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Mindfulness-based parenting programmes for improving psychosocial outcomes in children from birth to age 18 and their parents (Protocol)

Shlonsky A, Dennis JA, Devine B, Tufford L, Barlow J, Bjørndal A

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[Intervention Protocol]

Mindfulness-based parenting programmes for improving psychosocial outcomes in children from birth to age 18 and their parents

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ABSTRACT

This is a protocol for a Cochrane Review (Intervention). The objectives are as follows:

To assess the effectiveness of mindfulness-based parent training programmes on the psychosocial functioning of children (from birth to age 18 years) and their parents.

BACKGROUND

Description of the condition

Emotional and behavioural difficulties in children

Emotional or behavioural difficulties, or both (EBD) in children are common in Western societies with recent estimates showing that around 12% of children in high-income countries experience such problems (Costello 2005), and as many as 15% to 21% of preschool children (Skovgaard 2008; Skovgaard 2010). EBD is an 'umbrella term' and may cover a range of both externalising behaviours (including aggression and hyperactivity) and internalising behaviours (e.g. anxiety or depression, or both). Such problems are highly stable over time (Campbell 1995), and are the most important cause of functional disability in children (Meltzer 2000). They are predictive of a range of poor mental health, relationship and employment sequelae (Farrington 1994; Felitti 2002; Moffitt 2002), including a range of risky behaviours and criminality (Farrington 1999; Farrington 2002; Fergussson 2005), in adolescence and beyond. The prevalence, stability and long-term consequences of these problems have highlighted the impor-

tance of intervening to address them during the early years, when behavioural patterns are most easily modified (Tremblay 2006; Kaminski 2008).

Parenting practice and EBD

A range of factors are involved in the aetiology of EBD in children, with consensus emerging over the past decade that parenting plays a key role (Skovgaard 2008; Skovgaard 2010). Early behavioural research pointed to the negative impact of 'coercive' parenting practices in escalating negative child behaviours (Patterson 1989), and more recent research has shown that positive, proactive parenting (involving praise, encouragement and affection) is strongly associated with high child self-esteem, cognitive ability and social and academic competence, and is protective against later disruptive behaviour and substance misuse (Kumpfer 2004; Byford 2012).

Research has identified the important role played by the parent-infant/toddler interaction in the development of emotional or behavioural and other regulatory problems (Skovgaard 2008; Skovgaard 2010). Specifically, the child's developing capacity for affect regulation (i.e. to regulate their own emotions) (Schore 1994; Sroufe 2005; Moffitt 2011) is a function of their attachment relationship with their primary caregiver (Egeland 1993; Sroufe 1996). Significant associations have been identified between factors such as maternal sensitivity (Kemppinen 2007), disrupted maternal behaviour (Madigan 2006), deficits in the early caregiving environment (Shaw 2001), and preschool externalising behaviour problems.

Belsky 1984 hypothesised that parenting is influenced by a range of factors at the level of the parent, the child and the wider social context (e.g. marital relationships, parental occupation and adverse life events). This process model has been considerably elaborated by more recent research, which showed that parental personal factors, environmental factors and child factors are mediated by social support in terms of their impact on parental emotional well-being, quality of parenting, and family functioning, and also child functioning, in terms of self-esteem, competence and resilience (Armstrong 2005). Furthermore, the causal pathway between parenting and child emotional or behavioural problems, or both, can be described as 'bidirectional' (Furlong 2012), with parents and children impacting and shaping one another's behaviour (Patterson 2002; Long 2008). One of the consequences of bidirectionality is that parents with insufficient parenting skills may become involved in increasingly negative and coercive behaviours when dealing with non-compliance in children, which can have a cyclical effect, exacerbating child behaviour problems and, in turn, further increasing parental distress (Patterson 1992; Campbell 1997).

Description of the intervention

Mindfulness-based therapies are part of a relatively new generation of behavioural treatments and are commonly grouped together under the heading of 'the third wave' of cognitive behavioural therapy (CBT) (Hunot 2010). A common element of such therapies is a reduced emphasis on CBT's traditional reliance on the systematic "challenging" of irrational beliefs (Longmore 2007). Mindfulness techniques employ strategies to achieve change through a focus on acceptance, which may be a more effective method of facilitating the extinction of unwanted thoughts, feelings and impulses. CBT therapies that contain a large component of mindfulness include: Acceptance and Commitment Therapy (ACT) (Hayes 1999); Mindfulness Based Cognitive Therapy (MBCT) (Teasdale 1995), Dialectical Behaviour Therapy (DBT) (Linehan 1993; Lynch 2006), and the expanded model of Behavioural Activation (BA) (Martell 2001). Although most mindfulness practice that is used as part of mental health treatment programmes is taught without reference to the religious and cultural traditions from which they originate, all such therapies nevertheless rely essentially on a particular theory of paying attention, or remaining mindful, which generally has its origins in Eastern meditation practices (Baer 2003), and is aimed primarily at "bringing one's complete attention to the present experience" (Marlatt 1999, p 68) in nonjudgmental ways (Kabat-Zinn 1994). The practices that are labelled as 'mindfulness' draw heavily from traditional, Buddhist meditative techniques, although other contemplative traditions may also be present (Teasdale 1995; Baer 2003; Lynch 2006).

Parents involved in parent training programmes with a mindfulness component are invited to learn about strategies such as those described by Dumas as "facilitative listening" and "distancing" (Dumas 2005, p 779). Facilitative listening requires both clinicians and parents to move from a problem-solving approach to one of acceptance of things as they are. This is not easy for many Western parents for whom 'doing' comes more naturally than 'contemplating' (Dumas 2005, p 784). Distancing is a technique learned through meditation exercises, in which parents learn to distinguish between how they feel and their thought processes. Parents learn to identify their own levels of arousal (feelings), and by being able to recognise their feelings they can learn to pause before acting, thereby avoiding negative and unhelpful ways of thinking and behaving. Finally, parents are encouraged to develop appropriate, practical solutions or 'motivated action plans', which may involve specific behavioural strategies.

In common with other parent training programmes, mindfulness-based parenting interventions are brief (typically less than 20 sessions) and manualised (meaning that the content, duration and other details of the programme are described in a written format designed to help therapists deliver the intervention as designed, and to help ensure replicability). They are also nonreligious, nonesoteric and deliverable in group format (although homework in the form of mindfulness practice is an essential component).This reflects the fact that, unlike other parent training interventions more generally, the initial focus of mindfulness-based parenting

interventions is to assist participants to concentrate on attending to their own emotional states first, with the aim of promoting parental affect regulation. Key messages include the importance of "slowing down" and responding with equanimity and compassion towards one's children (Kabat-Zinn 2003). Typically, mindfulness-based parenting interventions include exercises to help parents focus on their breathing and awareness of their own physical and mental states through mindfulness practices, and to develop self-compassion as well as self-control. Goals then include the replacement of negative reactions (including criticising, projecting of anger, etc.) with positive responses (e.g. listening, showing affection or modelling positive self-care in the face of challenging circumstances) (Placone-Wiley 2001). Parents are thus assisted gradually to increase the intentionality (as opposed to the automaticity) of interactions with their children (Altmaier 2007).

Mindfulness-based parenting interventions are intended to bring about improved parenting through a two-stage process. The first involves becoming more observant and accepting of internal states and environmental conditions (including one's own state of mind, as well as one's child's behaviour). This growing awareness is achieved through fairly intensive periods of concentration (usually mindfulness practices or meditation) designed to examine these states and conditions, but not to respond to them. The aim is to support parents to live through the experience in an observant, non-reactive manner thereby learning at an experiential level that these states and conditions are not permanent and that they can be successfully lived through or at least tolerated. Training involves concerted periods of mindfulness, which may involve focusing on physical and mental sensations such as feelings in the body, sounds, sights, tastes, smells, thoughts and emotions. The intention of mindfulness practices is to develop the capacity to 'pay attention' (rather than, for example, as with some other meditation practices, to enhance the ability to concentrate). Gradually, parents are encouraged to pay attention to the patterns of their own minds, including noticing when and to what the mind wanders. Ultimately, it is anticipated that the person engaging in mindfulness meditation will still be practising mindfulness even when their attention is no longer upon their intended object of focus.

How the intervention might work

The anticipated outcome of these exercises is decreased parental stress and negative reactivity, which may lead to an increased aptitude for selecting more optimal parenting practices. The second stage involves bringing this experiential learning to parenting interactions through specific training in effective parenting techniques. The individual effectiveness of either the mindfulness training or the parenting training, as well as the extent to which the two components are well integrated, will influence the overall effectiveness of the intervention.

A recent review of potential mechanisms by which mindfulness-based parenting may influence mental health in both parents and children (Bögels 2010) identified the following:

1. the reduction of parental stress and resultant parental reactivity;
2. the reduction of parental preoccupation resulting from parental or child (or both) psychopathology;
3. the improvement of parental executive functioning in impulsive parents;
4. breaking the cycle of intergenerational transmission of dysfunctional parenting schemas and habits;
5. the increase of parental self-care or self-nourishing attention; and
6. the improvement of marital functioning and coparenting.

Whilst some of these goals are similar to parent training programmes underpinned by other types of theoretical models, mindfulness-based parenting interventions may help parents not just to make progress but also to maintain gains more easily. It is hypothesised that this is a consequence of the way in which such programmes may improve parents' capacity for self-regulation, in addition to improving their connections with others within and outside the family (Dumas 2005; Harnett 2012; Snyder 2012). Furthermore, mindfulness is intended to result in long-term benefits, by helping parents to develop the capacity to respond calmly with greater flexibility to events as they arise, and to sustain their attention in a less reactive manner. Thus, continued practice (mindfulness) may extend any benefits well beyond the immediate formal intervention period (Siegel 2007), as has occurred with other clinical populations (Scherer-Dickson 2004), thereby enhancing family relationships and lifecourse outcomes for parents (Burpee 2005) and children (Harnett 2012).

Evidence about likely mechanisms may be located in the growing body of research on the positive effects of mindfulness -based practices on caregiver stress (Lavretsky 2011); attentional control (Moore 2012); reframing aversive situations (Gootjes 2011); and self-regulation, even following challenges contrived to deplete one's resources for self-control (Friese 2012). These changes have been assessed using biological (Lavretsky 2011) and electrophysiological measures (Moore 2012) suggestive of long-term changes in those who practice the techniques of mindfulness meditation. Such intervention may be helpful for parents negotiating particular stresses, including the initial transition to parenthood (Perez-Blasco 2013), looking after children with chronic illness or disability (Macdonald 2010a; Benn 2012; Katyal 2012), facing the challenges of parenting adolescents (Duncan 2007; Boegels 2008; Snyder 2012), or facing divorce (Maloney 2007).

Why it is important to do this review

Evidence from systematic reviews of parenting programmes demonstrates that they can improve the emotional and behavioural adjustment of children under three years of age (Barlow 2010) and of children aged three to 10 years with conduct and behaviour problems (Dretze 2005). A systematic review has provided evi-

dence that such programmes can significantly improve a range of aspects of parental mental health, including anxiety, depression, and self-esteem (Barlow 2012).

Nevertheless, there is a significant group of parents for whom standard parent training programmes do not appear to be effective, and there is also some recognition of the need to add components to standard parent training programmes that are aimed at addressing issues such as parental anger or capacity for self-regulation (Sanders 2004). Furthermore, concerns remain about the long-term effectiveness of such programmes, and recommendations for a variety of supplementary interventions to support treatment gains (e.g. booster sessions) are common (Hudson 1986; Eyberg 1998; Nock 2003; Barlow 2012).

Systematic reviews of the effects of several mindfulness-based techniques provide strong evidence of effectiveness. Mindfulness Based Stress Reduction (MBSR) in particular has been shown to be effective in reducing stress and promoting health and functioning across a range of mental and physical conditions across a variety of adult populations (Grossman 2004; De Vibe 2012), and MBCT has been found to be effective in reducing depression in adult populations (Piet 2011). A number of MBCT researchers have also begun to examine the potential for improvements in parent-child interactions (Bailie 2012), which has resulted in a significant rise in mindfulness-based parenting interventions, underpinned by a focus on increasing the capacity for self-regulation in parents (Dumas 2005; Harnett 2012). Although there is still some debate about the value of such practice (Eyberg 2005), a formal call for research in the area of child and parenting research has recently been made in the *Journal of Child and Family Studies* (Sawyer Cohen 2010). Although evaluations have now been conducted across a variety of general and clinical samples from pregnancy and infancy to adolescence (Duncan 2010; Harnett 2012), to date, there has been no systematic review that examines the effectiveness of mindfulness-based parenting programmes in improving the emotional and behavioural adjustment of children. This review aims to address that gap.

OBJECTIVES

To assess the effectiveness of mindfulness-based parent training programmes on the psychosocial functioning of children (from birth to age 18 years) and their parents.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) or quasi-RCTs (i.e. trials where allocation has been made by some quasi-random method of allocation such as alternation, date of birth, or case record number).

Types of participants

Parents or primary caregivers of any age and regardless of gender, with children aged from birth to 18 years. We will include studies involving children aged older than 18 years if the mean age of the sample is not over 18 years.

Types of interventions

Manualised (or otherwise) standardised parent training programmes containing a well-defined mindfulness component, of any duration and frequency, and delivered one-to-one or in groups. The mindfulness component must include mindfulness training (breath, visualisation, listening, or other sensory focus) and, minimally, involve an explicit focus on:

1. present-focused attention; and
2. non-judgmental acceptance.

Studies reporting evaluations of programmes without explicit reference to such *foci* will not be included. We will include programmes that meet other criteria, but which are of atypical duration (either less than eight weeks or more than 20 weeks).

Eligible control groups may include participants receiving no treatment, wait-list control, attentional control (e.g. general discussion groups on parenting) or alternative parent training programmes.

Exclusion criteria

We will exclude studies commencing in the prenatal period, even where they continue into the postnatal period, because effectiveness of programmes that are delivered prior to the arrival of a baby may be different to programmes that are delivered to parents with children, and is properly the subject of a separate review.

Depending on what our original review produces, its subsequent update may take the form of a new protocol (with a methodology for network meta-analysis) to account for potential variation in comparator groups.

Types of outcome measures

Primary outcomes

1. Child emotional and behavioural adjustment, as measured by, for example, the Behaviour Screening Questionnaire (BSQ; Richman 1971); the Child Behaviour Checklist (CBCL; Achenbach 1991); the Eyberg Child Behaviour Inventory (ECBI; Eyberg 1999); the Child Behaviour Questionnaire

(CBQ; Rothbart 2001); the Dyadic Parent-Child Interaction Coding System (DPICS; Eyberg 1994), etc.

2. Adverse effects. Any adverse effects relating to child or parental psychosocial health or indeed, family functioning (unintended consequences of parent training may include, for example, feelings of disempowerment on the part of untrained spouses/partners/other carers related to the participants of the interventions).

A range of instruments, from single-item measures to multi-item scales, are used in this area of research and may vary in their psychometric properties. With the exception of data related to adverse events, the minimum standard for the inclusion of data from any outcome instrument used is that a full description of the instrument and its scoring is available. In addition, we will judge whether specific instruments adequately fit with the content area and will comment on any relevant evaluations of their reliability and validity. We will record the source of reporting (e.g. parent, child, therapist, teacher) for all outcome data and analyse data separately by source.

Secondary outcomes

1. Parental psychosocial outcomes, including:
   i) parenting skills, as measured by, for example, the Parenting Skills Assessment - 10th version (PSA-10; Reed 2009);
   ii) symptomatology related to depression or anxiety, as measured by, for example, the Beck Depression Inventory (BDI; Beck 1961); the Hamilton Rating Scale for Depression (HAM-D; Hamilton 1969); the Beck Anxiety Inventory (BAI; Beck 1988); the Hamiliton Rating Scale for Anxiety (HAM-A; Hamilton 1959); or a similar standardised instrument;
   iii) stress related to the parenting role, as measured by, for example, the Parenting Stress Index (PSI; Abidin 1986) or a similar standardised instrument;
   iv) mindfulness, as measured by validated scales such as the Mindful Attention Awareness Scale (MAAS; Brown 2003); and
   v) measures of self-compassion (e.g. Neff 2003).

We will present the outcomes stated above in a 'Summary of findings' table.

Search methods for identification of studies

Electronic searches

We will search the electronic databases and trial registers listed below.

1. Cochrane Central Register of Controlled Trials (CENTRAL, current issue) in the Cochrane Library, which includes the Cochrane Developmental Psychosocial and Learning Problems Group Specialised Register.
2. Ovid MEDLINE (1946 to current).
3. Ovid MEDLINE In-Process & Other Non-Indexed Citations (current issue).
4. Ovid MEDLINE Epub Ahead of Print (current issue).
5. Embase Ovid (1980 to current).
6. CINAHL Plus EBSCOhost (Cumulative Index to Nursing and Allied Health Literature; 1937 to current).
7. PsycINFO Ovid (1806 to current).
8. Sociological Abstracts ProQuest (1952 to current).
9. Social Sciences Citation Index Web of Knowledge (SSCI; 1970 to current).
10. Conference Proceedings Citation Index - Social Science & Humanities Web of Knowledge (CPCI-SS&H; 1990 to current).
11. ASSIA ProQuest (1987 to current).
12. ERIC Ovid (Education Resources Information Center; 1966 to current).
13. ProQuest Theses and Dissertations (all available years).
14. *Cochrane Database of Systematic Reviews* (CDSR; current issue) in the Cochrane Library.
15. The Campbell Collaboration Library of Systematic Reviews (all available years).
16. ClinicalTrials.gov (all available years; clinicaltrials.gov).
17. World Health Organization International Clinical Trials Registry Platform (WHO ICTRP; all available years; who.int/ictrp/en).

We will search Ovid MEDLINE using the strategy in Appendix 1 and adapt it, as appropriate, for other databases.

Searching other resources

We will examine the bibliographies of included studies, and of systematic and non-systematic review articles, to identify relevant studies.

We will contact experts in the field to identify reports of ongoing and unpublished data. Such experts will include the authors of included studies as well as experts identified through approaches to relevant centres for research on mindfulness-based therapies, including those listed below.

1. General: Mindfulness Research Guide (mindfulexperience.org).
2. Australia: Mindfulness - Integrated Cognitive Behaviour Therapy - Treatment, Training, Research (Hobart, Tasmania, Australia).
3. Canada: The Centre for Mindfulness Studies, Toronto.
4. UK:
   i) Exeter Mindfulness Network (University of Exeter, Exeter, England);
   ii) Oxford Mindfulness Centre (University of Oxford, Oxford, England);
   iii) Mindfulness Scotland (Glasgow, Scotland); and
   iv) Centre for Mindfulness Research and Practice (Bangor University, Bangor, Wales).

5. USA:

i) Center for Mindfulness in Medicine, Health Care and Society (University of Massachusetts Medical School, Norwood, Massachusetts);

ii) Duke Integrative Medicine (Duke University, Chapel Hill, North Carolina); and

iii) Mindful Awareness Research Center (MARC) (UCLA, Los Angeles, California).

Data collection and analysis

Selection of studies

We will store and organise citations in EndNote bibliographic software (EndNote 2013). Two review authors (JD and LT) will independently carry out an initial screening of abstracts and titles from the search to identify potential trials for inclusion. A second level of screening will then take place, where two pairs of review authors (AS, MM, JD and LT) will independently assess and select studies for inclusion against the inclusion criteria described above (Criteria for considering studies for this review). We will obtain full-text copies of relevant papers, and translate them if necessary, with the assistance of CDPLPG. When information is missing, we will contact investigators, where possible. We will include in the review studies that have been identified by mutual consent. In the event of disagreement concerning the eligibility of a given study, we will reach consensus through discussion and by consultation with another review author (JB). We will construct a flow chart of the process of trial selection in accordance with the PRISMA statement (Moher 2009).

Data extraction and management

Data extraction

Four review authors (MM, BD, JD and LT) will extract data independently in pairs using modified, piloted data-extraction sheets that have been previously used in other parent training reviews (Barlow 2010; Barlow 2012) (Appendix 2). All disagreements will be resolved by consensus or arbitration, or both, by a fifth or sixth review author (AS or JB).

Data collection

We will collect the following data for all trial arms.

1. Descriptive data, including participant demographics (age, gender, baseline measures of school achievement, social and economic status).
2. Intervention characteristics (including delivery, duration, and within-intervention variability).
3. Other interventions received (including delivery and duration).
4. Outcome measures listed above (Types of outcome measures).
5. Outcome data.
6. Data related to the conduct of the trial in accordance with Cochrane's 'Risk of bias' tool (Higgins 2011a).

Data will be entered into Review Manager 5 (RevMan) software (RevMan 2014).

Assessment of risk of bias in included studies

At least two review authors will independently assess risk of bias within each included study according to the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). All disagreements will be resolved by consensus or arbitration (or both), by a fifth or sixth author (AS or JB). Review authors will independently assess the risk of bias within the published reports of each included study based on the domains typically included within Cochrane reviews (sequence generation, allocation concealment, blinding of treatment providers and personnel, blinding of outcome assessors, incomplete outcome data, selective reporting bias, and other sources of bias), and assign ratings of high, low or unclear risk of bias in accordance with plans presented in Appendix 3. Due to the nature of the intervention, we expect that all studies will merit ratings of high risk of bias as regards blinding of treatment providers and personnel. We will also assess two other domains related to the extent to which the impact of additional services received by families and investigators' potential conflicts of interest may have introduced bias.

Measures of treatment effect

Binary data

For dichotomous (binary) data, we will use the odds ratio (OR) with a 95% confidence interval (CI) to summarise results within each study. We will use the OR because it has statistical advantages relating to its sampling distribution and its suitability for modelling, and because it is a relative measure and can therefore be used for the purpose of combining data across studies.

Categorical data

Where results are reported using short ordinal scales, we will use the methods of Whitehead and Jones to produce a single OR from each trial (Whitehead 1994). Where sufficient detail is not available, we will consider analysing such scales as continuous data, after investigating skew and appropriateness.

Continuous data

If continuous outcomes are measured identically across studies, we may calculate an overall mean difference (MD) and 95% CI. If the same continuous outcome is measured differently across studies, we may calculate an overall standardised mean difference (SMD) and 95% CI (Deeks 2011). We will calculate SMDs using Hedges' *g* (Hedges 1981).

Multiple outcomes

When a single study provides multiple measures of the same outcome (e.g. two measures are used to assess child behaviour problems) we will average the effects from the outcomes to arrive at a single effect for use in the meta-analysis. We acknowledge that the variance estimate of the average synthetic effect sizes that are calculated should appropriately account for the correlation between the two outcomes, and we intend to report the correlation value, and the source/means of arriving at such a correlation if it is not reported within the primary study/studies.

Unit of analysis issues

Cluster-randomised trials

Where trials have involved the randomisation of clusters, we anticipate that study investigators will have presented their results after appropriately controlling for clustering effects (using robust standard errors or hierarchical linear models).

Where it is unclear whether a cluster-randomised trial has used appropriate controls for clustering, we will contact the study investigators for further information. Where appropriate controls were not used, we will request individual participant data and re-analyse the data using multilevel models that control for clustering. Following this, we will conduct a meta-analysis of effect sizes and standard errors in RevMan using the generic inverse variance method (Deeks 2011; RevMan 2014). In the absence of individual participant data, we will seek information on an intraclass correlation coefficient (ICC), which describes the relative variability in outcome within and between clusters (Donner 1980). We will obtain this information from the study authors or, if this is not possible, use external estimates obtained from similar studies in parent training. As described in Macdonald 2010b, we will attempt to find the closest-matching scenarios (with regard to both outcome measures and types of clusters) from existing databases of ICCs (Ukoumunne 1999). If we are unable to identify any, we will perform sensitivity analyses using a high ICC of 0.15, a moderate ICC of 0.01 and a small ICC of 0.001 (Sensitivity analysis). Relatively arbitrary as these values may be, we prefer to use them to adjust effect estimates and their standard errors, due to the implausibility that the ICC is actually 0. Thereafter, we plan to combine the estimates and associated corrected standard errors from the cluster-randomised trials with those from parallel designs using the generic inverse variance method in RevMan (Deeks 2011; RevMan 2014). If there is insufficient information to control for clustering, we will enter outcome data into RevMan using individuals as the units of analysis, and then conduct a sensitivity analysis excluding such studies (Sensitivity analysis), to assess the potential biasing effects of inadequately controlled clustered trials (Donner 2001).

Studies with multiple treatment groups

We will report in the review all eligible outcome measures for all trial arms.

If two or more eligible intervention groups are compared to an eligible control, we will consider combining the data, providing that each meets all inclusion criteria, using the methods documented in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011b).

If a single eligible intervention group is compared to multiple eligible control groups, we will choose 'no-treatment' controls over other groups, for comparison and inclusion in meta-analyses (Lipsey 2001). For studies that do not have a no-treatment condition, we will have chosen the most appropriate eligible alternative (see list of comparisons under Types of interventions).

We will analyse separately studies comparing a mindfulness-based parenting programme with an active control (definable as an alternative parent training programme), and interpret any results with caution, unless or until evidence from a meta-analysis of the primary analyses (against no treatment) is strong. We will pay careful attention to ensure that 'active controls' are sufficiently similar in terms of programme content, format, and duration to justify the pooling of data.

Dealing with missing data

As per Macdonald 2010b, we will contact the primary investigator or corresponding author of included studies to request any unreported data (e.g. group means and standard deviations (SDs), details of dropouts, and details of interventions received by the control group). We will contact other authors if necessary. If a study reports outcomes only for participants completing the trial, or only for participants who followed the protocol, we will contact the study author(s) and ask them to provide additional information.

Assessment of heterogeneity

We will assess clinical variation across studies by comparing the distribution of important participant factors amongst studies (e.g. whether participants were recruited from the general population or as subsets, such as parents of children with developmental disabilities) and programme differences (duration, intensity).

We will assess the extent of heterogeneity using the three methods suggested by the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2011): visual inspection of forest plots, the Chi² statistic (increasing the level of significance to 0.10 to avoid underestimating heterogeneity), and using Higgins' I² statistic, which is designed to assess the impact of heterogeneity on the meta-analysis. I² describes the "percentage of the variability in effect estimates that is due to heterogeneity rather than sampling error (chance)" (Higgins 2002; Higgins 2003). However, it is advised that the thresholds of the I² statistic might be misleading and the following guide is offered:

- 0 to 40%: might not be important;
- 30% to 60%: may represent moderate heterogeneity;
- 50% to 90%: may represent substantial heterogeneity; and
- 75% to 100%: considerable heterogeneity.

We will bear in mind that the importance of the observed value of the I² statistic depends firstly, on magnitude and direction of effects and secondly, strength of evidence for heterogeneity (e.g. P value from the Chi² test or a confidence interval for I²).

Assessment of reporting biases

To investigate the possibility of reporting biases, including publication bias, we will draw funnel plots (Egger 1997; Sterne 2011). Asymmetry can be due to publication bias, but can also be due to a genuine relationship between trial size and effect size. We will examine clinical variation of the studies to explore asymmetry, as well as comparing results extracted from published journal reports with results obtained from other sources. We recognise that a minimum of 10 studies is required for funnel plots to be meaningful and that, even under these circumstances, funnel plots are inappropriate when heterogeneity is extreme, all studies are equally large, or when no studies with significant results have been identified.

Data synthesis

We will use RevMan 2014 to perform the following calculations. We will calculate all overall effects using inverse variance methods. It is likely that the studies will yield heterogeneous data because of differences in the study populations and variations in the intervention. Therefore, we will present the results of analyses using a random-effects model.

Where sufficient clinical and methodological homogeneity exists between trials, we will pool results. We are aware of the dangers of interpreting findings of single or even multiple studies in the absence of meta-analysis. Where meta-analysis is not possible, for example, where outcomes measure different domains such as 'parenting stress' and 'depression', we will provide reasons and report study authors' findings narratively.

'Summary of findings' tables

We will use GRADEpro 2014 to present the main results of this review in a 'Summary of findings' table(s), as necessary; one table per comparison.

Two review authors will judge the overall quality of the evidence for each outcome as 'high', 'moderate', 'low' or 'very low' according to the GRADE approach (Schünemann 2011). We will consider the following factors.

1. Impact of risk of bias of individual trials.
2. Precision of pooled estimate.
3. Inconsistency or heterogeneity (clinical, methodological and statistical).
4. Indirectness of evidence.
5. Impact of selective reporting and publication bias on effect estimate.

Subgroup analysis and investigation of heterogeneity

Large numbers of subgroups may lead to misleading conclusions and are best kept to a minimum (Yusuf 1991; Oxman 1992). If possible, this review will include separate effect estimates for the subgroups below.

1. Programme type (e.g. those which focus more on acceptance versus those with a more skills-based approach).
2. Gender of parents.
3. Age of children.
4. Diagnostic condition of participant children (e.g. children with disruptive behaviour disorders; children diagnosed with autism spectrum disorder; children of divorcing parents).

Sensitivity analysis

We will carry out sensitivity analyses to assess the impact of the following factors on the results.

1. RCTs versus quasi-RCTs.
2. Adjusted versus unadjusted cluster-randomised trials.
3. Loss to follow-up exceeds 20%.
4. Validated versus non-validated measures.
5. Published versus unpublished data.

Qualitative data

We may report qualitative data from included studies to better understand the delivery of interventions, uptake by participants, and context.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. Search strategy for MEDLINE via Ovid

1 Parenting/
2 exp Parent-Child Relations/
3 Family Relations/
4 exp Parents/
5 Paternal Behavior/
6 Maternal Behavior/
7 (parent* or famil* or father* or mother* or paternal* or maternal* or couple* or marital* or carer* or caregiver* or care giver* or foster*).tw.
8 (stepparent* or stepmother* or stepfather* or stepfamil* or (step adj (parent* or mother* or father* or famil*))).tw.
9 or/1-8
10 mindfulness/
11 meditation/
12 mindful*.tw.
13 meditat*.tw.
14 mbsr.tw.
15 mbct.tw.
16 or/10-15
17 9 and 16
18 randomised controlled trial.pt.
19 controlled clinical trial.pt.
20 randomi#ed.ab.
21 placebo$.ab.

22 drug therapy.fs.
23 randomly.ab.
24 trial.ab.
25 groups.ab.
26 or/18-25
27 exp animals/ not humans.sh.
28 26 not 27
29 17 and 28

Appendix 2. Data extraction sheet

Study ID (first surname + year):	**Initials of person extracting data & Date:**
Type of report (e.g. conference proceeding, peer reviewed journal article, book chapter, PhD dissertation, etc.):	
Language of report (if translation needed, note here):	
Full citation (refer also to any secondary publications):	
Design of study (e.g. randomised controlled trial, cluster design):	
Site of intervention (e.g. single site, multiple sites, country):	
Setting of intervention (e.g. urban, rural, mixed; community, outpatient, inpatient):	
Means of recruitment (from within primary care, school… via referrals, advertisement):	
Ethics committee approval?:	
Funding of study:	**Potential conflict of interest of trial investigators:**
Inclusion criteria:	
Exclusion criteria:	
Age of participants (e.g. mean, SD, range) Children: Parents:	

(*Continued*)

Sex of participants
Children:
Parents:

Ethnicity, SES, other demographics of participants:

Baseline characteristics of children:

Description of intervention(s) (including also control condition)
Intervention
At what level was the intervention? (individual, group, family?):

Describe content in detail (include explicit references/citations to/for theoretical underpinnings):

Characteristics of therapist (profession [e.g. clinical psychologist, social worker] training in mindfulness, level of experience):

Duration/intensity of intervention:

Timing of assessments:

Length of follow up:

Control (no treatment; wait-list control; attentional control - then, list as above)

Total number of participants randomised (total and by groups):

Total number of participants completing the study (total and by groups):

Unit of allocation:

Power calculation or sample size estimate:

Prospectively stated outcome(s). (List in order of our protocol - do not yet provide detail results (outcome data), merely categories of results and metrics as reported)
Primary outcomes
1. Child emotional and behavioural adjustment; and
2. Adverse effects.

Secondary outcomes
1. Parental psychosocial outcomes including:
   i) parenting skills;
   ii) symptomatology related to depression or anxiety;
   iii) stress related to the parenting role;
   iv) mindfulness, as measured by validated scales such as the MAAS (Brown 2003); and
   v) measures of self-compassion (e.g. Neff 2003).

OUTCOMES COLLECTED BY TRIALLISTS BUT NOT REQUIRED FOR OUR REVIEW:

(*Continued*)

Information for Risk of Bias Table

(1) Adequate sequence generation? (Was the allocation sequence adequately generated?)

Quote:

Judgment:

(2) Allocation concealment? (Was allocation adequately concealed?)

Quote:

Judgment:

(3) Blinding? (Was knowledge of the allocated interventions adequately prevented during the study?)

a) of participants?

Quote:

Judgment :

b) of personnel?

Quote:

Judgment :

c) of outcome assessors?

Quote:

Judgement :

(4) Incomplete outcome data addressed? Were incomplete outcome data adequately addressed? - consider, - details of attrition - also, was intention-to-treat analysis used and if so, what model?)

Quote:
Judgment:

(*Continued*)

(5) Selective outcome reporting? (Are reports free of suggestion of selective outcome reporting?)

Comment:

Judgment:

(6) Free of other bias? (Was study apparently free of other sources of bias?)

Comment:
Judgment:

Results (1) - outcome data relevant for review (see also EXCEL sheet):

Results (2) - outcomes not used within our review (do not include numerical data):

Results (3) - outcomes reported prospectively but not presented:

ITT analysis attempted?

Authors' own conclusions
Supply quotes - what did investigators themselves consider their main findings?

Other notes:

Need to contact investigator(s)?

Email address of corresponding author:

List of issues to ask author (e.g. how randomisation conducted; whether a protocol for the study exists; details of dropouts, etc.)

Footnotes
ID: identifier; **ITT**: intention-to-treat; **MAAS**: Mindfulness Attention Awareness Scale; **SD**: standard deviation; **SES**: socioeconomic status.

Appendix 3. Description of domains/assessments for risk of bias

Sequence generation

We will determine whether studies used computer-generated random numbers, table of random numbers, drawing lots or envelopes, coin tossing, shuffling cards, or throwing dice.

1. Low risk of bias: the study authors explicitly stated that they used one of the above methods.
2. High risk of bias: the authors did not use any of the above methods.
3. Unclear risk of bias: there is no information on randomisation method or it is not clearly presented.

Allocation concealment

We will evaluate whether investigators and participants could foresee assignments before screening was complete and consent was given.

1. Low risk of bias: researchers and participants were unaware of future allocation to treatment conditions.
2. High risk of bias: allocation was either not used or was not concealed from researchers before eligibility was determined or from participants before consent was given.
3. Unclear risk of bias: information regarding allocation concealment is not known or it is not clearly presented.

Blinding of treatment providers and personnel

Neither participants nor treatment providers (therapists) can be kept blind to the intervention condition in studies of this nature, therefore, we anticipate a rating of high risk of bias for this criterion in advance.

Blinding of outcome assessors

We will address the issue of whether or not outcome assessors were kept blind to treatment condition.

1. Low risk of bias: objective assessors were employed and kept blind to the treatment conditions.
2. High risk of bias: external assessors (e.g. teachers or investigators) were not blind to the treatment conditions or assessment was by parent self-report only, or both.
3. Unclear risk of bias: information on the blinding of assessors is unclear or unavailable from study authors.

Incomplete outcome data

We will identify the presence of incomplete outcome data as follows.

1. Low risk of bias: there are no dropouts or exclusions; there is some missing data but the reasons for missing data are unlikely to be related to the true outcome; or missing data are balanced in proportion across intervention groups, with similar reasons for missing data across groups.
2. High risk of bias: there is differential attrition across groups, reasons for dropout are different across groups, there was inappropriate application of simple imputation (e.g. assuming certain outcomes, last observation carried forward (LOCF), etc.).
3. Unclear risk of bias: the attrition rate is unclear or authors state that intention-to-treat analysis was used but provide no details.

Selective reporting bias

To assess outcome reporting bias, we will attempt to collect all study reports (and protocols, if possible) and will track the collection and reporting of outcome measures across all available reports for each included study.

1. Low risk of bias: all outcome measures and follow-ups are reported.
2. High risk of bias: data from some outcome measures are not reported.
3. Unclear risk of bias: it is not clear whether all data collected by study authors are reported.

Other sources of bias

Performance bias

We will assess whether there were treatment differences between groups other than the main intervention contrasts (e.g. additional services).

1. Low risk of bias: there were no treatment differences between groups other than the main intervention.
2. High risk of bias: there were treatment differences between groups other than the main intervention.
3. Unclear risk of bias: it is unclear whether there were differences between groups or this information was not available from study authors.

Conflicts of interest

Potential conflicts of interest will be coded as follows.

1. Low risk of bias: there is no evidence that researchers or data collectors would benefit if results favoured the intervention or control group.
2. High risk of bias: there is evidence that researchers or data collectors would benefit if results favoured the intervention or control group (study authors also created therapeutic intervention, study authors received funding from a particular therapeutic intervention, etc.)
3. Unclear risk of bias: it is unclear whether researchers or data collectors would benefit if results favoured the intervention or control group.

We will attempt to use the judgment of 'unclear risk of bias' as infrequently as possible, and intend to correspond with investigators to gain information on the conduct of their trials in all instances where information is missing. We anticipate that such correspondence will be productive, given the relatively recent development of interventions in this area.

CONTRIBUTIONS OF AUTHORS

Aron Shlonsky, together with Robyn Mildon (when employed by the Parenting Research Centre (PRC), Melbourne, Australia) obtained funding for the conduct of the review. Jane A Dennis managed the process of the title registration. All authors contributed to the development of the protocol by commenting on successive drafts and making recommendations about responses to editorial base comments and peer review comments.

Karianne Thune Hammarstrom (Oslo, Campbell Secretariat) will run searches, in collaboration with Margaret Anderson (Information Specialist of the Cochrane Developmental, Psychosocial and Learning Problems Group) and Jane A Dennis. Aron Shlonsky, Jane A Dennis, Ben Devine and Lea Tufford will each contribute to screening of studies and data extraction. Jane Dennis and Lea Tufford will write up results of the review. Aron Shlonsky and Jane Barlow will be responsible for the Discussion and Conclusions. Aron Shlonsky and Jane A Dennis will be responsible for updating the review in future.

DECLARATIONS OF INTEREST

The Parenting Research Centre of Australia (PRC) develops and evaluates parenting programmes in Australia and internationally. PRC have funded systematic reviews in the parenting area, including this one. They have no proprietary stake in this area and are a non-profit, non-government organisation. They would like to use the information from the review to inform the public about the effectiveness of services using this approach. While it is not anticipated that any PRC studies will be included in this review, it is possible that this will occur. Should this come to pass, steps will be taken to ensure that screening, extraction, and analyses are unbiased and transparent.

Aron Shlonsky (AS) is a professor at the University of Melbourne. He was an Associate Professor at the University of Toronto (Canada) and is the lead on a grant awarded to them from the PRC of Australia. AS is an active practitioner of mindfulness meditation and, in his role as Co-Chair of the Campbell Social Welfare Group, has edited work on Mindfulness Based Stress Reduction (MBSR).

Jane A Dennis (JAD) received payment for work on this review from a grant awarded to the University of Toronto (Canada) from The PRC of Australia. JD is a novice practitioner in mindfulness meditation. JD is the Feedback Editor for the Cochrane Developmental, Psychosocial and Learning Problems Group (CDPLPG).

Ben Devine (BD) holds a part-time post as Research Assistant with The PRC of Australia, and was employed in that role during the production of this protocol. BD is an active practitioner of mindfulness meditation.

Lea Tufford (LT) was a post-doctoral researcher at the University of Toronto Factor-Inwentash Faculty of Social Work and is now employed as an Assistant Professor in the School of Social Work at Laurentian University. She was employed in these roles during the production of this protocol. The University of Toronto (Canada) receives a grant from The PRC of Australia. LT is an active practitioner of mindfulness meditation and uses it within her practice.

Jane Barlow (JB) is an author of numerous systematic reviews in the area of parent training and has conducted trials in the area. JB is an active practitioner of mindfulness meditation. JB is an Editor for CDPLPG.

Arild Bjørndal is an active practitioner of mindfulness meditation and an author of a Campbell systematic review on MBSR (De Vibe 2012).

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