternal sensitivity or infant interactions up to six weeks, mother and child interactions up to 24 months (parent-infant relationship domain), or parenting stress up to two months (parent/caregiver psychosocial wellbeing domain) (Bennett 2013).

**Interventions for preventing postnatal depression** did not have a clear impact on maternal-infant attachment at 24 to 52 weeks postpartum (parent-infant relationship domain), parental stress at 52 weeks postpartum (parent/caregiver psychosocial wellbeing domain), maternal dissatisfaction at zero to eight weeks postpartum (parent view of the intervention domain), marital discord at 24 to 52 weeks postpartum, or perceived social support at 24 to 52 weeks postpartum (family relationships domain); however these interventions were shown to prevent postnatal depression at 12 to 24 weeks postpartum and anxiety at 24 to 52 weeks postpartum (parent/caregiver psychosocial wellbeing domain) (Dennis 2013).

**Interventions for treating maternal depression in the perinatal period** had no clear impact on children's emotional wellbeing, or behaviour and social function up to six months (primary outcome domain), however were shown to improve the quality of parenting behaviours up to six months (parent-infant relationship domain), and parental mental health up to six months (but not at 12 months) (parent/caregiver psychosocial wellbeing domain) (Bee 2014).

**NBAS-based interventions** were shown to increase parenting quality at eight days post-intervention to nine months postpartum (parent-infant relationship domain) (Das Eiden 1996).

**Interventions for enhancing sensitivity and/or attachment security** were shown to improve maternal sensitivity and attachment (Bakermans-Kranenburg 2003), but no clear impact on disorganised infant attachment was observed (Bakermans-Kranenburg 2005) (parent-infant relationship domain).

**Interventions for preventing later antisocial behaviour and delinquency** were shown to reduce child disruptive behaviour (behaviour domain) (Piquero 2008).

**Interventions for parents of infants at risk of developmental delays** were shown to improve overall developmental ability for infants with developmental delays (15 months to 18 years), infants at risk of intellectual disability (18 to 54 months) and preterm infants (three to 60 months) (development domain) (Wallace 2010).

Considering **interventions for preterm and low birthweight infants**, home visiting, parenting skills and/or developmental interventions were shown to improve cognitive development in infancy (from six months to two years) (Goyal 2013; Spittle 2012; Vanderveen 2009), at preschool (three to five years) (Spittle 2012; Vanderveen 2009), but not at school (five to 17 years) (Goyal 2013; Spittle 2012; Vanderveen 2009); motor development was also shown to be improved in infancy (six months to two years) (Spittle 2012; Vanderveen 2009), but not at preschool school (three to five years), and cerebral palsy rates were not improved up to six years (Vanderveen 2009) (development domain). While the home environment was improved with home visiting interventions at eight to 12 months

of age (Goyal 2013), relationship interventions did not clearly impact mother-infant interaction up to three months (Evans 2014) (parent infant relationship domain).

**Interventions for teenage parents** improved parent-child interactions post-intervention (six weeks) and at follow up (three months) (parent-infant relationship domain), though did not clearly impact sense of competence in parenting role at four to seven weeks (parent/caregiver psychosocial wellbeing domain) (Barlow 2011).

**Interventions for parents from low and middle income countries** addressing maternal mental health were shown to improve infant growth and development (development domain), the mother-infant relationship at six to 12 months (parent-infant relationship domain), and reduce maternal depression up to 12 months postpartum (parent/caregiver psychosocial wellbeing domain) (Rahman 2013).

Relationship-based **interventions for low-income/socially disadvantaged parents** were shown to increase supportive parent-child interactions at 1.5 to 30 months (parent-infant relationship domain) (Mortensen 2014).

#### ***Intervention/population categories with insufficient evidence to determine effectiveness (seven categories)***

For seven intervention/population categories there was insufficient evidence available to determine effectiveness.

For two intervention categories an improvement was seen for only one outcome, and the evidence was assessed as being of very low quality. With **day care interventions**, an increase in intelligence (IQ) was observed (development domain) (Zoritch 2000), while with **skin-to-skin care interventions**, an increase in breastfeeding at one to four months post birth was observed (parent/caregiver knowledge, practices and behaviours domain) (Moore 2012).

For one intervention category, no clear improvements were seen. With **interventions for parents with alcohol or drug problems**, no clear improvements were seen for cognitive development or psychomotor delay at 18 to 36 months (development domain), incomplete vaccination and infant death at six months (physical wellbeing and safety domain), continued illicit alcohol or drug use at six to 36 months, failure to enrol to remain in drug treatment program at three to 18 months (parent/caregiver knowledge, practices and behaviours domain), or infants not being in the care of their biological mothers at 12 to 36 months (systems outcomes domain) (Turnbull 2012).

For four intervention/population categories, there were no pooled results: **behavioural sleep interventions; anticipatory guidance interventions; interventions for promoting effective parenting; interventions for fathers.**

#### ***Harms***

No harms were identified within any primary or secondary outcome domain for the 21 intervention/population categories. In this context, harm refers to a significantly poorer outcome in the intervention group relative to the control group. Any harms outside of these domains have not been captured in the overview, though the domains were very broad and most, if not all, harms would have been covered. A small number of poorer outcomes were reported in single studies. However the majority of these were reported alongside other single study reports of positive results

for the same outcomes. Other poorer outcomes, such as greater uptake of services, may reflect increased parental awareness, although this may contribute to greater parental stress.

### ***Summary of the qualitative analysis***

Of the 21 intervention/population categories, 14 were regarded to be 'effective,' and thus we sought to identify the characteristics that may have contributed to the effectiveness of these interventions for optimal social and emotional development of infants.

#### ***Who could deliver the intervention, program or messages to optimise infant social and emotional wellbeing and development?***

There was some indication that professionals were more effective than others (e.g. paraprofessionals/lay persons) for antenatal and postnatal education and/or support interventions, in interventions for enhancing sensitivity and/or attachment security, and for interventions for low income/socially disadvantaged parents.

Long-term improvements with interventions for preventing later antisocial behaviour were seen with combined family support and education programs where home visitor-to-family ratios were generally one to 10 or better.

With kangaroo care interventions, training was usually delivered by nurses and doctors. Commonly nurses and physiotherapists delivered interventions for parents of preterm infants, finding improvements for cognitive development outcomes in particular. Regarding interventions for parents from low and middle income countries, mental health interventions delivered by supervised non-specialists were effective in reducing perinatal mental disorders.

For home visiting interventions, massage interventions, interventions for preventing postnatal depression, interventions for treating maternal depression in the perinatal period, NBAS-based interventions, interventions for parents of infants at risk of developmental delays, and interventions for teenage parents there were no clear relationships between who delivered the intervention and overall success of those interventions.

#### ***Where could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?***

By definition home visiting interventions were delivered in the home; antenatal and postnatal education and/or support interventions, interventions for preventing later antisocial behaviour, and interventions for low income/socially disadvantaged parents, were also mostly delivered in homes.

Neonatal units in hospitals were the usual sites for delivery of kangaroo care interventions. Most interventions for parents of infant 'at risk' were delivered in homes, hospitals, centres in the community and day care centres and sometimes as combinations (e.g. day care centres and homes).

In interventions for preterm and low birthweight infants, a benefit was seen for cognitive development at school age for interventions which commenced in hospital, compared with those that commenced post-discharge.

For massage interventions, interventions for preventing postnatal depression, interventions for treating maternal depression in the perinatal period, NBAS-based interventions, interventions for enhancing sensitivity and/or attachment security, interventions for teenage parents, and

intervention for parents from low and middle income countries there were no clear relationships between where the interventions were delivered and success of those interventions.

***To whom*** could the intervention, program or messages be delivered to optimise infant social and emotional wellbeing and development?

Antenatal and postnatal education and/or support interventions that focused exclusively on mothers had larger effects on parental mental health than interventions with couples. Most home visiting interventions targeted populations with multiple characteristics, often involving different types of disadvantage.

Kangaroo care interventions targeted low birthweight infants. Interventions for treating maternal depression in the perinatal period mostly included women with severe depression during the first year of their child's life.

Interventions to enhance sensitivity and/or attachment security that were implemented in groups with the risk primarily located in the child (e.g. prematurity, irritability, or international adoption), were more effective than those with parents at risk (e.g. maternal depression, maternal attachment insecurity, or poverty, social isolation and single parenthood) in reducing infant disorganised attachment. Study populations including parents referred for medical reasons (e.g. mothers with depression, or anxious-withdrawn children) were found to be more effective than interventions with other groups in enhancing maternal sensitivity; and interventions involving fathers were also shown to be more effective than those without fathers.

In interventions for preventing later antisocial behaviour and delinquency, programs which showed long-term benefits all targeted areas with the highest crime rates (urban, low-income communities).

For massage interventions, interventions for preventing postnatal depression, NBAS-based interventions, interventions for parents of infants at risk of developmental delays, interventions for parents of preterm and low birthweight infants, interventions for teenage parents, and interventions for low income/socially disadvantaged parents, there were no clear relationships between to whom the interventions were delivered and success of those interventions.

***When*** could be the best time for the intervention, program, or message delivery to occur? (In regards to caregiver preferences and accessibility; and in regards to improved outcomes for the infant, child and later on as the adolescent, and for the caregiver)

Antenatal or postnatal education and/or support interventions that started after childbirth were shown to have stronger effects on cognitive development than those that started earlier, and longer interventions were shown on average to have weaker effects on parenting and social development, than those of shorter durations.

In regards to interventions for enhancing sensitivity and/or attachment security, those interventions starting after six months of age for the infant were shown to be more effective than those starting antenatally or at less than six months of age for enhancing maternal sensitivity and infant attachment and preventing disorganising infant attachment. In regards to the number of sessions, interventions with less than five sessions were shown to be as effective as those with between five and 16 sessions for enhancing maternal sensitivity, however, interventions with more than 16 sessions were suggested to be less effective.

In interventions for low income/socially disadvantaged parents, those interventions with shorter durations in regards to total months, and total number of sessions, were shown to be more effective at enhancing supportive parent-child interactions.

Considering interventions for parents of infants at risk of developmental delays most interventions were of long duration and high intensity.

For home visiting interventions, kangaroo care interventions, massage interventions, interventions for preventing postnatal depression, interventions for treating maternal depression in the perinatal period, NBAS-based interventions, interventions for preventing later antisocial behaviour and delinquency, interventions for parents of preterm and low birthweight infants, interventions for teenage parents, and interventions for parents from low and middle income countries there were no clear relationships between when the interventions were delivered and the success of those interventions.

***How*** could the intervention, program or messages regarding infant social and emotional wellbeing and development be delivered?

The types of home visiting interventions spanned advice, counselling, educational modules, problem solving and infant stimulation.

In antenatal and postnatal education and/or support interventions, those that were held in a group format were shown to have greater effects on parental health promoting behaviour than those delivered to an individual/couple, but weaker effects on social development of the child.

With interventions for preventing postnatal depression, a variation in effect based on type of psychosocial intervention delivered was observed, with postpartum professional-based home visits and postpartum lay-based telephone support found to be associated with benefits for depressive symptomatology, while antenatal and postnatal classes, postpartum lay-based home visits, early postpartum follow-up and continuity/model of care were not associated with benefits.

In interventions to enhance maternal sensitivity and/or attachment security, those focused on sensitivity only were more effective than interventions with other focuses (including support only; representation only; and combinations of sensitivity, support and representation) for enhancing maternal sensitivity and infant attachment, and preventing disorganised infant attachment. Interventions with video feedback were shown to be more effective at enhancing maternal sensitivity, but less effective at enhancing infant attachment.

In interventions for low income/socially disadvantaged parents, relationship-based interventions that were 'direct' (providing targeted support to the parent-child dyad, e.g. parent coaching, reinforcement, modelling, video feedback) were shown to be more effective than those that were 'comprehensive' (providing similar parent-child relational guidance, but as one component within a broader intervention, e.g. mental/physical health services for parents and children, parent educational/employment assistance, economic assistance, community source referrals) for increasing supportive parent-child interactions. Parent-child interactions observed within the context of 'free play', compared with 'structured play' were also shown to be more supportive.

For kangaroo care interventions, massage interventions, interventions for treating maternal depression in the perinatal period, NBAS-based interventions, interventions for preventing later antisocial behaviour and delinquency, interventions for parents of infants at risk of developmental delays, interventions for parents of preterm and low birthweight infants, interventions for teenage



parents, and interventions for parents from low and middle income countries, there were no clear relationships between how the interventions were delivered and the success of those interventions.

*How could the intervention, program or messages regarding infant social and emotional wellbeing and development be **framed**?*

Very few reviews reported methods of intervention/program/message framing. For interventions for parents of preterm and low birthweight infants, parents perceived the most effective communication to be when nurses asked questions and encouraged them to ask questions, and when caring and reassuring communication was provided, allowing them to be equal partners in the care of the infant.

*What could **impede** or interfere with engagement with interventions or programs or caregivers enacting upon messages?*

It was discussed that longer antenatal and postnatal education and/or support interventions, may be less effective, possible due to attrition or losing focus on goals.

With interventions for treating maternal depression in the perinatal period, a perceived sense of culpability and a fear of how others may react to their experiences were highlighted as potential barriers to participation by women; the potential for discomfort with group formats was also reported.

In interventions for parents of infants at risk of developmental delays, cultural differences, inconsistent definitions for coaching, and the parental burden of home visits over extended periods were all mentioned as factors that may impede program success.

In interventions for parents of preterm and low birthweight infants, parents perceived communication to be ineffective when the information given was inconsistent, when the staff did not check if parents understood the information and when questions were not allowed.

*What could **facilitate** or drive engagement with interventions or programs or caregivers enacting upon messages?*

In regards to interventions for parents of preterm and low birthweight infants, parents reported feeling supported through individualised development and behavioural care programs, through being taught behavioural assessment scales, and through breastfeeding, kangaroo care and baby massage programs. Parents also felt supported through organised support groups and through provision of an environment where parents could meet and assist each other. Websites enabling individualised information were reported to help communication of complex issues and to humanise the experience of the intensive care. Mothers reported less anxiety with early intensive care discharge accompanied by an individualised discharge plan, followed by home nursing care. Discharge planning in general with education engendered a feeling of overall increased support.

In interventions for treating maternal depression in the perinatal period, factors facilitating engagement that were highlighted included: the importance of establishing an emotionally supportive alliance between parents and staff, such that parents were afforded the freedom to discuss their concerns; a safe and non-judgemental environment for mothers to share their feelings; the importance of approachable and communicative staff, with unbiased and affirming professionals who practically and routinely enquire about mothers' feelings; group interventions for providing a

route for much needed peer support, positive interpersonal relationships, for overcoming stigma and normalising parents' experiences.

It was reported that shorter interventions for low income/socially advantaged parents, may suit such caregivers. Involvement of the family, and providers building trust were appreciated by parents in interventions for parents from low and middle income countries.

## **Overall completeness and applicability of evidence**

There was some overlap in the included studies within the systematic reviews in the overview, however perhaps not as much as we may have expected in some cases. This may indicate a failure of some of the included reviews to identify all relevant studies.

Largely, we maintained the intervention 'categories' as determined by the authors of the included systematic reviews. We recognise however, that many of the resulting 21 intervention/population categories involved complex interventions which could have reasonably appeared within a number of categories. For example, a particular study may have been a home visiting intervention focused on parental education for parents of preterm infants, which could have been included in a number of the relevant intervention/population categories used in the overview.

Although we included over 1,000 relevant studies with more than 260,000 participants across the 51 included reviews, the body of evidence for which quality was assessed in this overview was substantially reduced, due to only half of the included reviews providing quantitatively pooled results. Further, the body of evidence assessed in this overview was restricted as a result of the decision to include only interventions commencing within the first year of life for infants, and due to poor synthesis and/or reporting methods of some reviews. In some cases we did not include reviews (or studies within the reviews) due to the assessed interventions commencing after the first year of life for the infants; at other times, systematic reviews reported insufficient detail to determine the ages of the children in the studies at intervention onset, or did not allow results to be easily separated based on age of children at intervention onset.

The median number of outcome domains across the 21 intervention/population categories with sufficient information (pooled outcomes measure(s) with the quality of evidence assessed using the GRADE system) to allow the development of Evidence Statements was one to two (range: zero to six). The most common outcome domains with reported outcome measures from the included reviews were development, the parent-infant relationship, and parent/caregiver psychosocial wellbeing; aside from the parent/caregiver views of the intervention, systems outcomes and family relationships outcomes domains, our primary outcome domain (infant social and emotional wellbeing or development) was the domain with the least number of outcome measures reported by the included reviews.

For the outcome domains related to the child, we sought to identify relevant outcome measures for the infant, child, and adolescent (up to 18 years of age). Unsurprisingly, outcomes reported were predominantly short-term outcomes and longer-term follow up results were most often not reported by the included systematic reviews; or, when such follow up results were reported, they related to a small proportion of the eligible studies/participants only. Some longer-term outcomes such as antisocial behaviour up to 16 years were reported, but by and large, the included reviews were 'silent' regarding longer-term effects, and thus there is an absence of evidence about the effects of these interventions into the adolescent years. There may be longer-term benefits of interventions supporting parenting practices/behaviours later over the course of infancy, but as this

overview was restricted to interventions that commenced in the first year of life, they will not have been included.

The evidence presented is limited to cases where the intervention commenced before a child turned 12 months of age, meaning it is likely to reflect only a selection of the available evidence on the effects of parenting interventions on children's social and emotional development. However without this requirement, the overview would have been addressing a different, broader question.

Across the included systematic reviews, and indeed across those reviews of interventions identified as 'effective,' detailed descriptions of methodologies and of included study characteristics (such as of participants, interventions and outcomes) were often missing. This therefore limited the ability of the qualitative analysis to identify characteristics that may have contributed to the effectiveness of these interventions for optimal social and emotional development of infants. There were also very few trials comparing two (or more) interventions in the included systematic reviews, and therefore, again, there was limited information available to identify particular characteristics relating to intervention effectiveness.

In the vast majority of included reviews, interventions were assessed with expecting mothers, or mothers of infants; only a minority of reviews included interventions with fathers. Fathers were the focus of one review, however it reported no pooled results and as such was deemed as having insufficient evidence to determine effectiveness. Most interventions were targeted to particular groups of either parents, infants or both. These groups were usually 'high risk' of some kind, though some interventions (such as skin-to-skin care or behavioural sleep interventions) were targeted to healthy or "typically developing" infants only. Some interventions (such as those using NBAS-based approaches) targeted high and low risk groups separately, with benefits seen for both groups. Some interventions were targeted across different types and levels of risk and showed differences in effect, for example, considering interventions for enhancing sensitivity and/or attachment security, interventions implemented in groups with the risk primarily located in the child (e.g. due to prematurity or adoption) were shown to be more effective than those with parents at risk (e.g. due to maternal depression, poverty or single parenthood). A minority of interventions were applied universally (including massage interventions, anticipatory guidance interventions, interventions for preventing postnatal depression, and interventions for promoting effective parenting). Where reported, benefits were seen for both universal and targeted approaches. The body of evidence in this review is considered generalisable to the Australian context, though some interventions such as kangaroo care and massage are not commonly used in Australia.

A small number of the included reviews reported moderator results using robust statistical methods, such as subgroup interaction tests, or regression analyses. Without such test results, it is challenging to determine which characteristics have and have not influenced outcomes. While for many reviews, descriptive data (relating to participant and intervention characteristics) were reported, and allowed summaries to be developed for the 'effective' intervention categories, these data cannot be reliably related to the effect, or lack of effect, of the interventions for particular outcomes.

## **Quality of the evidence**

As described in the Results, approximately one third of included systematic reviews were rated as high quality and low risk of bias (using AMSTAR and ROBIS). Although the two tools differ in their approaches to assessing review quality or risk of bias, they led to similar assessments regarding quality/risk of bias for the included reviews in this overview. Failure to critically appraise component studies and integrate these appraisals into the interpretation of findings were among the most common reasons reviews were judged to be of a lower quality, or at a higher risk of bias.

Using the GRADE system, the quality of the evidence across the outcome domains was assessed, and largely, moderate to very low evidence was found in the included systematic reviews. High quality evidence was rare, and was only found (for mostly one outcome measure) within the outcome domains: development, physical wellbeing and safety, parent/caregiver psychosocial wellbeing, and parent/caregiver knowledge, practices and behaviours. Where included systematic reviews did not assess or report on the study limitations (e.g. risk of bias) of the included studies, we shown these as assumed ratings for the quality of the evidence. Where included systematic review did not report information regarding two or more of the factors necessary to assess the quality of the evidence using the GRADE system (e.g. inconsistency and risk of bias), we have presented the quality of the evidence as unclear.

Neither the AMSTAR nor ROBIS tools proved useful for detecting selective outcome reporting bias within the included systematic reviews. Many of the systematic reviews reported only (or predominately) positive results. While this could be due reasons such as journal space considerations, there is also the possibility that null results (or indeed harms) have been omitted from these reviews; and as such there is the risk that the body of evidence is 'skewed' towards a more optimistic view than may be warranted.

## **Potential biases in the overview process**

This overview developed and adopted rigorous methods with the aim of reducing the impact of bias contributed by the overview process itself.

A major strength of this overview was the comprehensiveness of our searches. However, due to time and resource limitations, we selected or 'prioritised' reviews for inclusion in this overview based on relevance (see 'Differences between protocol and review'). The evidence we have presented is therefore only a selection of the total available evidence (related to all outcome domains). However, we developed and applied criteria to enable us to select reviews for inclusion in a consistent manner based on their focus and content. Further, we systematically assessed the quality of the included reviews using established tools, and all review selection and assessment steps for the overview were performed by two reviewers to maximise consistency of judgement.

We sought to reduce 'double counting' of the evidence where possible, by excluding reviews overlapping substantially in content with other reviews; however some individual studies have contributed evidence to multiple included reviews (and thus intervention/population categories), and this is a possible limitation.

We have only presented (and have only used the GRADE system to assess the quality of the evidence for) pooled results from the included systematic reviews in this overview. Thus, evidence in the Evidence Profiles and Evidence Statements, represents a selection of the total available evidence. We have, however, presented findings from individual studies from the included reviews within Evidence Tables in a Technical Report. We believe that the decisions not to attempt to assess the quality of the evidence for every individual study result (which would have been unmanageable), and not to pool results from these individual studies ourselves, were sensible, given that the authors of the included reviews were in the best position to judge whether it was/was not reasonable to pool results based on clinical heterogeneity, and/or other reasons. Including only pooled results has likely had minimal impact on the findings of the overview.

## **Agreements and disagreements with other studies or reviews**

A handful of overviews of systematic reviews in this general area have been published; we located one that is comparable, although only conducted narrative pooling of results from the 52 included reviews (Stewart-Brown 2010). Thirteen of the included reviews in Stewart-Brown 2010 were also included in our overview – many of the reviews included in the overview have been superseded by later versions (e.g. Cochrane systematic review updates), and a number of other reviews which we have not included did not report on interventions which commenced in the first year of life for infants. For example, a systematic review on media-based parenting programs (Montgomery 2006) which was included in Stewart-Brown 2010 was classified as relevant, but then not included in our overview due to none of the component studies reporting on interventions commencing before or in the first 12 months of an infant's life.

Some findings of Stewart-Brown 2010 were consistent in direction with our findings, such as the beneficial effects of home visiting. However Stewart-Brown 2010 reported antenatal education interventions to be less effective than was found in this overview, likely due to more recent material able to be included in our overview. Conversely, Stewart-Brown 2010 found some benefits from interventions for parents with alcohol or drug problems whereas our overview did not show clear benefits of these interventions, which could be related to our overview only including interventions commencing within the first year of life for infants, or due to our overview results and conclusions being based on quantitatively pooled results only. New evidence from updated Cochrane reviews on kangaroo care and skin-to-skin care caused some differences in the evidence base between this overview and Stewart-Brown 2010. However both overviews showed some benefits for kangaroo care and skin-to-skin care interventions.

## **Authors' conclusions**

### **Implications for practice**

Fourteen intervention categories (or interventions for particular populations) were identified as effective in this overview, with effectiveness related to improvements seen in one or more of the outcome domains associated with improved social and emotional development of the infant, child and later on as the adolescent.

Home visiting interventions showed improvements for outcome measures across the following domains: development, behaviour, physical wellbeing and safety, parent-infant relationship, parent/caregiver knowledge, practices and behaviours, and systems outcomes. Antenatal and postnatal education and/or support interventions were also associated with improvements for outcome measures across a number of domains including: development, behaviour, parent-infant relationship, parent/caregiver psychosocial wellbeing, parent/caregiver knowledge, practices and behaviours, family relationships, and systems outcomes.

Kangaroo care interventions led to improvements for outcome measures in the development, physical wellbeing and safety, and parent/caregiver knowledge practices and behaviours domains, while massage interventions showed improvements for outcome measures in the development and behaviour domains. While interventions for parents of infants at risk of developmental delays only showed benefits for outcome measures in the development domain, interventions for preterm and low birthweight infants showed benefits for outcome measures in both the development and the parent-infant relationship domains. Interventions for parents from low and middle income countries showed improvements for outcomes measures in the development, parent-infant relationship and parent/caregiver psychosocial wellbeing domains.

Interventions for preventing postnatal depression led to clear improvements only in the parent/caregiver psychosocial wellbeing domain, while interventions for treating maternal depression in the perinatal period showed benefits for outcomes measures across the parent-infant relationship and parent/caregiver psychosocial wellbeing domains.

NBAS-based interventions, interventions for enhancing sensitivity and/or attachment security, interventions for teenage parents, and interventions for low/income socially disadvantaged parents showed improvements only for outcomes measures in the parent-infant relationship domain. Interventions for preventing later antisocial behaviour and delinquency led to improvements for outcome measures only in the behaviour domain.

Interventions where there was insufficient evidence available to determine effectiveness (according to the criteria for effectiveness in this overview), were: day care intervention, skin-to-skin care interventions, interventions for parents with alcohol or drug problems, behavioural sleep interventions, anticipatory guidance interventions, interventions for promoting effective parenting, and interventions for fathers.

The body of evidence in this review is considered generalisable to the Australian context. Most interventions were targeted to high risk groups with very few adopting a universal approach. From the qualitative analysis, very few conclusions could be drawn regarding the specific characteristics that contribute to the effectiveness of the above mentioned interventions for optimal social and emotional development of infants. There was some indication that interventions delivered by professionals may be more effective than those delivered by others (paraprofessionals/lay persons), that targeting children's risk factors (i.e. prematurity) may be more effective than targeting parental risk factors (e.g. maternal depression or single parenthood), that antenatal commencement may not be necessary (or beneficial) for some interventions, and that interventions that are more direct or with a restricted focus may be more beneficial than those which are more comprehensive, or have multiple foci.

## **Implications for research**

The quality of included systematic reviews was less than optimal and many reviews were unable to be included in this overview due to poor reporting. The ability to use evidence from reviews would be enhanced by adequate reporting of characteristics (e.g. ages of children at intervention onset) and through the conduct and reporting of rigorous risk of bias assessments in the reviews. Use of review formats and guidelines, similar to those of the Cochrane Collaboration, may help to ensure better conduct and reporting.

There is a need to standardise outcomes and their definitions for assessing infant social and emotional wellbeing and development, along with a need for agreement on which are the preferred scales/tools to measure specific outcomes.

Larger primary studies, including 'head-to-head' comparisons such as of home visiting interventions, and/or of antenatal or postnatal education and/or support interventions may be warranted. Infants in any future studies should be followed up into childhood and adolescence to assess longer-term intervention benefits and/or harms. Further investment is required in areas including the involvement of fathers in early parenting interventions.

Additional research is required to determine the specific characteristics that contribute to the effectiveness of interventions for optimal social and emotional development of infants. Ideally,

studies to determine how interventions/programs/messages should be framed, along with those assessing factors impeding or facilitating parent/caregiver engagement with interventions should be embedded within future intervention studies. To determine characteristics such as who should deliver these interventions, where, when, how and to whom, intervention studies (and reviews) should where possible, consider the conduct of subgroup or regression analyses considering these factors; large, well-designed qualitative studies to determine these characteristics are also required.

## Differences between protocol and review

**Question One:** Criteria for considering reviews for inclusion: The original proposed criteria for 'Types of reviews' indicated that only reviews meeting all components of the quoted Cochrane Collaboration's definition would be included. So as to not limit the evidence available for review, this was revised to include those reviews that were identified to be (or identified as) systematic reviews but did not satisfy all components of the definition, acknowledging that relevant information regarding review limitations would be captured in the assessment of review quality (using both AMSTAR and ROBIS).

**Question One:** Prioritisation of reviews: The original approach to Question One, to include in the overview all systematic reviews reporting results relevant to any of the pre-specified primary or secondary outcome domains, was revised in light of the higher than anticipated number of relevant reviews identified, in the context of resource and time limitations. A prioritisation process was determined to ensure that the included reviews were those what would yield the most relevant information (this approach was approved by the Office of the NHMRC on 18 November 2014). The approach was to firstly prioritise those reviews meeting the inclusion criteria and reporting the primary outcome, then to cascade to reviews reporting one or more secondary outcomes. Reviews reporting only maternal secondary outcomes (and no infant or child outcomes), not clearly reporting the ages of the children, or substantially overlapping in content with another more comprehensive or recent review, were given a lower priority.

**Question One:** Search method for identification of reviews: The original proposed search strategy for Question One included searching of the following databases: Cochrane Central Register of Controlled Trials (CENTRAL); Applied Social Sciences Index and Abstracts Database (ASSIA); Trials Register of Promoting Health Interventions (TRoPHI); and Current Educational Research in the United Kingdom (CERUK). This was revised, and these four databases were not searched, due to being identified as databases for locating trials (not reviews) (CENTRAL; TRoPHI) and due to an inability to access (ASSIA; CERUK). The original search strategy also proposed examining forward citations of articles and the contents of key journals, searching Google Scholar and the websites of key organisations and government agencies, as well as relevant child development research centres/institutes, and making contact with those in the field. This was revised (and those searches not conducted), in light of the higher than anticipated number of relevant reviews identified through database searching, in the context of resource and time limitations.

**Question One:** Pooled results: The original approach to Question One, to assess the quality of the evidence for all results from the included systematic reviews (including from single studies) was revised in light of the large number of single study results reported by the included systematic reviews, and recognition that presentation of these results in the Evidence Profiles would not prove useful for decision-making. Thus only the quality of the evidence from pooled results from the systematic reviews has been assessed using the GRADE system and primary studies whose results were not pooled, but which reported evidence of effectiveness have been excluded from the Evidence Evaluation Report (but are available in the Technical Report). This approach was approved by the Office of the NHMRC on 6 May 2015.

**Question One:** Quality of the evidence: In applying the GRADE system to assess the quality of the evidence for Question One in the overview, a system was developed to ensure consistent and transparent use in cases where there was no information available from the systematic reviews to assess one or more of the five features required to determine the quality of the evidence for each outcome. This approach was not clearly articulated in the original protocol approved by the Office of NHMRC on 24 October 2014.



**Question Two: Approach:** The original approach to Question Two was revised in light of the findings from the overview, in which we determined that the originally planned systematic review to address Question Two (protocol approved by the Office of NHMRC on 24 October 2014), would no longer yield enough useful information to complement the overview. This change also accounted for the longer than anticipated time it took to complete the overview by reducing the time required to complete the qualitative analysis. The revised methodologies for the qualitative analysis for Question Two were approved by the Office of the NHMRC on 9 September 2015.

The original approach to Question Two specified that where limited useful information for addressing question two and sub-questions was able to be obtained from the included systematic reviews for a particular 'effective' intervention category we would identify and extract useful narrative information from the primary studies, and if still insufficient, from the 'Relevant but excluded' or 'Excluded' reviews. This was revised to extracting qualitative information only from the systematic reviews identified as addressing 'effective' interventions which contributed pooled results, as we deemed that documenting modifiers of effectiveness needed to be based on the data from 'effective' interventions as described in this report.

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