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Parent-Infant Psychotherapy for Improving Parental and Infant Mental Health: Protocol for a Systematic Review

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PROTOCOL



THE CAMPBELL COLLABORATION

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1 Background

1.1 DESCRIPTION OF THE CONDITION

The Copenhagen Child Cohort Study (n = 6090) found a population prevalence of mental health disorders (for example, emotional and behavioural, eating and sleeping disorders) in children aged 1.5 years to be in the region of 18% ([Skovgaard 2008](#); [Skovgaard 2010](#)). Infant regulatory disturbances such as excessive crying, feeding or sleeping difficulties and bonding/attachment problems represent the main reasons for referral to infant mental health clinics ([Keren 2001](#)).

Problems of this nature are significant predictors of longer-term difficulties. For example, infant regulatory problems have a strong association with delays in motor, language and cognitive development, and continuing parent-child relational problems ([DeGangi 2000a](#); [DeGangi 2000b](#)). In one study, 49.9% of infants and toddlers (aged 12 to 40 months) showed a continuity of emotional and behavioural problems one year after initial presentation ([Briggs-Gowan 2006](#)). Another study showed an association between difficult temperament, non-compliance and aggression in infancy and toddlerhood (age one to three years) with internalising and externalising psychiatric disorders at five years of age ([Keenan 1998](#)). Similarly, insecure and disorganised attachment in infancy is associated with poorer outcomes in later childhood across a range of domains such as emotional, social and behavioural adjustment, scholastic achievement and peer-rated social status ([Granot 2001](#); [Sroufe 2005a](#); [Sroufe 2005b](#); [Berlin 2008](#)), particularly in the case of disorganised attachment, which is a predictor of significant later psychopathology ([Green 2002](#)).

Recent research has begun to show that infant regulatory and attachment problems can best be understood in a relational context. Significant risk factors for emotional, behavioural, eating and sleeping disorders are disturbances in the parent-child relationship and parental psychosocial adversity ([Skovgaard 2008](#); [Skovgaard 2010](#)). Early research in the field of infant mental health and developmental psychology highlighted the significant role that the infant's primary caregiver plays in regulating the

infant ([Beebe 1988](#); [Tronick 1989](#); [Sroufe 1997](#); [Tronick 1997](#)), and more recently, the way in which this process is influenced by the parents' own capacity for self-regulation ([Beebe 2010](#); [Beeghly 2011](#)).

Research focusing on the factors that influence the parent-infant interaction has derived mostly from the field of developmental psychology and, in particular, infant attachment research. This rapidly developing body of literature has found only modest correlations between 'maternal sensitivity' and infant attachment security ([De Wolff 1997](#)), prompting a search for more specific predictive factors. Recent research has focused on:

1. the specific nature or quality of the attunement or contingency between parent and infant ([Beebe 2010](#)); and
2. the parent's capacity for what has been termed 'maternal mind-mindedness' ([Meins 2001](#)) or 'reflective function' ([Slade 2001](#)).

Parental reflective function refers to the parent's capacity to understand the infant's behaviour in terms of internal feeling states. Research shows that reflective function is strongly associated with maternal parenting behaviours such as flexibility and responsiveness and that low maternal reflective function is associated with emotionally unresponsive maternal behaviours (withdrawal, hostility, intrusiveness). ([Slade 2001](#); [Slade 2005](#); [Grienenberger 2005](#)). Maternal reflective function is also associated with beneficial infant outcomes, such as greater use of mother as a secure base ([Grienenberger 2005](#)). Research also shows a significant association between parental 'mind-mindedness' (the parent's capacity to accurately interpret what their child is thinking and feeling) and later development including attachment security at 12 months ([Meins 2001](#)).

Recent research has also highlighted a number of 'atypical' parenting behaviours that can occur during the postnatal period, including affective communication errors (for example, mother positive while infant distressed), disorientation (frightened expression or sudden complete loss of affect) and negative-intrusive behaviours (mocking or pulling infant's body) ([Lyons-Ruth 2005](#)). A meta-analysis of 12 studies found a strong association between disorganised attachment at 12 to 18 months and parenting behaviours characterised as 'anomalous' (that is, frightening, threatening, looming), dissociative (haunted voice, deferential/timid) or disrupted (failure to repair, lack of response, insensitive/communication error) ([Madigan 2006](#)). These atypical parenting practices were identified in parents described as 'unresolved' with regard to previous trauma ([Jacobvitz 1997](#); [Cicchetti 2006](#); [Cicchetti 2010](#)). However, disturbances to the mother-infant relationship are common and are associated with a range of maternal problems including postnatal depression ([Murray 2003](#); [Toth 2006](#); [Timmer 2011](#)), personality disorder ([Crandell 2003](#); [Pawlby 2005](#); [Newman 2008](#); [Pawlby 2010](#)),

psychotic disorders ([Chaffin 1996](#)), substance misuse ([Suchman 2005](#); [Tronick 2005](#)) and domestic violence ([Lyons-Ruth 2003](#); [Lyons-Ruth 2005](#)).

1.2 DESCRIPTION OF THE INTERVENTION

Over the past two decades, a range of interventions have been developed to address developmental problems in the infant, and problems in the parent-infant relationship, with a view to promoting optimal infant development. Parent-infant psychotherapy is rooted in findings from developmental and clinical research, and involves a parent-infant psychotherapist working directly with individual parent-infant dyads (or triads if two parents are involved) in the home, clinic or hospital setting, to address a wide range of problems that can arise during the antenatal and postnatal periods. Parent-infant psychotherapy comprises a theoretically guided dyadic intervention (that is, delivered concurrently to the parent and infant) that focuses on improving infant attachment security by targeting parental internal working models. The approach is essentially psychodynamic in that it involves identifying unconscious patterns of relating and seeing the parent-infant relationship itself as the focus of the intervention.

The earliest approach, developed by Selma Fraiberg ([Fraiberg 1980](#)) focused primarily on the mother's 'representational' world ('representation-focused' approach) or the way in which the mother's current view of her infant is affected by interfering representations from her own history, the aim of therapy being to help the mother to recognise the 'ghosts in the nursery' (that is, the unremembered influences from her own past) and to link them to her current functioning, thereby facilitating new paths for growth and development for both mother and infant ([Cramer 1988](#)). Fraiberg's model has been further developed and evaluated by others (for example, [Lieberman 1991](#); [Toth 2006](#)), and, more recently, representational and behavioural approaches have been combined ([Cohen 1999](#)). For example, 'Watch, Wait and Wonder' is an 'infant-led' parent-infant psychotherapy that involves the mother spending time observing her infant's self-initiated activity, accepting the infant's spontaneous and undirected behaviour, and being physically accessible to the infant (behavioural component). The mother then discusses her experiences of the infant-led play with the therapist with a view to examining the mother's internal working models of herself in relation to her infant (representational component) ([Cohen 1999](#)). Parent-infant psychotherapy may also work with the father, or with both parents together. The duration of delivery of the intervention depends on the presenting problems but typically ranges from 5 to 20 weeks, usually involving weekly sessions. Parents may be referred to this service by a clinician (for example, GP or health visitor in the UK) or may self-refer to privately run services. Parent-infant psychotherapy services typically target infants less than two

years of age at the time of referral. This reflects the importance of the first two years of life in terms of children's later development (as described above).

1.3 HOW THE INTERVENTION MIGHT WORK

The logic model underpinning representational forms of parent-infant psychotherapy is that changes to the mother's representations (internal working models) will improve the mother's sensitivity and behaviour towards her infant (for example, [Lieberman 1991](#)) and make it more possible for her to see the infant as someone with a 'mind of their own'. Maternal sensitivity is strongly associated with more optimal parent-infant interaction, which is in turn associated with infant attachment security ([De Wolff 1997](#)). Secure attachment is associated with resilience and optimal social functioning ([Lecce 2008](#)), while both insecure (for example, [Granot 2001](#); [Sroufe 2005a](#); [Sroufe 2005b](#); [Berlin 2008](#)) and disorganised attachment ([Green 2002](#)) are associated with a range of compromised outcomes. The addition of behavioural components provides opportunities for parent and infant to interact, which then become the focus of exploratory discussions between therapist and parent, aimed once again at changing maternal representations about the infant ([Cohen 1999](#)). The empathic relationship between the therapist and parent plays a key role in helping parents to revise their internal working

1.4 WHY IT IS IMPORTANT TO DO THIS REVIEW

Parent-infant interaction is a significant factor in infant mental health (for example, [Fonagy 2002a](#)), and problems with the parent-infant relationship are common ([Keren 2001](#)). Government policy is increasingly emphasising the importance of early intervention and the need to develop evidence-based models that can support vulnerable parents and their children, and this reflects an increased recognition at a policy level that both health and social inequalities have their origins in early parent-infant interaction ([Field 2010](#)), and that the social gradient in children's access to positive early experiences needs to be addressed ([Marmot 2010](#)).

There is a growing body of evidence pointing to the effectiveness of parent-infant psychotherapy in terms of improving both parental functioning ([Cohen 1999](#); [Cohen 2002](#)) and fostering secure attachment relationships in young children ([Toth 2006](#)), and some evidence to suggest that different forms of

the therapy may be differentially effective for parents with different types of attachment insecurity ([Bakermans-Kranenburg 1998](#)).

However, there has to date been only one 'thematic' summary of the evidence about the effectiveness of parent-infant psychotherapy ([Kennedy 2007](#)), which did not involve a systematic search for evidence. As such, there is an urgent need for a systematic review to identify whether this unique method of working has benefits for parents and infants, and whether the outcome is affected by duration or the use of additional components, so as to inform and improve the delivery of early intervention programmes.

2. Objectives of the review

- 1. To assess the effectiveness of parent-infant psychotherapy in improving parental and infant mental health and the parent-infant relationship.**
- 2. To identify the programme components that appear to be associated with more effective outcomes and factors that modify intervention effectiveness (for example, programme duration, programme focus).**

3 Methods

3.1 CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

3.1.1 Types of studies

We will include randomised controlled trials (RCTs) and quasi-randomised controlled trials in which participants have been randomly allocated to an experimental or a control group, the latter being a waiting-list, no treatment, treatment as usual (normal service provision) or a placebo control group. Quasi-randomised controlled trials are defined as trials where allocation was done on the basis of a pseudo-random sequence, for example, odd or even hospital number, date of birth or alternation ([Higgins 2011](#)). We will also include studies comparing two different therapeutic modalities (that is, without a control group).

3.1.2 Types of participants

Parent-infant dyads in which the parent is experiencing mental health problems, domestic violence, substance misuse or child abuse, and/or the infant is showing signs of attachment and/or dysregulation problems. We will include all infants irrespective of the presence of problems such as low birthweight, prematurity or disabilities. We will include studies targeting infants and toddlers and in which the maximum age of the infant is 24 months or less at the point of referral.

3.1.3 Types of interventions

Parent-infant psychotherapy programmes in which the intervention meets all of the following criteria:

- underpinned by a psychodynamic model, that is, which involves making unconscious patterns of relating conscious by targeting parental internal working models or object relations;
- delivered jointly to both parent and infant/toddler and aimed primarily at improving infant socioemotional functioning via the parent-infant relationship/interaction;

- delivered by a parent-infant psychotherapist/specialist on a dyadic basis in any setting (clinic, hospital or home) over any period of time.

3.1.4 Types of outcome measures

Primary outcomes

The following primary outcomes will be extracted provided that they have been measured using a standardised (parent-report or independent observation) measure of the type listed as examples for each outcome.

Timing of outcome assessments will include immediately post-intervention and 6-, 12- and 24-month follow-up time points, and all of the outcome data will be presented in a 'Summary of findings' table.

Parent outcomes

- Parental mental health; for example, depression (for example, Beck Depression Inventory (BDI) ([Beck 1961](#)); anxiety (for example, Beck Anxiety Inventory (BAI) ([Beck 1988](#)); parenting stress (for example, Parenting Stress Index (PSI) ([Abidin 1983](#))).

Parent-infant relationship outcomes

- Parent-infant interaction; for example, CARE-Index ([Crittenden 2001](#)), Emotional Availability Scales (EAS) ([Biringen 1993](#)), Parent-Child Early Relational Assessment (ERA) ([Clark 1985](#)), Dyadic Parent-Child Interaction Coding System (DPICS) ([Robinson 1981](#)), Nursing Child Assessment of Feeding Scale (NCAFS) ([Barnard 1978](#)) or the Nursing Child Assessment Teaching Scale (NCATS) ([Barnard 1978a](#)).

Infant outcomes

- Infant emotional well-being, including infant attachment security; for example, Strange Situation Procedure (SSP) ([Ainsworth 1971](#)), Preschool Measure of Attachment ([Crittenden 1992](#)) and other measures of emotional and behavioural adjustment (for example, Infant and Toddler Social and Emotional Adjustment Scale - ITSEA ([Carter 2000](#)), Eyberg Child Behaviour Inventory (ECBI) ([Eyberg 1978](#)), the Behaviour Screening Questionnaire (BSQ) ([Richman 1971](#)), the Child Behaviour Questionnaire (CBQ) ([Rutter 1970](#))).

Adverse outcomes

- Any adverse effects of interventions will be included as an outcome including a worsening of outcome on any of the included measures.

Secondary outcomes

Parent outcomes

- Parental reflective function; for example Parent Development Interview - PDI ([Slade 2004](#)).
- Parental sensitivity; for example, Maternal Sensitivity Scale ([Ainsworth 1974](#)), Atypical Maternal Behavior Instrument for Assessment and Classification (AMBIANCE) (assesses the degree of anomalous maternal behaviours towards infants which are linked with disorganised attachment in infancy) ([Bronfman 1999](#)), Frightened/Frightening (FR) Coding System Frightened/Frightening (FR) Coding System ([Main 1992](#)).

Infant outcomes

- Infant stress; for example, salivary or urinary cortisol measured in standardised units such as µg/dl or ng per ml.
- Infant development, including social, emotional, cognitive and motor development; for example, Bayley Scales ([Bayley 1969](#)).

3.2 SEARCH METHODS FOR IDENTIFICATION OF STUDIES

3.2.1 Electronic searches

No language or date restrictions will be used and RCT filters will be applied where appropriate. The search terms below will be used across the following electronic databases.

- Cochrane Central Register of Controlled Trials (CENTRAL), part of the Cochrane Library
- Ovid MEDLINE
- Embase
- CINAHL
- BIOSIS
- PsycINFO
- Sociological Abstracts
- Social Sciences Citation Index
- ERIC
- *meta*Register of Controlled Trials

1 psychotherapy/ or exp psychoanalytic therapy/ or exp psychotherapeutic processes/ or psychotherapy, brief/ or psychotherapy, multiple/ or psychotherapy, rational-emotive/ or exp socioenvironmental therapy/

2 Psychoanalytic Interpretation/

3 (psychotherap\$ or psycho-therap\$ or psychoanalytic\$ or psycho-analytic\$ or psychodynamic\$ or psycho-dynamic\$).tw.

4 Family Therapy/

5 or/1-4

6 exp maternal behavior/ or parent-child relations/ or father-child relations/
or mother-child relations/ or parenting/ or paternal behavior/

7 Mothers/px or Fathers/px or Parents/px

8 Object Attachment/

9 Reactive Attachment Disorder/

10 ((attachment adj3 disorder\$) or (insecure adj3 attachment\$) or (secure
adj3 attachment\$) or (dysregulation adj3 disorder\$)).tw.

11 ((parent\$ or mother\$ or maternal\$ or father\$ or paternal\$ or infant\$ or
child\$) adj3 (attachment\$ or bond\$ or interaction\$ or relationship\$ or
dyad\$ or triad\$)).tw.

12 or/6-11

13 exp infant/

14 infant behavior/

15 (baby or babies or infant\$ or child\$ or toddler\$).tw.

16 or/13-15

17 5 and 12 and 16

18 (parent\$ adj3 (baby or babies or infant\$ or child\$ or toddler\$) adj3
(psychother\$ or psycho-therap\$ or psychodynamic\$ or psycho-
dynamic\$)).tw.

19 (mother\$ adj3 (baby or babies or infant\$ or child\$ or toddler\$) adj3
(psychother\$ or psycho-therap\$ or psychodynamic\$ or psycho-
dynamic\$)).tw.

20 (maternal\$ adj3 (baby or babies or infant\$ or child\$ or toddler\$) adj3
(psychother\$ or psycho-therap\$ or psychodynamic\$ or psycho-
dynamic\$)).tw.

21 (father\$ adj3 (baby or babies or infant\$ or child\$ or toddler\$) adj3
(psychother\$ or psycho-therap\$ or psychodynamic\$ or psycho-
dynamic\$)).tw.

22 (paternal\$ adj3 (baby or babies or infant\$ or child\$ or toddler\$) adj3
(psychother\$ or psycho-therap\$ or psychodynamic\$ or psycho-
dynamic\$)).tw.

23 (parent\$ adj3 (baby or babies or infant\$ or child\$ or toddler\$) adj3
(psychoanalytic\$ or psycho-analytic\$ or psychodynamic\$ or psycho-
dynamic\$)).tw.

24 (mother\$ adj3 (baby or babies or infant\$ or child\$ or toddler\$) adj3
(psychoanalytic\$ or psycho-analytic\$ or psychodynamic\$ or psycho-
dynamic\$)).tw.

25 (maternal\$ adj3 (baby or babies or infant\$ or child\$ or toddler\$) adj3
(psychoanalytic\$ or psycho-analytic\$ or psychodynamic\$ or psycho-
dynamic\$)).tw.

26 (father\$ adj3 (baby or babies or infant\$ or child\$ or toddler\$) adj3
(psychoanalytic\$ or psycho-analytic\$ or psychodynamic\$ or psycho-
dynamic\$)).tw.

27 (paternal\$ adj3 (baby or babies or infant\$ or child\$ or toddler\$) adj3 (psychoanalytic\$ or psycho-analytic\$ or psychodynamic\$ or psychodynamic\$)).tw.

28 or/18-27

29 17 or 28

3.2.2 Searching other resources

- Contact with authors and experts in the field to identify unpublished studies
- Reference lists of articles identified through database searches will be examined for further relevant studies. We will also examine bibliographies of systematic and non-systematic review articles to identify relevant studies

3.3 DATA COLLECTION AND ANALYSIS

3.3.1 Selection of studies

Titles and abstracts of studies identified through searches of electronic databases will be screened by two authors (CB and JB) to determine whether they meet the inclusion criteria. Two authors (CB and JB) will independently assess full copies of papers that appear to meet the inclusion criteria. We will resolve any uncertainties by discussion with the third author (NM).

3.3.2 Data extraction and management

Two review authors will extract data independently (CB and JB) using a data extraction form and enter the data into Review Manager 5 ([Review Manager](#)) software. Where data are not available in the published trial reports, we will contact study investigators to supply missing information. Data to be extracted include: study design; participant characteristics; primary and secondary outcome measures; intervention design; primary and secondary outcome data.

3.3.3 Assessment of risk of bias in included studies

Risk of bias assessments will be carried out by CB and JB, using the Cochrane 'Risk of bias' assessment tool ([Higgins 2011](#)). We will resolve differences by consultation with the third review author (NM).

Risk of bias will be assessed for each trial in the following areas: sequence generation, allocation concealment, blinding of participants, personnel and outcome assessors, incomplete outcome data and whether there was any assessment of the distribution of confounders. Where there is insufficient information in the trial report to make a judgement, we will contact trial investigators for further information.

All domains will be assessed as at low, high or unclear (uncertain) risk of bias.

Sequence generation

The method used to generate the allocation sequence will be assessed to determine if it produced comparable groups.

Allocation concealment

We will assess the method used to conceal allocation sequence to see whether it was adequate in terms of whether the intervention schedules could have been foreseen in advance of, or during, recruitment.

Blinding

An assessment will be made as to whether any steps were taken to blind participants, personnel and outcome assessors to which intervention a given participant might have received.

Incomplete outcome data

Where studies do not report intention-to-treat analyses, attempts will be made to obtain missing data by contacting the study authors. We will assess whether incomplete data was dealt with adequately by the study investigators, and how data on attrition and exclusions were reported, compared with the total randomised.

Selective outcome reporting

We will assess whether any attempt had been made to reduce the possibility of selective outcome reporting by investigators.

Other sources of bias

We will assess whether the study was apparently free of other problems that could put it at a high risk of bias (for example, contamination).

We will examine baseline or pre-treatment means if available, to determine if any imbalance exists in those participant characteristics that are strongly related to outcome measures, as imbalance can cause bias in intervention effect estimates ([Higgins 2011](#), Chapter 8.14.1.2).

3.3. 4 Measures of treatment effect

Dichotomous outcome data

For dichotomous endpoint measures, we will present the number of parents or infants who show an improvement as a proportion of the total number of parents/infants treated. Risk ratios will be calculated and presented with 95% confidence intervals and standard deviations.

Continuous outcome data

For the meta-analyses of continuous outcomes, mean differences (MDs) between groups will be estimated. In the case of continuous outcome measures where data are reported on different scales, data will be analysed using the standardised mean difference (SMD). We will present the SMDs, calculated by dividing the mean difference in post-intervention scores between the intervention and control groups by the standard deviation of outcome among participants with 95% confidence intervals for individual outcomes in individual studies.

Where the above data are not available, we will present significance levels reported in the paper.

3.3.5 Unit of analysis issues

The randomisation of clusters can result in an overestimate of the precision of the results (with a higher risk of a Type I error) where their use has not been compensated for in the analysis. In the unlikely event that we include a cluster RCT, the impact of the inclusion of data from such a study in the meta-analyses will be explored using a sensitivity analysis and any necessary adjustments to the data will be made, using available estimates of ICC. We are unlikely to identify cross-over studies as the effects of therapy are intended to be long term so cross-over from a therapy arm to no-treatment arm would not be feasible.

For studies where there was more than one active intervention and only one control group, we will select the intervention that most closely matches our inclusion criteria and will exclude the others (see [Higgins 2011](#), Chapter 16.5.4).

3.3.6 Dealing with missing data

Missing data and attrition will be assessed for each included study and reported in the 'Risk of bias' tables. Where appropriate, authors will be contacted to supply data missing from included studies. In the event that

missing data cannot be provided, we will report and calculate the available data only (that is, no imputation will be used).

3.3.7 Assessment of heterogeneity

We will assess clinical heterogeneity by considering the extent of between-trial differences including methods, populations, interventions or outcomes. We will assess statistical heterogeneity using the I^2 statistic. The importance of the observed value of I^2 is dependent on the magnitude and direction of effects and strength of evidence for heterogeneity (for example, P value from the Chi^2 test, or a confidence interval for I^2) ([Higgins 2002](#)), and we will interpret $I^2 > 50\%$ as evidence of substantial heterogeneity.

We will perform a Chi^2 test of heterogeneity and a significance level less than 0.10 will be interpreted as evidence of heterogeneity.

3.3.8 Assessment of reporting biases

Funnel plots (estimated differences in treatment effects against their standard error) will be drawn if there are a sufficient number of included studies (more than 10), to identify asymmetry due to publication bias.

3.4 DATA SYNTHESIS

3.4.1 Data synthesis

We will use meta-analyses to combine comparable outcome measures across studies. Meta-analysis will be undertaken where there is sufficient clinical homogeneity in the intervention delivered, the characteristics of the study participants (such as age or the definition of 'at risk' participants including mental health problems, domestic violence, substance misusers) and the use of similar outcome measures.

We will only combine studies if the between-study differences are minor (for example, we would combine trials treating mother and infant or family group and infant; we would combine studies that used different outcome measures of, for example, depression or parent-infant interaction). While we will attempt to combine data where at all possible, there may be some circumstances where it is not possible; for example, some primary studies may report an outcome as a dichotomous measure and others use a continuous measure of the same construct (this may occur for the outcome depression if some studies measure numbers of participants experiencing a

depressive episode while others measure scores from the Beck Depression inventory). In cases like this, we will carry out two separate analyses. For single outcomes, we will present the individual effect sizes and 95% confidence intervals.

For meta-analyses that combine comparable outcome measures across studies, we will initially employ both fixed- and random-effect models, to assess the impact of statistical heterogeneity. We plan to present the only the results from the random-effects model, unless the model is contraindicated; for example, by severe funnel plot asymmetry. In the event of severe funnel plot asymmetry, we will present both fixed-effect and random-effects analyses, under the assumption that asymmetry suggests that neither model is appropriate. In the event that the analyses do not agree, we will report this. We will calculate overall effects using inverse variance methods.

All analyses will include all participants in the treatment groups to which they were allocated, whenever possible.

3.4.2 Subgroup analysis, moderator analysis and investigation of heterogeneity

We will explore possible reasons for heterogeneity by scrutinising the studies to determine the extent of between-trial differences (for example, age of infant; presenting problems; programme duration, programme focus) and, where appropriate, by performing subgroup analyses.

Subgroup analysis will be conducted to explore the programme components that appear to be associated with more effective outcomes, and factors that modify intervention effectiveness. These analyses will be exploratory as they may involve non-experimental (cross-study) comparisons and we will treat any conclusions with caution.

3.4.3 Sensitivity analysis

Sensitivity analyses will be conducted to test if the findings of the meta-analyses are robust to the decisions made in the process of this review. We will re-analyse the data excluding studies on the basis of design (for example, removing quasi-RCTs) and risk of bias.

4 Acknowledgments

We acknowledge the support of the Cochrane Developmental, Psychosocial and Learning Problems Group in developing this review protocol.

This review is coregistered with the Cochrane Developmental, Psychosocial and Learning Problems Group, and also appears on *The Cochrane Library*.

5 Contribution of authors

JB secured funding for the review and is the contact author and guarantor of the review.

JB drafted the text of the protocol with NM and CB.

NM and CB provided additional references and comments on the text of the protocol. CB provided support to the authors in the use of RevMan and maintained the supplementary reference manager databases.

6 Declarations of interest

Funding for this review has been received from PIP UK, a charitable organisation led by Andrea Leadsom (MP) to establish and evaluate parent-infant psychotherapy programmes.

Jane Barlow - editor with the Cochrane Developmental, Psychosocial and Learning Problems Group and Co-Chair of the Campbell Social Welfare Group.

Cathy Bennett - proprietor of Systematic Research Ltd, a company providing research services; employee of that company; received a consultancy fee from the PIP UK grant for contribution to this review, as well as travel expenses for travel to work related meetings and conferences. Cathy has also received consultancy fees for other Cochrane reviews.

Nick Midgley - employed by Anna Freud Centre, which offers parent-infant psychotherapy; recipient of funding to conduct the review from PIP UK.

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8 Sources of support

8.1 INTERNAL SOURCES

No sources of support specified

8.2 EXTERNAL SOURCES

- PIP UK, UK

Charitable organisation with a remit to establish parent-infant psychotherapy services across England