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Preschool and school-based mindfulness programmes for improving mental health and cognitive functioning in young people aged 3 to 18 years (Protocol)

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[Intervention Protocol]

Preschool and school-based mindfulness programmes for improving mental health and cognitive functioning in young people aged 3 to 18 years

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ABSTRACT

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

To assess the effects of preschool and school-based mindfulness programmes for improving psychosocial health and cognitive functioning in young people aged 3 to 18 years.

BACKGROUND

Description of the condition

Positive mental health and well-being is crucial to enable children and young people to lead fulfilling lives, both personally and socially as well as academically. However, child and adolescent mental health problems are common. For example, [Fazel 2014](#) suggests prevalence rates of 8% to 18%, with many more children experiencing varying degrees of psychological distress. The most common problems include anxiety and mood disorders, attention deficit and hyperactivity disorders, behaviour disorders and substance use problems ([Green 2005](#)). It is widely recognised that childhood mental health difficulties impact on the quality of chil-

dren's lives and often persist into adulthood, negatively affecting academic achievement, relationships and employment ([Fazel 2014](#); [Harden 2001](#); [Murphy 2012](#)). They also result in significant costs to health and social services as well as the education and criminal justice systems ([Harden 2001](#); [Snell 2013](#)).

Schools and preschools - where nearly all children and young people congregate for a large portion of their day - are increasingly considered to be important for mental health promotion and intervention because they provide ready access to almost entire populations. The 'reach' of schools is increasingly recognised, especially given that only a minority of children with mental health problems access mental health services ([Ford 2008a](#); [Ford 2008b](#); [Merikangas 2009](#)). Recently, [Fazel 2014](#) called for a closer alignment between health and education services or systems, arguing that mental health services routinely embedded within school sys-

tems can create a continuum of integrative care that improves both mental health and educational attainment for all children. School- and preschool-based mental health interventions (e.g. mindfulness, social and emotional skills programmes, interventions based on principles of cognitive-behavioural therapy) may be targeted specifically at children and young people who are considered to benefit most, such as those who have encountered significant adversity or risk. However, they may also be delivered as part of a universal preventative approach, which offers the potential to enhance the lives of all children and not just those experiencing difficulties. It has been argued that universal approaches may enable personal and interpersonal success as well as reducing the total number of people in the long term who develop common mental disorders (Huppert 2009). These kinds of school-based programmes are also appealing in terms of cost-effectiveness and in reducing stigma associated with accessing specialist mental health interventions (Kuyken 2013). Thus, there is now a growing interest in understanding the characteristics of successful school-based mental health initiatives (Macnab 2014; Rowling 2009; Weare 2013; Wells 2003), and mindfulness-based interventions are amongst those which are attracting the most attention.

Description of the intervention

Mindfulness is a 2500-year-old practice, which originates from the contemplative traditions of Buddhism, and emphasises awareness and non-judgmental acceptance of a person's moment-to-moment experience (Sangharakshita 2007). The secularisation and popularisation of mindfulness was initiated in the 1970s by Jon Kabat-Zinn, who drew on his own experience of contemplative practice to develop an eight-week, structured, mindfulness skills training programme, known as Mindfulness Based Stress Reduction (MBSR), for people experiencing a range of medical problems, including chronic pain (Kabat-Zinn 1982; Kabat-Zinn 1990). The MBSR curriculum was later adapted to incorporate principles of cognitive behaviour therapy. This programme, known as Mindfulness Based Cognitive Therapy (MBCT) is primarily used to prevent relapse in adults with previous depression (Segal 2002). Both MBSR and MBCT are experiential learning programmes that include weekly group sessions and regular home practice. Activities include mindful breathing, the body scan, sitting meditations, movement and walking meditations.

During the past three decades, there has been increasing interest in mindfulness and mindfulness interventions due to a wealth of theoretical and empirical research linking them with positive psychosocial, cognitive and health outcomes (Keng 2011). Therefore, it is unsurprising that there is growing interest in adapting the techniques for use with child and adolescent populations (Semple 2010; Shapiro 2008). Mindfulness activities have been advocated as both prevention and treatment for childhood mental health difficulties, and as a tool to enhance cognitive functioning (Flook 2010; Greenberg 2011). Methods, materials and activities

for younger age groups are generally light-hearted, with a focus on fun and with less emphasis on long periods of silence. An explicit focus on meta-cognition (i.e. standing back from thoughts, seeing that they are not facts, and being aware of thinking) is generally introduced in later childhood or adolescence, as it is a difficult concept for young children to grasp (Weare 2013). Increasingly, mindfulness activities are being recommended for children from preschool age onwards (Zelazo 2012), as well as for children with developmental disabilities, autism and conduct disorder (Felver 2014; Singh 2007).

As mindfulness becomes increasingly researched and practised in the Western world, there have been a number of attempts to define and delineate the practices involved. Bishop 2004 proposed a definition of mindfulness that includes two key components. The first component involves the self-regulation of attention so that it is maintained on immediate experience; the second involves adopting a particular orientation toward present experiences characterised by curiosity, openness and non-judgemental acceptance. We will use this widely accepted definition of mindfulness as a criterion for eligibility in this review. Thus, we will include studies that incorporate both key components.

1. The self-regulation of attention by including one or a combination of the following types of activities: mindfulness of the breath, the body scan, mindful movement, mindfulness in everyday activities (e.g. mindful eating).

2. The cultivation of a non-judgemental attitude, to include an emphasis on one or some of the following: an orientation of self-acceptance; kindness toward self or others; noting thoughts, emotions, bodily sensations without judgement or elaboration; simply being.

Mindfulness interventions vary widely from single sessions to daily practice over weeks or months. Consistent with the approach taken by De Vibe 2012 in their systematic review of MBSR, this review will only include studies in which mindfulness exercises are delivered over at least four group-based sessions (we expect that the duration of sessions will vary depending on the children's age). Mindfulness techniques are often taught as part of multi-component interventions, such as those that include elements of cognitive behavioural therapy (Semple 2010) or traditional Eastern practices (yoga, tai chi, qigong). This review will include multi-component interventions, provided that the mindfulness component corresponds with the Bishop 2004 definition outlined above and is delivered on a repeated or ongoing basis over at least four sessions.

School-based mindfulness programmes can be delivered by external professionals with specific expertise in mindfulness or by trained school staff. It has been hypothesised that delivery by external experts may enhance implementation fidelity leading to increased effectiveness (Wilson 2007). However, teachers, rather than external staff, are in a much better position to 'get to the heart' of the school process and there is growing awareness of the utility of adopting a flexible and non-prescriptive style, which al-

lows for end user involvement and adaptation to the local context (Weare 2011). Thus, in this review, we seek to contribute to the existing knowledge-base regarding the relative benefits of programme fidelity versus end-user involvement, by exploring differential effects according to whether the intervention is delivered by external experts or school staff. In addition, school-based mindfulness programmes often include a home practice option (e.g. mindfulnessinschools.org). This is generally facilitated by involving parents in information evenings and providing details of tasks or activities that might be completed at home. Engagement with such activities is considered to be important for the integration of mindfulness into children's everyday lives and for the effectiveness of these programmes (Vickery 2015). For this reason, this review will examine differential effects for those who complete home practice versus those who do not.

How the intervention might work

There have been numerous attempts at identifying the psychological and neurophysiological processes involved in mindfulness interventions. Recently, a number of studies have investigated changes in brain structure and function as a result of meditation practice. These studies, which use fMRI (functional magnetic resonance imaging) techniques, typically compare the neural activation patterns and brain morphology of novice versus expert meditators (Fox 2014; Lutz 2014). Effects have been found in multiple brain regions, which include, but are not limited to: the anterior cingulate cortex (ACC), an area involved in self-regulation of attention and emotions; the frontopolar cortex, which may be related to enhanced meta-awareness following meditation practice; the hippocampus, an area involved in memory processes; and the corpus callosum, a region involved in intra- and inter-hemispherical communication (Fox 2014; Lutz 2014; Tang 2015). Overall, these findings suggest that mindfulness meditation involves complex interactive networks in the brain. However, it remains unclear how the observed changes in neural structure relate to changes in well-being and behaviour. It is also unclear how the various types of meditation practices (e.g. focused attention, open monitoring) differentially affect particular brain regions (Tang 2015).

In relation to cognitive and behavioural processes, mindfulness meditation is thought to cultivate a skill known variously as 'de-centring' (Baer 2003; Baer 2009), 'diffusion' (Hayes 1999), 're-perceiving' (Shapiro 2006), and 'mindsight' (Siegel 2010). These terms generally refer to the ability to stand back from our thought processes, allowing thoughts and feelings to be observed and noted as mental events that come and go, rather than as aspects of the self or as important truths that must dictate behaviour (Baer 2009). The cultivation of this skill is considered to bring about a fundamental shift in perspective, allowing people to observe and label thoughts and emotions without getting caught up in elaborate, repetitive and analytical processing that characterise maladaptive rumination.

Mindfulness also draws on attentional and executive function processes. 'Executive functions' refer to cognitive processes involved in sustaining attention, overcoming impulses and emotional regulation (Chan 2008; Diamond 2013). As noted earlier, a central skill in mindfulness is the ability to focus attention on an intended object (e.g. the breath). Thus, through mindfulness practice, individuals strengthen skills in initiating attention, detecting distraction, and disengaging attention from the source of distraction, thereby redirecting attention to the intended object (Lutz 2008). Such skills are important precursors for any learning task and are linked to improvements in academic performance, mental flexibility and emotional regulation (Chiesa 2011; Flook 2010; Heeren 2009; Malinowski 2013; Wallace 2006).

Why it is important to do this review

The past three decades has seen an exponential increase in mindfulness research and huge public interest in mindfulness practices (Williams 2011). In schools, teachers are encouraged to incorporate mindfulness into the school day and there is a growing market for mindfulness training courses, CDs (compact discs), apps (applications: a piece of software designed to perform a specific function), and other merchandise (see, for instance, the Mindfulness in Schools Project based in the UK (mindfulnessinschools.org); or the MindUpTM programme in the USA (thehawnfoundation.org/mindup). Despite the surge of interest, research on mindfulness with children is far less developed than that for adults and there are a number of issues in relation to school-based mindfulness that warrant further exploration. At present, little is known about differential effects of mindfulness by children's age or socioeconomic and educational context. Indeed, while positive effects on adolescents have been noted (Mendelson 2010; Raes 2014), there are also suggestions that meditation practice during early adolescence might bring about increased self-reflection at a time when heightened introspection is common, particularly amongst girls (Schonert-Reichl 2010). In addition, data need to be collated to take account of children's sociocultural and educational context, since there may be differential effects or differential levels of acceptability, or both, for marginalised and ethnically-diverse student populations (Bluth 2016; Kavanagh 2009). Thus, this review will collate and assess the available evidence in order to establish for whom, and under what conditions, mindfulness programmes are likely to be effective.

At least four narrative reviews on mindfulness programmes for children and adolescents have been conducted (Burke 2010; Greenberg 2011; Rempel 2012; Weare 2013). In addition, Zenner 2014 conducted a systematic review and meta-analysis, concluding that school-based mindfulness, "holds promise, particularly in relation to cognitive performance and resilience to stress" (p 1). However, there are a number of methodological limitations to this review, including that the results from different study designs (randomised and non-randomised studies) were combined rather

than analysed separately, thereby increasing the risk of overestimating the effectiveness of the interventions (Kunz 2007). Another review, which is currently registered with Campbell at protocol stage, seeks to explore mindfulness-based interventions for improving academic achievement, behaviour and socioemotional functioning of primary and secondary students (Maynard 2015). Our review differs from the Maynard 2015 review in a number of important ways. Firstly, this review includes studies conducted in preschool settings, thereby potentially contributing important knowledge to early intervention and prevention literature. Secondly, unlike the Maynard 2015 review, this review will only include randomised controlled trials. Thirdly, we will include analyses of costs and cost-effectiveness, when available. At present, there are no registered reviews incorporating an economic appraisal of school-based mindfulness. Such an appraisal will be of considerable interest to policy makers in education and health, particularly in view of recent findings, which show that the costs associated with childhood mental ill-health are borne largely by frontline education and special education services (Snell 2013). Finally, our review proposes a different set of subgroup analyses to incorporate an examination of possible differential effects in areas noted above (i.e. effects related to children's age and experience of risk or socioeconomic disadvantage; along with differences arising from the nature of the intervention - mode of delivery, multi-component versus stand-alone, and targeted or universal). These analyses will be critical for a nuanced understanding of what works best for children within educational settings.

OBJECTIVES

To assess the effects of preschool and school-based mindfulness programmes for improving psychosocial health and cognitive functioning in young people aged 3 to 18 years.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs) with or without cluster randomisation, and quasi-RCTs (where the methods of allocation include date of birth and alternation).

Types of participants

All children aged between 3 and 18 years in a school, preschool, kindergarten or nursery setting. We will include both typically developing children and those with specified difficulties, such as attention deficit hyperactivity disorder (ADHD), anxiety problems and developmental disabilities.

Types of interventions

Structured mindfulness interventions, including interventions delivered either by school (or preschool or kindergarten) staff or by external 'experts' who come into the school to deliver the programme.

On the basis of the two-component definition of mindfulness offered by Bishop 2004 (see [Description of the intervention](#) above), we will include dominant mindfulness-based approaches, such as Mindfulness Based Cognitive Therapy (MBCT) programmes, adapted for children and traditional Buddhist meditation practices. We will exclude mantra meditations (Transcendental Meditation®, Relaxation Response, Clinically Standardized Meditation) because, although these often emphasise paying attention, they do not focus on cultivating a 'mindful' or non-judgemental attitude (Ospina 2007).

We will include multi-component interventions (e.g. mindfulness with yoga or tai chi) provided that the mindfulness component forms a substantial and explicit part of the overall intervention as evidenced by its inclusion across at least four intervention sessions. Comparisons: wait-list or no treatment controls.

We will exclude head-to-head studies comparing two different types of mindfulness programmes without a control group.

Types of outcome measures

Primary outcomes

1. Psychosocial functioning:
 - i) an increase in well-being, self-esteem, resilience and pro-social behaviour, as assessed using reliable and validated measures such as the Personal Well-being Index - School Children (Cummins 2005), Scales of Psychological Well-being (Ryff 1995), and Affective Self-Regulatory Efficacy Scale (Caprara 2008); and
 - ii) a reduction in depression, anxiety, stress and behaviour problems, as measured by, for example, the Depression, Anxiety and Stress Scale (Lovibond 1993), the Multidimensional Anxiety Scale for Children (March 1997) and the Strengths and Difficulties Questionnaire (Goodman 1997).
2. Cognitive functioning:
 - i) improvements in executive functions, attention, self-regulation and mental processing, as measured using standardised tests such as the Test of Everyday Attention for Children (Heaton 2001) and the Behaviour Rating Inventory of Executive Functioning (Gioia 2000); and

ii) improvements in academic outcomes, as measured by standardised maths and literacy tests (e.g. Wechsler Individual Attainment Test; [Wechsler 2005](#))).

3. Adverse effects such as an increase in distress or rumination, or a reduction in pro-social behaviour.

We will include both child self-reported rating scales and third party (teacher or parent, or both) ratings, which we will analyse separately.

Secondary outcomes

1. Acceptability of the intervention from the perspective of children, teachers or parents, as measured quantitatively (e.g. number of sessions completed) or qualitatively (e.g. interview data reported within eligible studies).

2. Bullying and school violence, as measured by child- or teacher-reported incidents of violent injuries or aggressive/violent behaviours, or by validated tools such as The Revised Olweus Bully/Victim Questionnaire ([Olweus 1996](#)).

3. Truancy, as measured by child-, teacher- or parental-reported attendance or absence.

4. Costs, cost-effectiveness and resource utilisation data. We will include cost and resource utilisation studies that meet the participant and intervention criteria set out above. We will include relevant, non-controlled study designs.

We will explore outcomes measured at the following time points: postintervention, three to six months' follow-up, six to 12 months' follow-up, and follow-up of more than 12 months.

Search methods for identification of studies

Electronic searches

We will conduct separate searches for RCTs and cost-effectiveness studies (see the MEDLINE strategies in [Appendix 1](#) and [Appendix 2](#) respectively). We will modify these searches as necessary for use with the databases and trials registers listed below. We will not apply any restrictions on language, date or place of publication. We will search the following electronic databases and trials registers for randomised studies:

1. Cochrane Central Register of Controlled Trials (CENTRAL; current issue) in the Cochrane Library, which includes the Cochrane Developmental, Psychosocial and Learning Problems Specialised Register;
2. MEDLINE Ovid (1946 to current);
3. Embase Ovid (1974 to current);
4. PsycINFO Ovid (1887 to current);
5. ERIC EBSCOhost (Education Resources Information Center; 1966 to current);
6. Applied Social Sciences Index and Abstracts ProQuest (ASSIA; 1987 to current);

7. British Education Index EBSCOhost (BEI; 1974 to current);

8. Scopus Elsevier (all available years);

9. Conference Proceedings Citation Index - Social Science & Humanities Web of Science (1990 to current);

10. Proquest Dissertations and Theses (1986 to current);

11. Database of Promoting Health Effectiveness Reviews (DoPHER; eppi.ioe.ac.uk/webdatabases4/Intro.aspx?ID=9);

12. EPPI-Centre database of Health Promotion Research (Bibliomap; eppi.ioe.ac.uk/webdatabases/Intro.aspx?ID=7);

13. Campbell Systematic Reviews The Campbell Library (campbellcollaboration.org/library.html);

14. Epistemonikos (www.epistemonikos.org);

15. PubMed (www.ncbi.nlm.nih.gov/pubmed);

16. Clinicaltrials.gov (clinicaltrials.gov/ct2/home);

17. ISRCTN Registry (ISRCTN; www.isrctn.com);

18. Trials Register of Promoting Health Interventions (TRoPHI; eppi.ioe.ac.uk/webdatabases4/Intro.aspx?ID=12); and

19. World Health Organization International Clinical Trials Registry Platform (WHO ICTRP; apps.who.int/trialsearch).

We will search the following electronic databases for cost-effectiveness studies:

1. MEDLINE Ovid (1946 to current);

2. Embase Ovid (1974 to current);

3. Cost-Effectiveness Analysis Registry (CEA Registry; healthconomics.tuftsmedicalcenter.org/cear4/Home.aspx); and

4. Econlit EBSCOhost (1886 to current).

Searching other resources

We will contact key organisations and experts in the field as well as first authors of included studies for advice as to other relevant published, unpublished and ongoing studies that should be considered for inclusion. We will also search reference lists of included studies and relevant reviews to identify further relevant studies. In addition, we will handsearch the Tables of Contents from 2012 onwards of key journals (including *Mindfulness*, *Journal of Applied School Psychology*, *Advances in School Mental Health Promotion* and *Health Education*), and we will search school mindfulness websites, including Mindfulness in Schools Project (mindfulnessinschools.org) and MindUp (thehawnfoundation.org/mindup).

Data collection and analysis

Selection of studies

Two review authors (COT and MF) will read the titles and abstracts of the identified references and independently eliminate any studies that clearly do not meet the study criteria. If no abstract is available, but we find a title that seems relevant, we will

look for a full text of that study. We will then obtain the full text of all potentially relevant studies and, based on the [Criteria for considering studies for this review](#), two review authors (COT and MF) will independently assess their eligibility. In the event of a disagreement, we will seek consensus through discussion, involving a third review author (SMcG), if necessary. We will contact study authors for further information if the eligibility of the study for inclusion is unclear. We will document the specific reasons for exclusion for each study that might reasonably have been expected to have been included, but which did not meet the inclusion criteria. We will provide citation details and any available information about ongoing studies, and collate and report details of duplicate publications, so that each study (rather than each report) is the unit of interest in the review. We will report the screening and selection process in an adapted PRISMA flow chart ([Liberati 2009](#)). We will seek translations of articles in languages other than English.

Data extraction and management

Two review authors (COT and MF) will independently extract data from the original reports using a form adapted from the 'Data extraction and assessment' template provided by Cochrane Public Health ([CPH 2011](#)). We will pilot the adapted form on a small sample of studies ($n = 5$) before finalising the design. One review author (COT) will enter all extracted data into Review Manager 5 (RevMan 5) ([RevMan 2014](#)) and a second review author (MF), working independently, will check for accuracy against the data extraction sheets. When necessary, we will contact the primary authors of studies for further information or clarifications. In case of disagreements, we will first compare published and extracted information to identify transcription and comprehension errors. We will resolve any remaining disagreements by discussion and consensus, and arbitration with remaining review authors (SMcG and AB), if necessary. We will also incorporate an 'Equity checklist' in our data extraction form as outlined by the Cochrane and Campbell Equity Methods Group ([CCEMG 2012](#)).

We will extract the following data.

1. General: author; year, title, journal, country and language of publication; funding source and declaration of interest;
2. Trial: study design (RCT, cluster-RCT, quasi-RCT).
3. Setting and school type: preschool (kindergarten or nursery), primary (elementary) or second-level (high-school); student mix (single-sex/coeducational); religious ethos or patronage; rural or urban and sociodemographic contexts; mainstream or alternative school contexts.
4. Participant: age, gender, ethnicity, diagnosis or specific characteristics; sample size.
5. Intervention: details of the elements of any multi-component programmes (e.g. cognitive behavioural therapy, yoga), components of the intervention (e.g. mindfulness of breathing, body scan), length of the intervention, duration of

sessions, participant attendance, inclusion of a home practice component, implementation fidelity, targeted or universal delivery, delivery by school staff or external experts.

6. Control: other type(s) of school-based intervention or control group condition.

7. Methodological quality: details of study bias as outlined in [Assessment of risk of bias in included studies](#).

8. Outcomes: methods of measurement, self-report or third party ratings, time points for assessment, adverse effects, satisfaction.

9. Economic analysis: we will collect details of the characteristics and results of cost, resource utilisation, or cost-effectiveness studies. This will include details of study design, details of intervention and comparator, unit costs associated with interventions, discount rates, source(s) of resource use, decision-making jurisdiction, geographical and organisational setting, analytic perspective, and time horizon for both costs and effects. We will use price year and currency to calculate costs and incremental costs, as recommended by [Shemilt 2011](#).

Assessment of risk of bias in included studies

We will conduct and report a 'Risk of bias' assessment in accordance with the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2011a](#)) and the guidelines of Cochrane Consumers and Communication ([Ryan 2013](#)). The approach will involve a domain-based evaluation, in which we will make critical assessments across the following seven domains: sequence generation and allocation concealment (selection bias); blinding of participants and providers (performance bias); blinding of outcome assessment (detection bias); incomplete outcome data (attrition bias); selective outcome reporting (reporting bias); and other sources of bias (e.g. baseline imbalance between intervention and control groups, inappropriate influence of funders, or contamination between intervention and control groups). We will judge each item and outcome separately as being at high, low or unclear risk of bias, as set out in the criteria provided by [Higgins 2011a](#), and provide any relevant quotes from the study report and a justification for our judgement for each item in the 'Risk of bias' table. In all cases, two review authors (COT and MF) will independently assess the risk of bias of included studies. We will resolve any disagreements by discussion and consensus involving all review authors, as necessary. We will contact study authors for additional information about the included studies, or for clarification of the study methods, as required. We will incorporate the results of the 'Risk of bias' assessment into the review using standard tables or graphs, and systematic narrative description and commentary about each of the elements. With regard to the cost-effectiveness analysis, we will use the 'Drummond checklist' ([Drummond 1996](#)), in conjunction with the CHEERS (Consolidated Health Economic Evaluation Reporting Standards) checklist for economic studies ([Husereau 2013](#)), to critically appraise

the methodological quality of any included health economic studies (Shemilt 2011).

Measures of treatment effect

Dichotomous data

For any reported dichotomous or binary variables (e.g. presence or absence of anxiety symptoms), we will calculate risk ratios (RRs; Deeks 2011) and their 95% confidence intervals (CI), comparing the intervention to the control group for each included study.

It will sometimes be necessary to calculate odd ratios (ORs) rather than RRs, for instance, when studies report the same outcome using both dichotomous and continuous data (see below). However, we will transform the ORs into RRs for ease of reporting and interpreting the findings, using RevMan 5 (RevMan 2014).

Continuous data

For continuous data (e.g. scores on anxiety or depression scales, self-worth scales, etc.), we will calculate mean differences (MD) using means and standard deviations when studies employ the same outcome measures. When scales measure the same clinical outcomes (e.g. children's anxiety problems) in different ways, we will estimate standardised mean differences (SMD) or Cohen's *d* using RevMan 5's formula for SMD; this is based on Hedges' *g*, which includes an adjustment for small sample bias. We will use 95% CIs for individual study data and pooled estimates throughout.

If we cannot calculate MDs or SMDs using means and standard deviations, we will use other statistical tests (e.g. from *t* tests, *F* tests, or exact *P* values) when other appropriate data are available. If reports have insufficient data, we will request additional information from the study authors.

When some studies report an outcome as a dichotomous measure and others use a continuous measure of the same construct, we will first conduct two separate meta-analyses (one for ORs and another for SMDs). Next, in order to increase the statistical power of the meta-analyses, we will convert ORs to *d* indices (where *d* is the effect size used to indicate the standardised difference between two means), using the Cox formula (log OR divided by 1.65) (Sánchez-Meca 2003), and we will perform another meta-analysis that includes all possible studies. For studies that provide both dichotomous and continuous measures of the same construct, we will calculate study average effect sizes (ES) with Hedges' *g*.

When studies report the same outcome construct (e.g. level of anxiety) using both dichotomous and continuous data, we will transform the effect size metric with the smaller proportion into the metric with the larger proportion, using current Cochrane guidance for transforming ORs into SMDs and vice versa (Deeks 2011). This will allow us to analyse all effect sizes for that outcome category together.

Economic data

We will initially classify studies according to whether they are partial or full economic evaluations, that is, whether they include only resource-related costs or a more detailed cost-benefit analysis or incremental cost-effectiveness ratios (ICER). We will assess these studies for risk of bias using the Drummond checklist (Drummond 1996), before making a decision to pool any studies, particularly in relation to whether the metric in question has equivalent meaning across studies (Shemilt 2011). In circumstances where there is evidence of little variation in resource or cost use between studies, it may be regarded as legitimate to present a pooled estimate. Otherwise we will clearly present the distribution of costs (Shemilt 2011).

If we decide to conduct meta-analyses of resource use or cost data, this will be supported by a thorough critical appraisal of the methods used to derive such estimates within the corresponding health economics studies, alongside use of 95% CIs and statistical methods to investigate and incorporate between-study heterogeneity (e.g. *I*² statistic (Higgins 2003), *Chi*² test, random-effects models). We will adjust cost estimates collected from multiple studies to a common currency and price year before pooling these data. We will carefully consider the jurisdiction, analytic perspective and time horizon for both costs and effects.

Unit of analysis issues

Cluster-randomised trials

We will analyse any relevant cluster-RCTs that we identify using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011b). If cluster-RCTs are included, we will check for unit-of analysis errors (e.g. when the effects of clustering are not taken into account). If we find errors and sufficient information is available, we will re-analyse the data using the appropriate unit of analysis by taking account of the intracluster correlation co-efficient (ICC) and the design effect. Using this information, we will calculate an effective sample size (i.e. reduced sample size to take account of clustering). We will contact authors of included studies to obtain ICC estimates if these are not clearly available from the trial reports, or impute them using estimates from external sources (i.e. from a study of a similar population). If it is not possible to obtain sufficient information to re-analyse the data, we will report the effect estimate and annotate 'unit-of analysis error'.

Multiple treatment groups

When a study includes multiple, eligible treatment groups, we will calculate study effect sizes, using Hedges' *g* and standard errors for each treatment group, and conduct pair-wise comparisons of treatment versus control groups (Higgins 2011b).

Multiple publications

It is common for the findings of a study to be reported in more than one publication, or for a single publication to present the findings of multiple studies. Thus, we will take care to ensure that included studies are reporting independent findings. We will contact study authors to provide clarification, when necessary.

Dealing with missing data

Any meta-analysis will use data from all originally randomised participants when possible. If data are missing from the relevant comparisons, we will contact the study authors using email addresses on the study's publication. If there is no response via email, we will follow up with a telephone call, accessing telephone directories from the author's documented affiliated organisation. If data are available, we will conduct analyses that include the participants who were excluded by study authors. We will assess missing data and dropouts or attrition for each study and report this information in a 'Risk of bias' table. We will report numbers, reasons and characteristics of dropouts.

If the data can reasonably be assumed to be missing at random, we will proceed with analysing only the available data. We will not impute values. We will conduct sensitivity analyses when data cannot be assumed to be missing at random, attrition is higher than 20%, or where an appropriate intention-to-treat (ITT) analysis was not conducted in the primary study (see [Sensitivity analysis](#)). We will be guided by the definition provided in the *Cochrane Handbook for Systematic Reviews of Interventions* whereby an ITT analysis should aim to include all randomised participants in the trial regardless of what happened subsequently ([Higgins 2011b](#)). We will also describe, in the discussion, the extent to which the results might be biased by the missing data. In addition, we will use GRADE to report the extent to which the results might be biased by missing data ([GRADE Working Group 2004](#)).

Assessment of heterogeneity

We will assess the degree of heterogeneity by visually inspecting forest plots and by examining the I^2 statistic, a quantity that describes the approximate proportion of variation in point estimates that is due to heterogeneity rather than sampling error ([Higgins 2003](#)). This will be supplemented by the Q or Chi^2 test, where a P value lower than 0.10 indicates heterogeneity of treatment effects (i.e. studies do not share a common effect size) ([Deeks 2011](#)). In addition, we will estimate and present Tau^2 , along with its 95% CIs, as an estimate of the magnitude of variation between studies. This will provide an estimate of the amount of between-study variation. We recognise that statistical heterogeneity is likely given the clinical and methodological diversity that occurs in meta-analyses. We will discuss the possible reasons for observed heterogeneity and conduct subgroup analyses accordingly (we will consider issues of sample size and power in each study in our interpretation and reporting of the results). Details of further analyses to

investigate possible heterogeneity are provided below in the sections on [Subgroup analysis and investigation of heterogeneity](#) and [Sensitivity analysis](#).

Regarding the economic evaluations, we will give careful attention to whether the metric in question has equivalent meaning across studies before pooling the data ([Shemilt 2011](#)). Studies may vary by analytic perspective (i.e. they may include public sector costs of service provision as well as personal costs of attending services) or by type of costs reported (some restricted to costs to individual schools, others including a broader set of costs relating to school district or regions). We will not pool studies employing different analytic perspective or metrics. We will adjust cost estimates collected from multiple studies to a common currency using purchasing power parity and price year before pooling these data.

Assessment of reporting biases

If we identify 10 or more studies for inclusion, we will construct funnel plots to investigate any relationship between effect size and standard error. Such a relationship could be due to publication or related biases, or due to systematic differences between small and large studies. Any such relationships will be illustrated using the funnel plot method ([Egger 1997](#)).

Data synthesis

We will decide whether or not to conduct a meta-analysis based on whether the included studies are sufficiently similar in terms of participants, interventions, comparisons and outcome measures to ensure meaningful conclusions from a statistically pooled result. For data that can be combined, we will use MD or SMD effect sizes for outcomes on continuous measures and RRs for outcomes presented as dichotomous variables.

Due to the anticipated variability in the intervention (e.g. MBCT, multi-component programmes) and participants (e.g. age, gender) of included studies, we will use a random-effects model for meta-analysis ([DerSimonian 1986](#)). The random-effects model generally provides a more conservative result and takes into account the fact that various studies are estimating different, yet related, intervention effects.

We will use Mantel-Haenszel methods for combining binary outcome data across studies and use the inverse variance method for combining continuous data across studies.

We will calculate random-effects, weighted mean effect sizes for all studies using 95% CIs and display results in forest plots. We will use estimates of Cochrane's Q, I^2 , and Tau^2 to assess variability in the effect sizes. We will use endpoint data in these analyses ([Schünemann 2011a](#)).

We will combine cluster-RCTs with individual RCTs and then conduct a sensitivity analysis, removing any non-adjusted cluster trials (see [Sensitivity analysis](#)).

If we are unable to pool data, we will include a narrative summary of included studies, including the design and analytical viewpoints

adopted, the primary outcome measure used for the evaluation, resource use and unit cost data, and the generalisability of the conclusions drawn for other jurisdictions (Drummond 1996). We will organise this narrative summary into categories or clusters (e.g. types of intervention, types of participants) that best explore the heterogeneity of the studies.

Subgroup analysis and investigation of heterogeneity

We will assess and quantify inconsistency across studies using forest plots and the statistics described above. If there are enough available comparable data (i.e. at least 10 studies; Deeks 2011), we will undertake subgroup analyses using a random-effects model (DerSimonian 1986) in RevMan 5 (RevMan 2014). We have based the proposed subgroup analyses on the following issues that have emerged from the literature.

1. Age of children or young people. We will examine three groups to explore any age-related effects: early childhood (three to six years of age), middle childhood (seven to 11 years of age), and adolescence (12 to 18 years of age).
2. School type. To explore any differential effects, we will examine three different school types: disadvantaged schools, defined as schools located in areas of social deprivation (i.e. inner city, low socioeconomic status profile of enrolled children); non-disadvantaged schools (i.e. those not located in areas of disadvantage, including private or fee-paying schools); and designated special schools.
3. Targeted versus universal delivery. We will examine two groups: those in receipt of a universal, preventative mindfulness intervention versus those receiving a targeted intervention due to underlying diagnosis or specific characteristics.
4. Mode of delivery. We will examine whether delivery by school staff or external experts differentially impacts on the effectiveness of intervention.
5. Multi-component interventions. We will compare three different categories of mindfulness intervention: those that incorporate principles of cognitive behavioural therapy; those that include another form of traditional Eastern practice (yoga, tai chi, qigong); and stand-alone interventions (defined as those that do not incorporate any other type of practice or component).
6. Home practice. We will examine two groups: those that engaged in home practice (any amount) versus those that did not engage in home practice.

Sensitivity analysis

We will conduct sensitivity analyses to evaluate the robustness of the pooled effect sizes across various components of methodological quality, including:

1. randomisation versus quasi-randomisation;
2. combined cluster- and individual-RCTs with any non-adjusted cluster trials removed;
3. studies with blind assessment of outcomes versus those without blind assessment of outcomes; and
4. studies where missing participants cannot be assumed to be missing at random, with attrition rates larger than 20%, or where an appropriate ITT analysis was not conducted in the primary study.

Summary of findings

Based on the methods described in Chapter 11 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2011b), we will prepare a 'Summary of findings' table to present the meta-analysis results, using GRADEpro GDT 2015. We will present results for the main comparisons of the review (as outlined in the [Subgroup analysis and investigation of heterogeneity](#) section), for our three primary outcomes (psychosocial functioning, cognitive functioning and adverse effects) and two of our secondary outcomes (acceptability of the intervention, and costs and cost-effectiveness data), as outlined in the section on [Types of outcome measures](#). Using methods developed by the [GRADE Working Group 2004](#), two independent review authors will assess and rate the quality of evidence as high, moderate, low or very low, according to five criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Schünemann 2011b). These criteria are: the limitations of design (risk of bias tables), inconsistency (heterogeneity), indirectness, imprecision, and reporting or publication bias. If a meta-analysis is not possible, we will present the results in a narrative 'Summary of findings' table format (drawing on Chan 2011 as an example).

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* Indicates the major publication for the study

APPENDICES**Appendix I. Ovid MEDLINE strategy to find randomised and quasi-randomised studies**

- 1 Mindfulness/
- 2 mindful\$.tw,kw.
- 3 Meditation/
- 4 meditat\$.tw,kw.
- 5 MBSR.tw,kw.
- 6 MBCT.tw,kw.
- 7 Kabat Zinn.tw,kw.
- 8 "Body Scan".tw,kw.
- 9 "Soles of the Feet".tw,kw.
- 10 mind-body therapies/
- 11 yoga/
- 12 yoga.tw,kw.
- 13 tai ji/
- 14 (tai?ji or tai?chi or tai?qi).tw,kw.
- 15 breathing exercises/
- 16 Qigong/ (
- 17 (ch?i kung or qi?gong).tw,kw.
- 18 "Acceptance and Commitment Therapy".tw,kw.
- 19 Dialectical Behaviour Therapy.tw,kw.
- 20 or/1-19
- 21 exp child/
- 22 adolescent/
- 23 (child\$ or preteen\$ or pre-teen\$ or teen\$ or adolescen\$ or youth\$ or young people or boys or girls).tw.
- 24 Students/

25 pupil\$.tw. not (eye\$ or ophthalm\$).af.
 26 student\$.tw.
 27 Schools/
 28 Schools, Nursery/
 29 (school\$ or pre-school\$ or preschool\$ or kindergarten\$ or nurser\$ or classroom\$).tw.
 30 or/21-29
 31 20 and 30
 32 randomized controlled trial.pt.
 33 controlled clinical trial.pt.
 34 randomi#ed.ab.
 35 placebo\$.ab.
 36 drug therapy.fs.
 37 randomly.ab.
 38 trial.ab.
 39 groups.ab.
 40 or/32-39
 41 exp animals/ not humans.sh.
 42 40 not 41
 43 20 and 30 and 42

Appendix 2. Ovid MEDLINE strategy to find cost-effectiveness studies

1 Mindfulness/
 2 mindful\$.tw,kw.
 3 Meditation/
 4 meditat\$.tw,kw.
 5 MBSR.tw,kw.
 6 MBCT.tw,kw.
 7 Kabat Zinn.tw,kw.
 8 "Body Scan".tw,kw.
 9 "Soles of the Feet".tw,kw.
 10 mind-body therapies/
 11 yoga/
 12 yoga.tw,kw.
 13 tai ji/
 14 (tai?ji or tai?chi or tai?qi).tw,kw.
 15 breathing exercises/
 16 Qigong/
 17 (ch?i kung or qi?gong).tw,kw.
 18 "Acceptance and Commitment Therapy".tw,kw.
 19 Dialectical Behaviour Therapy.tw,kw.
 20 or/1-19
 21 exp child/
 22 adolescent/
 23 (child\$ or preteen\$ or pre- teen\$ or teen\$ or adolescen\$ or youth\$ or young people or boys or girls).tw.
 24 Students/
 25 pupil\$.tw. not (eye\$ or ophthalm\$).af.
 26 student\$.tw.
 27 Schools/
 28 Schools, Nursery/
 29 (school\$ or pre-school\$ or preschool\$ or kindergarten\$ or nurser\$ or classroom\$).tw.
 30 or/21-29

31 20 and 30
32 economics/
33 exp “Costs and Cost Analysis”/
34 economics.fs.
35 (economic\$ or cost or costs or costly or costing or price or prices or pricing).tw,kw.
36 (expenditure\$ not energy).tw,kw.
37 value for money.tw,kw.
38 budget\$.tw,kw.
39 or/32-38
40 31 and 39

CONTRIBUTIONS OF AUTHORS

Catriona O’Toole (COT) wrote the text of the protocol with input and amendments advised or provided by all members of the review team (Mairead Furlong (MF), Sinéad McGilloway (SMcG), and Arild Bjørndal (AB)).

COT and MF developed the search strategy.

COT has overall responsibility for the review.

DECLARATIONS OF INTEREST

Catriona O’Toole - none known.

Mairead Furlong - none known.

Sinead McGilloway - none known.

Arild Bjørndal - none known.

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