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School-based self management interventions for asthma in children and adolescents: a mixed methods systematic review (Protocol)

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[Intervention Protocol]

School-based self management interventions for asthma in children and adolescents: a mixed methods systematic review

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

This review has two primary objectives.

- To assess the effects of school-based interventions for improvement of asthma self management on children's outcomes.
- To identify the processes and methods that are aligned with effective and non-effective interventions.

BACKGROUND

Description of the condition

Asthma is a chronic respiratory condition characterised by bronchoconstriction, airway inflammation and mucus hypersecretion leading to variable airflow limitation. Symptoms include wheeze, dyspnoea, cough and tightness in the chest. No definitive diagnostic 'test' is available for asthma; instead asthma is diagnosed through clinical assessment performed to evaluate respiratory symptoms and response to pharmacotherapy; evidence of reversible airflow limitation with use of pre-bronchodilator and post-bronchodilator spirometry; or evidence of airway hyperresponsiveness with direct or indirect challenge (Levy 2014). Asthma is the most common chronic disease among children (Neuzil 2000; To 2012). At any time, more than a million children (one in eleven) in the UK are thought to be living with asthma (Asthma UK 2013), although this number and the number of children experiencing asthmatic symptoms may be greater. Many countries report high prevalence rates of childhood asthma. Although considerable variation has been noted, the ISAAC study found the highest prevalence of childhood wheeze in Latin America and North America and in English-speaking countries in Australasia and Europe

(Asher 2006). Much of the extant evidence on asthma interventions derives from North America; here, prevalence among six- to seven-year-olds stood at 21.5% and 16.7% for boys and girls, respectively, and at 19.8% and 23.3% among children 13 to 14 years of age (Mallol 2013). More children will have the experience of living with asthma than current prevalence levels reflect, for example, among children seven years of age, 16% had experienced asthma at some point in their lives (Kneale 2010), and these estimates increased to one in five among children 12 to 14 years of age (Kaur 1998).

Risk of asthma is not uniform among children; several characteristics are known to be variable. In the UK, children from Caucasian and African ethnic backgrounds are thought to be at higher risk than children from South Asian backgrounds (Netuveli 2005), although substantial variation has been found within these broad groupings (Kneale 2010). Successful management of asthma among UK children reflects broader indicators of social position and socioeconomic status: Although South Asian children may be at lower risk of asthma, they, along with black children, are at higher risk than white children of admission following asthma complications (Netuveli 2005). A systematic review of socioeconomic status and health outcomes found evidence to suggest that risk of developing asthma was higher amongst children in the UK from lower-income families (Spencer 2012). Overall, the UK government estimates that a billion pounds is spent annually through the National Health Service on the treatment and prevention of asthma among adults and children (Department of Health 2012).

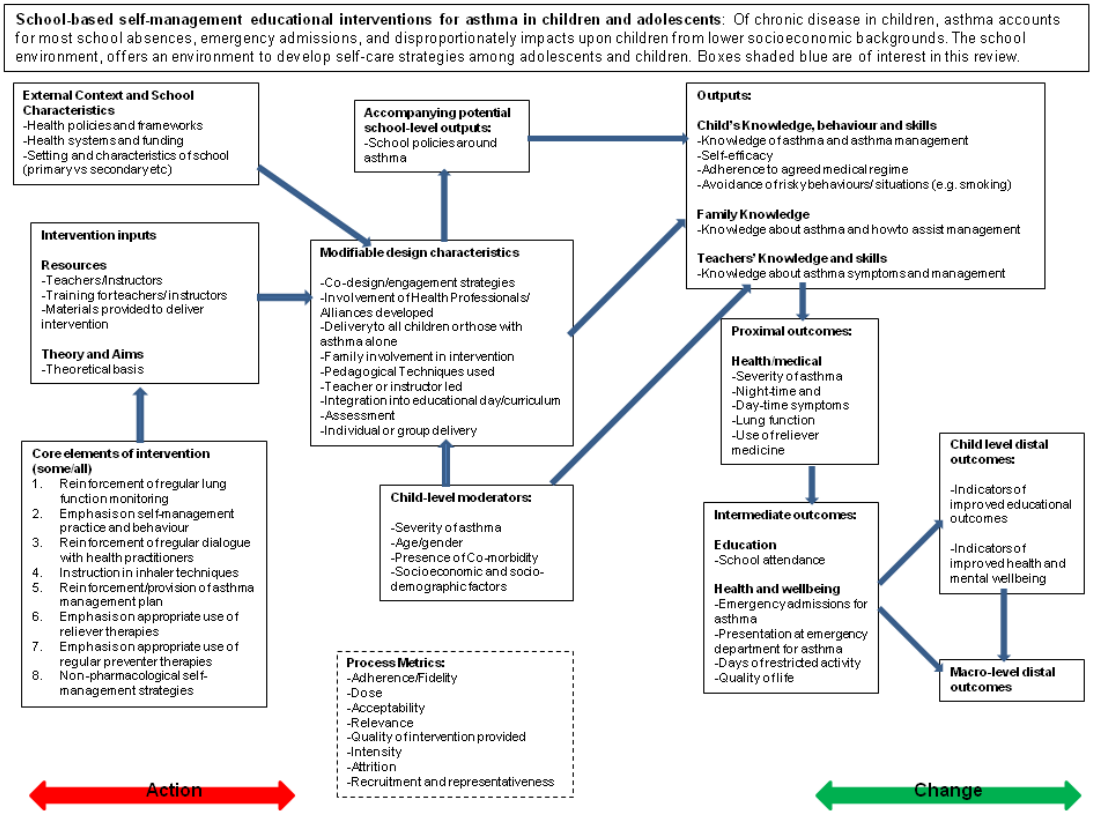
Description of the intervention

The central purpose of this review is to analyse research papers that include a school-based self management intervention for children with asthma. Self management is the goal of the systematic process of educating and enabling patients to control their asthma symptoms, thereby preventing future exacerbations (Kotses 2010); self management is a cornerstone of treatment for patients with asthma (Bateman 2008). Asthma control refers to the degree to which asthma symptoms can be observed and subsequently improved with treatment (GINA 2014). Well-controlled asthma consists of reduced daytime and night-time symptoms, decreased long-term morbidity and diminished risk of life-threatening asthma attacks (Juniper 2006). Asthma control improves with age among children; one study reported excellent or satisfactory control in 38% of children four to six years of age and in 66% of children 13 to 16 years of age (Kuehni 2002).

Most asthma self management interventions involve improving knowledge of asthma and promoting asthma control; in contrast to self care (looking after oneself in a healthful way [NHS Choices 2014]), self management encourages an alliance between the physician or healthcare professional and the patient for the purpose of managing asthma (Kotses 2010). The school is a good site for teaching asthma self management techniques among children for several reasons, including the familiar environment for learning that it provides for children, and the potential for identification of large numbers of children with asthma at a single location (Ahmad 2011; Bruzzese 2009; Coffman 2009). This focus on the school is echoed among advisory groups to UK policymakers, who view the integration of health and educational (and social care) services as critical in improving the quality of life of children with long-term conditions such as asthma, and in reducing differentials in outcomes such as school attendance (Lewis 2012).

Absence from school constitutes one of the main indirect costs of childhood asthma, while the costs of hospitalisation and of asthma medication account for most of the direct costs (Bahadori 2009). Although delivery of an asthma self management intervention in schools may hold potential for reducing asthma burden, uncertainty remains as to the effectiveness of this approach across various proximal, intermediate and distal outcomes (see Figure 1 for examples). Furthermore, although the intervention setting may represent a common thread between studies, several factors could influence intervention success. These factors reflect variations in treatment settings and populations, and in the ways in which school-based asthma interventions and intervention components are delivered, as well as the role of intervention mediators such as changes in school-level policies around asthma or asthma medication (Al Aoola 2014).

Figure 1. Logic Model of School-based Asthma Interventions.



How the intervention might work

Previous reviews of self management interventions among children with asthma have found these to be positively associated with moderate improvements in lung function, school absenteeism, emergency visits to hospital and self efficacy (Guevara 2003); other reviews have found that targeted interventions can lead to reduced hospital admissions among those at risk of hospitalisation (Boyd 2009). Participants in both of these reviews were children from birth to 18 years of age with a diagnosis of asthma. Guevara and colleagues (2003) excluded children with a pulmonary diagnosis other than asthma. No participant co-morbidities were noted in either study. Many reviews suggest that educational interventions delivered to children with asthma can be effective; however, these reviews have considered interventions delivered within schools alongside those delivered in other settings, including clinical and home settings (e.g. Smith 2005; Wolf 2008), and some reviews point to lack of consensus around the optimal setting for asthma intervention (Welsh 2011). To date, two systematic reviews have taken place to evaluate the evidence for interventions delivered exclusively within the school environment. These reviews reported similar results in terms of positive impact on school absenteeism, but provided less conclusive evidence on the impact of health outcomes such as hospitalisation (Ahmad 2011; Coffman 2009). One extant review is examining outcomes for primary school age children only (Al Aloola 2014).

Furthermore, extant reviews rarely include analysis of accompanying process-level measures, such as changes in school policy, in part because they have used searching strategies that do not include a focus on process evaluation. Analysis of such process measures would further illuminate the modifiable components of interventions that may be most critical in determining the success (or failure) of interventions, and in mapping out the diversity of processes undertaken as part of the intervention.

Reviews of asthma self management interventions among adults highlight the importance of gaining a deeper understanding of accompanying process measures, for example, Denford and colleagues (2013) found that active involvement of participants was associated with greater effect sizes, but that a pedagogical focus on stress management techniques was potentially counterproductive (Denford 2013). Previous studies have tended to focus on child-

level moderators; consequently the impact of different intervention components of school-based asthma interventions aimed at children on study heterogeneity is relatively unknown. . Some of the hypothesised components that may be influential are outlined in our logic model in Figure 1, which was developed by the protocol authors, although our analysis plan involves gaining a deeper understanding of these processes and how they contribute to (1) successful intervention implementation; and (2) effect size. Intervention implementation outcomes are mainly represented in Figure 1 as 'process metrics', although others may be identified during the course of our analyses. Other components of the 'action' part of the logic model include the external school context, inputs provided and already in place to run the intervention and the actors involved in delivering and receiving the intervention. The 'change' part of the model depicts stages of change and processes necessary to reach intended outcomes. We constructed the logic model by identifying our outcomes of interest and then working backwards to identify the changes and stimuli that may be necessary to reach those outcomes. Use of a logic model in this way helped to distinguish between outputs of the intervention and outcomes, and assisted us in identifying the types of data that may need to be captured is we are to gain an understanding of intervention components and implementation processes. This matches our overall objectives in terms of identifying both the impact of school-based asthma interventions and the components and circumstances associated with change and impact.

This proposed review expands on an earlier Cochrane protocol that was published (Lasserson 2010) and has been withdrawn. The new proposal differs in these ways: (1) It includes a focus on the processes undertaken during implementation of school-based asthma interventions, which will be synthesised using qualitative-based methods; and (2) it is linked to a planned trial that is taking place among schools in London, where the review team will work with trialists to incorporate into the trial design learnings attained from the review.

Why it is important to do this review

Children who experience an asthma exacerbation are at risk of hospitalisation and death. Of the 65,000 hospitalisations for asthma occurring in 2011/12 in the UK, more than a third (38%) involved children (aged birth to 14 years); moreover in an in-depth study of asthma deaths, 14% of confirmed deaths from asthma in the UK occurred among children and young people 20 years of age and younger (Levy 2014). Effective self management of asthma could reduce levels of hospitalisation, which may positively impact the financial implications of asthma and improve outcomes for children and adults with asthma.

Living with asthma can impact many other child health and social outcomes as well, and asthma, particularly severe asthma, has been found to be co-morbid with several developmental, emotional and behavioural problems (Blackman 2007). Some studies suggest that children with asthma are disadvantaged in terms of their peer relationships (and are more likely to be bullied). Moreover, they are more likely to experience limited participation in activities as the result of dyspnoea and other asthma-related symptoms (Van Den Bemt 2011).

Children with asthma have poorer school attendance rates than their peers (Rodriguez 2013). One US study suggests that children living with asthma miss an average of 1.5 additional days of school annually compared with their peers, and increased asthma severity was associated with an increase in the number of days absent from school (Moonie 2006). Furthermore, average school days missed masks large heterogeneity in experience, which is worsened by the fact that some children miss a large number of school days as the result of asthma. A London-based study conducted a survey among 284 parents of children with asthma and found that school absence due to wheezing illness was reported by 58%. Moreover, 12% of parents reported that their child missed more than 30 days of school as a result of their asthma (Anderson 1983). A later study, looking at the impact of chest problems including wheeze and cough on school absences among children in Southampton, presented data suggesting that around a quarter of children diagnosed with asthma (23%) missed more than five days of school because of chest problems, compared with 4% among children who had not been diagnosed with asthma (Doull 1996). School absenteeism may contribute towards poorer relationships of children with asthma with their school colleagues, as well as lower academic achievement. Additionally, grade failure has been found to be more frequent amongst children with asthma (Fowler 1992). Educational differentials may be amplified among children from lower socioeconomic groups and/or ethnic minority groups (Milton 2004). Similar lines of disadvantage also influence patterns of service usage, with children from some ethnic groups more likely than others to report asthma-related hospitalisation (Netuveli 2005); this may reflect naturally occurring morbidity patterns, or in fact may indicate the success of self management. Given that the school environment offers a platform by which children from all socioeconomic backgrounds can receive the same asthma self management interventions, delivery of interventions at this level could reduce inequalities in self management, thus helping to level the differences between outcomes of children with asthma and their peers.

Schools have been identified as effective sites for delivery of asthma self management interventions because the school environment is commonly associated with learning of new skills. However, 'school age' (usually five to 18 years old) spans a wide spectrum of child development stages, and consequently represents different pedagogical needs and variable responses to self management interventions. Understanding processes of implementation (and their success) is essential for development of mechanistic theories of how and why interventions work, which can be understood in the context of the child's characteristics. Among reviewers, this approach can help to convert the logic model (Figure 1) into a causal the-

ory of change model, with the latter including specifications of underlying assumptions on 'how' and 'why' the implementation of different components and groups of components can lead to variations in intervention implementation and outcome success among diverse groups of children.

This review places strong emphasis on documenting and understanding the different processes that occur during school-based asthma interventions. This approach will help us to understand the different mechanisms involved and will allow us and future trial implementers to consider the generalisability of the processes and outcomes described and measured. Results of this review will be used directly to inform the development of a school-based asthma intervention now taking place in secondary schools in the UK.

Although levels of hospitalisation for asthma among children may be low in London (based on data from 2010/11 for Primary Care Trusts), levels of hospitalisation for adults with asthma exhibit a different trend, with disproportionately high levels reported in several areas of London (Department of Health 2012). Such a difference between child and adult patterns of hospitalisation could be indicative of many factors, but given that most people are diagnosed with asthma during childhood (e.g. Yunginger 1992), a potential explanation could include deficiencies in the development or implementation of self management skills acquired during childhood among people living with asthma. Globally a large proportion of asthma patients do not receive self management education in primary care, and in England, more than a quarter of people (adults and children) living with asthma have not received an asthma review in the previous 15 months (HSCIC 2014). Similarly, the Australian Centre of Asthma Monitoring reports that many patients with asthma are not under the regular care of a general practitioner (GP). An analysis of Australian GP consultations found that only 54% of 396 patients with asthma who had visited the GP in the past 12 months had their asthma managed on at least one occasion. Of the 171 patients who had not had their asthma managed by a GP in the previous 12 months, 70.2% stated that it had been longer than two years since such management was provided by their GP (Australian Centre for Asthma Monitoring 2011). These data suggest that many patients may not have access to services that enable them to master asthma self management, which is a cornerstone of effective asthma management. Moreover, inadequate knowledge of the condition and patient non-adherence with clinician recommendations for asthma treatment (e.g. overuse of long-acting beta$_2$-agonists, under-use of inhaled corticosteroids) may contribute towards poor asthma management amongst children (Piecoro 2001; Walsh 1999).

This review will serve as an exemplar along several dimensions. First, it will contribute towards furthering understanding of the processes and efficacy of self management education for children. This will be achieved by synthesising the evidence using recognised and robust quantitative or qualitative methods. Another worthy feature of this review is the implementation of a mixed methods approach, reflecting the need to generate testable hypotheses of the underlying mechanisms of implementation and change based on findings within the literature. Although other reviews have set out to include a mixed methods approach (Hurley 2013; Husk 2013), this will be among the first to also consider how the results are generalisable to trialists in real-world settings. As we elaborate in later sections, this review will serve as a model through its use of qualitative comparative analysis (QCA) to analyse different configurations of components. We intend to make active use of the logic model (Figure 1) to help structure and synthesise review findings, in accordance with the practices described in previous reviews (Glenton 2013). This review will be among the first to adhere to Cochrane standards and to use EPPI-Reviewer 4 software (Thomas 2010) (EPPI-Reviewer is part of the Cochrane CAST programme and will be linked with Archie during 2015; this review may be one of the first to use this link). Finally, in addition to the points outlined earlier, results of this review will be used directly to inform the development of a school-based intervention, which will involve the review author team. Results of this exercise will contribute towards an understanding of the types of evidence that are most appropriate in directly informing trial design.

OBJECTIVES

This review has two primary objectives.

- To assess the effects of school-based interventions for improvement of asthma self management on children's outcomes.
- To identify the processes and methods that are aligned with effective and non-effective interventions.

METHODS

Criteria for considering studies for this review

Types of studies

This study represents an investigation of (1) the impact of school-based asthma interventions across different student populations and school environments, and (2) the processes aligned with intervention success.

Assessing the impact of school-based asthma interventions across different student populations and school environments

For assessment of children's outcomes and the impact of school-based asthma interventions, we will include only those studies with a randomised parallel-group design and clustered-randomised controlled trials.

Identifying the processes aligned with intervention success

We will address this second aim using meta-analysis and qualitative comparative analysis (QCA), which allows us to extract evidence from two sets of literature.

- For assessment of process-related outcomes and factors in meta-analyses, we will include in our outcomes assessment any linked 'sibling study' of those included above.
- We will consider a broader set of studies that measure process-level factors for inclusion in our main meta-analyses, as well those that do not. These processes can be described and later analysed using QCA. We will include studies that use any recognised qualitative methods of data collection from any discipline or theoretical standpoint, as well as studies that collect or analyse process-related outcomes by using recognised quantitative instruments or tools.

We will impose criteria around the date on which studies were published to help ensure that the content of self management interventions will be broadly relevant to today's recommendations. Recommendations around the management of asthma in the UK were first developed in 1990 on the basis of articles that had appeared in *British Medical Journal* and *Archives of Diseases in Childhood* from 1989 onwards (British Asthma Guidelines 1997) and were developed in the USA around the same time (National Institute of Health 1997); therefore we will exclude studies that pre-date the impetus around developing guidelines for the management (and self management) of asthma, and we will include only studies published from 1995 onwards (corresponding with publication of the first Global Initiative for Asthma (GINA) guidelines, which provided a foundation for asthma guidelines globally). We will include only studies published in English. Current evidence around the introduction of potential bias through restrictions on publication language is mixed, with some recent studies finding no systematic bias on effect size estimates when languages other than English were excluded (Morrison 2012), although many remain concerned that the results of ineffective trials will be submitted to local (non-English language) journals, leading to the potential for language restrictions and systematic bias (Guyatt 2011). To assess the potential impact of this type of bias, we will conduct sensitivity analyses, as described later.

Types of participants

Participants will include school-aged (five-year-old to 18-year-old) children and young people with diagnosed asthma who participate in the intervention within the school environment (Al Aloola 2014). When the intervention includes young people and adults (e.g. when it is provided in colleges with pupils 16 to 24 years of age), these studies will be included only if most participants are 18 years of age or younger. Interventions may also include some components that are delivered to peers, teachers and/or parents and families, although they must involve at least partial delivery of the intervention to school-aged participants with asthma within school environments. We will include studies looking at children and young people with intermittent or mild (diagnosed) asthma through to severe or persistent asthma.

We will conduct subgroup analyses to assess the effects of these interventions in Organisation for Economic Co-operation and Development (OECD) countries. We will not impose criteria over the types of educational establishments that will be included in our scope, as long as the establishment represents the physical location where intervention participants receive most of their education.

Types of interventions

We will select interventions that aim to develop and enhance self management of asthma among children through at least one or all of the following components.

- Increasing knowledge of asthma and its management.
- Enhancing self management skills.
- Improving self management behaviours and practice.

Among studies that seek to improve asthma self management skills, behaviour and/or knowledge, the intervention should include the active transfer of information around at least one of the aspects of asthma self management outlined below. However, we recognise that for asthma self management to be effective, a combination of these must be incorporated into the interventions.

- Reinforcement of regular monitoring of lung function.
- Emphasis on the importance of self management practice and behaviour.
- Development of a partnership/alliance between patient and primary care/healthcare practitioners (including school nursing staff) for the management of asthma.
- Instruction on inhaler techniques.
- Reinforcement/provision of an individualised written asthma management plan.
- Emphasis on the importance and appropriate use of reliever therapies such as beta$_2$-agonists (BTS 2014).
- Emphasis on the importance and appropriate use of regular preventer therapies such as inhaled corticosteroids and combination inhaled corticosteroid and long-acting beta$_2$-agonist therapies (BTS 2014).
- Non-pharmacological self management strategies focused on avoiding or reducing the risk of experiencing asthma or asthma attacks, including lifestyle and behavioural modifications (as set out in BTS 2014).

Asthma treatment is standardised across all individuals with asthma over the age of five years (BTS 2014). Treatment for asthma

is prescribed on the basis of asthma severity. Treatment differs for younger children, who may be prescribed lower doses.

Eligible studies will be those that include in the intervention children and young people with asthma. However, the intervention could also include improving knowledge and support behaviours among others, although these are not considered as the main outcomes of interest. Outcomes of interventions that include children with and without asthma will be included only when the outcomes primarily represent those of children with asthma or when the outcomes of children with asthma alone are presented or can be extracted from studies of the following:

- Parents/guardians/family members.
- Teachers and school staff.
- Peers.

Studies may focus on improving the climate for asthma self management within schools, for example, by changing school policies around the way that teaching staff may assist in asthma self management. However, studies that do not include the development of asthma self management skills and behaviours among children will not be eligible.

The intervention could be provided by a trained educator, nurse (including school, practice or community nurse), doctor or physician, peer or social worker, and most delivery or access must be undertaken on the premises of the school attended by the pupils. Interventions for which the school setting is not instrumental in delivery will not be eligible for inclusion.

Comparison

Usual care or a self management or health intervention with a focus other than asthma. Comparison groups will include the same parameters in terms of study population and delivery site.

Types of outcome measures

Our primary outcomes are based on those identified as indicators of good asthma control (BTS 2014), represented as intermediate outcomes in Figure 1. We are also interested in several other secondary outcomes (represented as proximal and intermediate outcomes in Figure 1, as well as a measure of acceptability in withdrawals from the intervention).

Primary outcomes

- Exacerbations leading to admission to hospital (children with one or more admissions or admission rates).
- Asthma symptoms leading to emergency hospital visits.
- Parent-reported absence from school.
- Days of restricted activity.

Secondary outcomes

- Unplanned visit to hospital or GP due to asthma symptoms.
- Experience of daytime and night-time symptoms.
- Lung function (e.g. forced expiratory volume in one second (FEV_1) in clinic, peak flow at home).
- Use of reliever therapies such as $beta_2$-agonists.
- Corticosteroid dosage and/or use of add-on therapies (e.g. long-acting $beta_2$-agonists (LABAs) or leukotriene receptor antagonists (LTRAs)).
- Health-related quality of life (HRQoL) as measured by a validated questionnaire.
- Withdrawal from the study.

When outcomes reflect how children (or their families/carers) function or feel in relation to their asthma and its management (patient-reported outcomes), which may be seen in measures around HRQoL and to a lesser extent days of restricted activity, we will prioritise those measures when evidence around validation, reliability and in particular responsiveness is found. We will extract data for all points at which the outcomes above were measured and will pool data as appropriate (e.g. by stratifying analyses by post-test vs follow-up measures).

In line with our first objective, we are also interested in where interventions were successfully implemented and the underlying processes surrounding these. A measure of successful intervention implementation is included above in our secondary outcomes as withdrawal from the study, although other process outcomes such as acceptability may be analysed as part of our QCA. These are represented in Figure 1 as process metrics.

Methodological problems may occur, as different studies may measure asthma severity in different ways. The review team will consider asthma severity as it is defined by the GINA guidelines (e.g. through the presence of daytime and night-time symptoms and FEV_1 measures); however some research papers may measure severity through assessment of asthma control (e.g. using the Asthma Control Test). We will include common components from both asthma severity and asthma control measures.

Search methods for identification of studies

Electronic searches

We will search the Cochrane Airways Group Specialised Register (see Appendix 1) for trials, using the strategy included in Appendix 2, which was developed by the Trials Search Co-ordinator (Liz Stovold).

Searching other resources

As we will additionally search for process evaluations for our qualitative analyses, we intend to expand the breadth of the search for

process evaluation studies of school-based asthma interventions, in accordance with guidance set out by the Cochrane Qualitative and Implementation Methods Group (Booth 2011). Therefore in addition to the searches above, we will conduct similar searches using the databases below. These searches will be based on the search criteria included in Appendix 1, although they will be modified to account for the different search syntax/parameters used in additional databases. For example, although Medical Subject Heading (MeSH) terms are included in the main search strategy, these will take the form of thesaurus terms in some of the databases listed; we will record all modifications in the final report.

- Database of Promoting Health Effectiveness Reviews (DoPHER).
- Cochrane Database of Systematic Reviews (CDSR).
- Database of Abstracts of Reviews of Effects (DARE).
- The Campbell Library.
- National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme website/journals library.
- Health Technology Assessment (HTA) database.

We will apply these search strategies for a comprehensive search of the following clinical, public health, psychology and social care databases from 1995 to the present*.

- Applied Social Sciences Index and Abstracts (ASSIA).
- BiblioMap (EPPI-Centre Database of Health Promotion Research)
- Cochrane Database of Systematic Reviews (CDSR).
- Cochrane Central Register of Controlled Trials (CENTRAL).
- Health Management Information Consortium (HMIC).
- International Bibliography of the Social Sciences (IBSS).
- National Health Service Economic Evaluation Database (NHS EED).
- PubMed.
- Sociological Abstracts (SOCABS).
- Social Policy and Practice (SPP).
- Social Services Abstracts
- Web of Knowledge.

We will also handsearch Google Scholar, Social Policy Digest and other sources such as the British Thoracic Society and Asthma UK for further studies.

We will identify integral process evaluations (sibling studies) through backwards and forwards citation searches initially; we will also write to the authors of included trials to request process evaluations that they may have undertaken. We expect that multiple process evaluations will be available for single-outcome/impact studies; our strategy also allows for inclusion of process evaluations (provided they pass our screening criteria) without linkage to a trial included for quantitative analyses.

*MEDLINE, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), EMBASE, Allied and Complementary Medicine Database (AMED) and PsycINFO will be included within the Cochrane Airways Group Specialised Register search.

Data collection and analysis

Selection of studies

We will apply inclusion and exclusion criteria successively to titles, abstracts and full reports. We will obtain full-text reports when studies appear to meet the criteria for title and abstract, or when information is insufficient for a decision. In the literature that examines outcome measures, screening criteria will cover populations (children five to 18 years of age), disease status (diagnosed asthma), interventions (school-based and focused on self management), comparators (school-based and lower intensity/usual care), study design (randomised controlled trials), date (publication year after 1995 (year first Global Strategy for Asthma Management and Prevention was developed)) and language (English language). We will apply inclusion criteria successively to titles and abstracts. We will enter information from these full-text reports into EPPI-Reviewer and will reapply the inclusion and exclusion criteria; we will include in the review studies that meet these criteria. We will develop a similar set of inclusion criteria for process evaluation studies covering populations (children five to 18 years of age), disease (diagnosed asthma), interventions (school-based and focused on self management), date (publication year after 1995 (year first Global Strategy for Asthma Management and Prevention was developed)) and language (English language); however we will include additional criteria in the full-text screening to filter out studies that do not evaluate intervention processes.

In piloting the screening criteria, the review authors involved in study screening (DK and KH) will take part in a moderation exercise whereby results are discussed to ensure consistency in applying the review exclusion criteria. Disagreements will be discussed and, if necessary, will be resolved by senior members of the review team. We will calculate and report measures of inter-rater agreement (percent agreement and Cohen's kappa). A 90% agreement rate will be required before we proceed to independent screening. Following pilot screening and moderation, review authors (DK and KH) will independently screen all remaining titles and abstracts.

Data extraction and management

Data management

We will upload records of the research identified by searches to the specialist systematic review software, EPPI-Reviewer 4, for duplicate stripping and screening (Thomas 2010). This software will record the bibliographic details of each study considered by

the review, the origins of studies (including search strings) and reasons for their inclusion or exclusion. We will first extract all data into EPPI-Reviewer 4 and will later export them, as appropriate, into other software for synthesis (RevMan 2014/STATA etc.).

Outcome measures - data extraction

Two review authors (DK and KH) will independently extract study characteristics and numerical outcome data from studies meeting eligibility criteria of the review. We will resolve discrepancies by discussion in 'agreement meetings'; disagreements that cannot be resolved by discussion will be arbitrated by senior members of the review team and agreements reached.

Process evaluation measures - data selection

As our focus here is specifically on the effectiveness of schools as the delivery setting for self management interventions, we will prioritise measures that reflect modifiable aspects of delivery at the school level as our primary process measures above those that evaluate other implementation factors such as acceptability and fidelity. Our primary process-level measures are likely to include those listed below (represented as modifiable design characteristics in the logic model). However, further conditions with greater explanatory power may be identified during the course of the analyses.

Intervention design factors

- Type of intervention instructor (e.g. teacher, peer, healthcare professional).
- Pedagogical technique(s) used (e.g. problem-based learning).
- Composition of intervention participants (only children with asthma or with teachers/peers/family).

School-level factors

- Presence of/change in internal school policies in support of an intervention (e.g. around storage of medication).
- Resources and support available (e.g. active role for school nurse).
- Teachers' engagement and perceptions.

Alliances and engagement

- Relationships/alliances with primary care providers.
- Relationships/alliances with parents/family.
- Relationships/alliances with teachers.

Our secondary process-level factors will include factors reflecting other implementation factors such as children's satisfaction with the intervention (acceptability) and their attendance at and participation in sessions (fidelity). For qualitative studies consisting of integral process evaluations, findings will relate to the context, components and processes of interventions, both positive and negative, as reported by those delivering and participating in school-based asthma interventions. Data in the form of key themes and concepts related to primary and secondary measures of interest will be extracted.

Process evaluation measures - data extraction

Two review authors (DK and KH) will independently extract process evaluation measures of interest (including quantitative data when available) from studies that meet the eligibility criteria of the review and will code this information; senior members of the review team (JT, TL, VM, JG) will resolve disagreements in coding. In the case of qualitative and 'views' data, we will prioritise extracting participants' quotes verbatim first, followed by the study authors' narrative and analysis.

Assessment of risk of bias in included studies

We will assess the following sources of bias in terms of how they are deemed to affect the results of an individual study.

- **Sequence generation:** Studies that use a computer-generated allocation procedure, a random number table or other recognised low-risk means will be deemed to be at low risk of bias (as advised by the tool of The Cochrane Collaboration for assessing risk of bias). Studies that use procedures such as clinic visit date or date of birth when the order of treatment group assignment is predictable or open to external influence will be deemed to be at high risk of bias. For cluster-randomised studies, timing of assignment in relation to recruitment of the cluster (the school or the classroom) will be taken into consideration. We will describe studies for which we are unable to ascertain methods of randomisation and allocation as having risk of bias that is 'unclear'. Given the potential impact of socioeconomic imbalance between cluster sites within the same study, we will also consider whether stratification on socioeconomic variables was undertaken.
- **Allocation concealment:** Studies for which measures were taken to prevent disclosure of treatment group assignment, such as off-site allocation or allocation by a third party not involved in the study, will be deemed to be at low risk of bias. For cluster-randomised studies, an additional consideration is timing of recruitment into the study in relation to assignment. If clusters are recruited after treatment group assignment is known, they will be considered at high risk of bias.
- **Blinding (performance bias and detection bias):** Studies for which measures were taken to ensure that personnel collecting data were unaware of participants' treatment group assignment will be deemed to be at low risk of bias. However, given the nature of the intervention and the difficulty involved in blinding recipients, a degree of performance bias may impact

outcomes in some studies.

- **Handling of missing data and attrition:** Studies for which data sets are complete, or for which reasons for missing data are not related to treatment, will be deemed to be at low risk of bias. When attrition rates are particularly high or imbalanced and unexplained, and only an available case set is presented, the study will be deemed to be at high risk of bias. Studies for which the attrition rate is not reported separately for treatment and control groups, and for which we are unable to determine satisfactorily the reasons for withdrawal, will be deemed at high risk of bias.
- **Selective reporting:** We will restrict assessments of selective reporting to examination of the availability of data related to outcomes included in the 'Summary of findings' table.
- **Other bias:** We will examine **baseline imbalances** in the characteristics of participants (see also the first point around stratification) for potential bias. For studies that do not cluster at the school level, we will also look for evidence of contamination between intervention and control groups. We will restrict sensitivity analysis to primary outcomes of the review, and we will derive overall judgements for each study at the outcome level (see *Cochrane Handbook for Systematic Reviews of Interventions*).

We will assess the quality of process evaluation studies using elements of two tools. The first tool was developed at the EPPI-Centre (Harden 2004) to assess the methodological rigour of 'views' studies - those studies aiming to collect information on people's experiences from trials - and considers whether findings are grounded in the data and reflect people's views. This tool considers seven criteria, including (1) whether the study includes an explicit theoretical framework and/or literature review; (2) clearly stated aims and objectives; (3) a clear description of context; (4) a clear description of the sample and how it was recruited; (5) a clear description of methods used to collect and analyse data; (6) attempts made to establish the reliability or validity of data analysis; and (7) inclusion of sufficient original data to mediate between evidence and interpretation. The second tool, which was developed by the EPPI-Centre to assess the quality of process evaluation data as part of an existing review (O'Mara-Eves 2013), assesses (1) methods of data collection; (2) a description of process evaluation participants; (3) timing of the process evaluation with respect to the intervention; (4) process evaluation data collection methods; (5) process evaluation data analysis methods; (6) whether findings were supported by data; (7) breadth and depth of findings; (8) the extent to which the process evaluation gave privilege to the views of participants; (9) reliability of findings; and (10) usefulness of process evaluation. As some of these domains overlap, elements from both tools will be combined to assess the quality of process measures. This strategy also covers the main domains set out in the Cochrane Qualitative Methods Group guidance for appraising the quality of qualitative research (Hannes 2011).

Assesment of bias in conducting the systematic review

We will conduct the review according to this published protocol and will report deviations from it in the 'Differences between protocol and review' section of the systematic review.

Measures of treatment effect

Continuous data

As set out in the *Cochrane Handbook for Systematic Reviews of Interventions*, we will calculate mean differences (MDs) when continuous data were measured by the same scale or unit. When similar outcomes were measured by different scales or units, we will use standardised mean differences (SMDs) (Hedges' (adjusted) *g*).

Dichotomous data

For dichotomous (binary) data, we will calculate odds ratios (ORs), and when appropriate, we will combine results from different trials.

Ordinal data

As set out in the *Cochrane Handbook for Systematic Reviews of Interventions* (9.2.4) (2008), we will analyse ordinal outcomes (such as quality of life scales) as continuous variables, or when appropriate thresholds are identified, we will analyse them as dichotomous variables.

Count data

We will calculate rate ratios for any count data we encounter that represent the ratio of events experienced between two groups, such as episodes of hospitalisation or absences from school.

Unit of analysis issues

Cluster-randomised studies

We will include cluster-randomised controlled trials in which schools or classes within schools rather than individuals with asthma are the unit of allocation. As variation in response to treatment between clusters may also be influenced by cluster membership, meaning that cluster members' data can no longer be considered independent of one another, we will extract data when study authors have undertaken analysis that properly adjusts for a clustered design. However, only around three-fifths of cluster-randomised trials account for clustering in their analyses, and even fewer do so when calculating their sample sizes (Eldridge 2004).

When study authors have not adjusted their analyses for clustering, we will first contact them for an estimate of the intracluster correlation co-efficient (ICC) (if none is given in the text). If the ICC is not provided by the text or by the study authors directly, we will estimate the ICC and the design effect according to methods recommended in Chapter 16 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We will seek estimates of the ICC from other sources and will calculate an average value. When dichotomous data are available, we will divide both the numerator and the denominator for the events by the design effect. We will adjust other effect estimates by inflating their standard errors by multiplying the standard error by the square root of the design effect (as described in Higgins 2011).

Choice of measurement point

For trials that report outcomes at multiple time points, such as at post-test with longer follow-up, we will select outcomes measured post-test (expected to be the most consistently reported among trials) and will include a follow-up measure using the longest available duration of follow-up.

Dealing with missing data

When study characteristics and numerical outcome data are missing from studies, we will contact study authors directly to obtain missing information. We will record the extent and nature of data missing from studies. For quantitative aspects of process evaluation, such as satisfaction or participation data, we will apply the same procedure. Recording of the 'missingness' of qualitative data in the process evaluations that we include is more oblique, although we will record the 'contribution' of studies to each of the processes that we draw out to understand the different weight given across included studies, as has been suggested elsewhere (Hurley 2013).

Assessment of heterogeneity

We will assess statistical heterogeneity by using the I^2 measure (Higgins 2003). We will explore possible sources of variation when the I^2 value exceeds 25%by thoroughly conducting prespecified sensitivity and subgroup analyses and performing thorough meta-regression analysis.

We will construct random-effects meta-regression models using STATA, and will aim to construct multi-variate models that allow us to model the impact of different co-variates simultaneously, after first exploring the impact of these potential effect size study-level moderators in univariate models. We will assess model fit by examining changes in τ^2 through the value of adjusted R-squared. When appropriate, and when the data allow, we will construct hierarchical meta-regression models for longitudinal measurements that we may encounter, and we will explore the utility of other modelling techniques for analysing complex measures or data structures (Higgins 2011).

Assessment of reporting biases

We will record the number of studies when we are not able to ascertain the analysis of data related to our primary outcomes. We will also record the number of studies when we are not able to extract process measures, and we will assess the breadth and depth of those studies with process information.

We will plot the distribution of effect sizes for each (outcomes) study against study standard errors as a funnel plot for primary outcomes and will base our assessment of publication bias on visual inspection (if 10 or more studies contribute to the outcome); we will also undertake formal tests for small-study publication bias using Egger's test (Harbord 2009).

Data synthesis

Our analytical strategy in this review involves undertaking qualitative comparative analysis first, as an exercise in its own right to uncover the configurations of processes aligned with successful intervention implementation, but also as an exercise to generate hypotheses about significant processes that can be tested in later regression modelling exercises.

Process-level measurements using qualitative comparative analysis

We will carry out qualitative comparative analysis (QCA) to identify which configurations of child (e.g. age, ethnicity), intervention (e.g. pedagogical techniques) and contextual characteristics (e.g. school-level factors) are most commonly associated with successful intervention implementation (Thomas 2014). This approach, has been applied to systematic reviews by one of the members of this review author team (JT), aims to generate theories about necessary and sufficient components associated with effective interventions, and takes a case-based (accounting for all of the study's observed characteristics simultaneously) rather than a variable approach, so that the focus is on different configurations of conditions, rather than on single variables. Two review authors (KH and DK) will identify and independently code these conditions to form a data table. We will analyse and develop this data table into a truth table; following investigation of the truth table and resolution of logical inconsistencies, we will apply Boolean minimisation algorithms to this truth table to identify the most logically simple expression of truth table contents. Results will be subjected to a careful process of interpretation, and further consideration will be given to configurations of components with no cases.

In line with the goals of QCA, the analyses of process measures will be useful products in themselves, but in the context of this review, we aim to utilise these data to develop hypotheses about

potentially effective intervention strategies for testing in the regression analyses below. These analyses therefore also will help us identify intervention components most commonly associated with effective interventions. (This will be particularly useful in shaping the intervention, which will be designed and evaluated (using a randomised controlled trial (RCT)) in response to the findings of this review.)

Quantitative data

We will combine data in Review Manager (RevMan 2014) 5.1, although we will conduct more complex analyses, such as regression, in Stata. For dichotomous variables (such as hospital admission or withdrawal), we will combine data with a random-effects odds ratio (OR) and 95% confidence intervals. For continuous data variables (such as symptoms and quality of life), we will combine data with a random-effects mean difference and 95% confidence intervals. When substantial statistical heterogeneity is detected, we will explore potential sources and will consider using a random-effects model. For count data, we will use rate ratios.

Rating the quality of the evidence

The quality of evidence rating reflects the extent to which recommendations can confidently be based on the review evidence (Guyatt 2008). We will rate the quality of the evidence for our main outcomes using methods developed by the GRADE (Grades of Recommendation, Assessment, Development and Evaluation) Working Group (http://www.gradeworkinggroup.org/publications/JCE˙series.htm). We will consider the possible impact of each of the following factors on our outcomes of interest.

- Risk of bias.
- Imprecision.
- Inconsistency.
- Indirectness.
- Publication bias.

We will attempt to identify a representative control group risk to illustrate the effects of our meta-analysis results in absolute terms. We will tabulate GRADE ratings alongside absolute and relative effects in a 'Summary of findings' (SoF) table for the following outcomes.

- Unplanned visit to hospital or GP due to asthma symptoms.
- Parent-reported absence from school.
- Days of restricted activity.
- Exacerbations leading to admission to hospital.
- Experience of daytime and night-time symptoms.
- Lung function (e.g. spirometry, peak flow).
- Use of reliever therapies such as beta$_2$-agonists.
- Corticosteroid dosage and/or use of add-on therapies (e.g. long-acting beta$_2$-agonists (LABAs) or leukotriene receptor antagonists (LTRAs)).
- (Health-related) quality of life.

The SoF table will be generated using GRADE Guideline Development tool (GDT). Further analysis exploring heterogeneity in effect size is described elsewhere.

In addition, we will update the logic model (Figure 1) to reflect the evidence uncovered; we will develop this model into a theory of change representing evidence around the underlying mechanisms of what works, for whom and in which contexts.

Subgroup analysis and investigation of heterogeneity

We will conduct a statistical test for heterogeneity across subgroups using an I^2 statistic. When data allow, our aim will be to construct a multi-variate meta-regression model based on our results for different outcomes.

We will undertake prespecified analyses to investigate heterogeneity on the basis of the following characteristics, which are represented in our logic model as child-level, school-level and contextual moderators, as well as modifiable design characteristics of the intervention itself, to be classified in earlier qualitative analyses.

- Setting: elementary/primary school versus secondary/high school.
- Age: five to 10 years; 11 to 15 years; 16 years and older.
- Socioeconomic level: low or high.
- Severity of children's asthma (as defined by GINA guidelines).
- Delivery of intervention: healthcare provider (e.g. health educator, school nurse, other healthcare professional) versus other professional (e.g. teacher, mixture) versus other model of delivery (e.g. peer led).
- Other (prespecified) intervention moderators developed from hypotheses generated through syntheses of process evaluation data (see data synthesis section above).

It is anticipated that socioeconomic status will be measured very differently; thus we will keep the groupings for this characteristic very broad and will base them on income, social class or other indicators of social position, such as being in receipt of means tested benefits.

We will not apply a qualitative equivalent, although as we extract process measures, we may identify further processes that we wish to investigate in subgroup analyses. We will undertake the synthesis of process evaluations conducted before the RCTs to remain blinded to the possible impact of specific measures.

Sensitivity analysis

We will undertake sensitivity analyses on the basis of the following.

- Risk of bias assessment: We will include all studies in the primary analysis and then will restrict included studies to those at low risk of bias.
- Fixed-effect modelling.
- Exclusion of cluster study data from outcomes when external or imputed ICCs have been used.

- Application of alternative estimated ICCs to studies for which these values are missing.

We will not apply a qualitative equivalent, although we will record the degree to which findings are supported by studies of high and moderate quality. For qualitative findings, we will consider the degree to which individual and contextual factors can explain any variation in the types of views identified.

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* *Indicates the major publication for the study*

APPENDICES

Appendix 1. Sources and search methods for the Cochrane Airways Group Specialised Register (CAGR)

Electronic searches: core databases

Database	Frequency of search
CENTRAL	Monthly
MEDLINE (Ovid)	Weekly
EMBASE (Ovid)	Weekly
PsycINFO (Ovid)	Monthly
CINAHL (EBSCO)	Monthly
AMED (EBSCO)	Monthly

Handsearches: core respiratory conference abstracts

Conference	Years searched
American Academy of Allergy, Asthma and Immunology (AAAAI)	2001 onwards
American Thoracic Society (ATS)	2001 onwards
Asia Pacific Society of Respirology (APSR)	2004 onwards
British Thoracic Society Winter Meeting (BTS)	2000 onwards
Chest Meeting	2003 onwards
European Respiratory Society (ERS)	1992, 1994, 2000 onwards
International Primary Care Respiratory Group Congress (IPCRG)	2002 onwards
Thoracic Society of Australia and New Zealand (TSANZ)	1999 onwards

MEDLINE search strategy used to identify trials for the CAGR

Asthma search

1. exp Asthma/
2. asthma$.mp.
3. (antiasthma$ or anti-asthma$).mp.
4. Respiratory Sounds/
5. wheez$.mp.
6. Bronchial Spasm/
7. bronchospas$.mp.
8. (bronch$ adj3 spasm$).mp.
9. bronchoconstrict$.mp.
10. exp Bronchoconstriction/
11. (bronch$ adj3 constrict$).mp.
12. Bronchial Hyperreactivity/
13. Respiratory Hypersensitivity/
14. ((bronchial$ or respiratory or airway$ or lung$) adj3 (hypersensitiv$ or hyperreactiv$ or allerg$ or insufficiency)).mp.
15. ((dust or mite$) adj3 (allerg$ or hypersensitiv$)).mp.
16. or/1-15

Filter to identify RCTs

1. exp "clinical trial [publication type]"/
2. (randomised or randomised).ab,ti.
3. placebo.ab,ti.
4. dt.fs.
5. randomly.ab,ti.
6. trial.ab,ti.
7. groups.ab,ti.

8. or/1-7
9. Animals/
10. Humans/
11. 9 not (9 and 10)
12. 8 not 11
The MEDLINE strategy and RCT filter are adapted to identify trials in other electronic databases.

Appendix 2. Search strategy to identify relevant trials from the CAGR

SCH-AST: search strategy for the Airways Group Register (via the Cochrane Register of Studies - CRS)

#1 AST:MISC1
#2 MeSH DESCRIPTOR Asthma Explode All
#3 asthma*:ti,ab
#4 #1 or #2 or #3
#5 MeSH DESCRIPTOR Schools Explode All
#6 MeSH DESCRIPTOR School Health Services
#7 MeSH DESCRIPTOR School Nursing
#8 school*:ti,ab,kw
#9 academ*:ti,ab,kw
#10 colleg*:ti,ab,kw
#11 lesson*:ti,ab,kw
#12 pupil*:ti,ab,kw
#13 #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12
#14 MeSH DESCRIPTOR Self Care Explode All
#15 MeSH DESCRIPTOR Health Education Explode All
#16 MeSH DESCRIPTOR Case Management
#17 MeSH DESCRIPTOR Patient Education as Topic
#18 educat*:ti,ab,kw
#19 manag*:ti,ab,kw
#20 self-car*:ti,ab,kw
#21 self NEXT car*:ti,ab,kw
#22 train*:ti,ab,kw
#23 instruct*:ti,ab,kw
#24 teach*:ti,ab,kw
#25 patient-cent*:ti,ab,kw
#26 patient NEXT cent*:ti,ab,kw
#27 MeSH DESCRIPTOR Patient-Centered Care
#28 patient-focus*:ti,ab,kw
#29 patient NEXT focus*:ti,ab,kw
#30 coach*:ti,ab,kw
#31 skill*:ti,ab,kw
#32 knowledge NEXT develop*:ti,ab,kw
#33 tutor*:ti,ab,kw
#34 #14 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33
#35 #4 AND #13 AND #34
[Note: in search line #1, MISC1 denotes the field in the record in which the reference has been coded for condition, in this case, asthma]

CONTRIBUTIONS OF AUTHORS

Role	Author
Drafting the protocol	KH, DK, TL, JG, VM, JT
Developing a search strategy	KH, DK, TL, JG, VM, JT
Searching for trials	KH, DK
Obtaining copies of trials	KH, DK
Providing subject expertise	TL, JG, VM
Providing methodological expertise	JT, TL
Selecting which trials to include	KH, DK, JG, JT
Extracting data from trials	KH, DK
Entering data into RevMan	KH
Carrying out the analysis	KH, DK
Interpreting the analysis	KH, DK, TL, JG, VM, JT
Drafting the final review	KH, DK, TL, JG, VM, JT
Updating the review	KH, DK

Dylan Kneale and Katherine Harris are the joint lead authors of this review.

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