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Shared decision-making for people with asthma (Protocol)

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Shared decision-making for people with asthma

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A B S T R A C T

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

To assess the benefits and potential harms of shared decision-making for asthma.

B A C K G R O U N D

Description of the condition

Asthma is a chronic disease that affects the airways. It is usually characterised by chronic inflammation of the airways, which causes wheeze, shortness of breath, chest tightness, cough and variable airflow limitation (GINA 2016). Symptoms vary significantly in their nature, frequency and severity both within and between individuals with a diagnosis of asthma. Day-to-day symptoms often vary according to the presence of external stimuli (e.g. exercise, allergens), and people with asthma can also experience flare-ups or 'exacerbations' which are associated with significant morbidity and mortality worldwide (GINA 2016; Global Asthma Network 2014; NRAD 2014). The long-term goals of asthma management are to maintain control of symptoms and to minimise the risk of exacerbations, airflow limitation and treatment side-effects (GINA 2016). Educating people to self-manage their asthma is widely recognised as integral to achieving these goals both for adults (Gibson 2002) and children (Guevara 2003).

Description of the intervention

Shared decision-making (SDM) should involve at least two participants (the physician and the patient) and involve the mutual sharing of information to build a consensus about the preferred treatment, which culminates in an agreed action (Charles 1997). Decisions about the management of long-term conditions are based on a multitude of factors, including the relative efficacy and safety of treatments, cost and palatability. SDM is a way of balancing these factors by considering the values and preferences of the patient and the opinions of the healthcare provider. Légaré 2013 describe the three essential elements of SDM as follows.

1. Recognizing and acknowledging that a decision is required.
2. Knowing and understanding the best available evidence.
3. Incorporating the patient's values and preferences into any decision.

For asthma, management guidelines increasingly recognise the role of "the patient and healthcare provider partnership" for a shared-care approach (GINA 2016). Interventions to encourage patient-centered care in clinical consultations across a range of conditions generally put the onus on the healthcare provider (Dwamena 2012), but some are aimed at providing a pathway for patients

or parents to better engage in their asthma care (e.g. Fiks 2015; Wilson 2010), or a mixture of both, and these different approaches may have different aims and outcomes. Interventions aimed at changing health provider behaviour might include open communications, identifying and addressing patient and family concerns about asthma and its treatment, discussing treatment preferences and barriers to implementation, shared development of treatment goals, and encouraging active self-assessment and self-management (NHLBI/NAEPP 2007).

How the intervention might work

The potential benefit of SDM is dependent on the willingness and ability of both sides to interact, which might depend on factors such as "ethnicity, literacy, understanding of health concepts (health literacy), numeracy, beliefs about asthma and medications, desire for autonomy, and the health care system" (GINA 2016). As such, SDM will not necessarily be equally acceptable to all patients or carers or applicable in the same way across healthcare contexts. Benefits of SDM may be seen for individuals and more widely for health services and society by enhancing uptake of evidence-based options and reducing overuse of options that have minimal benefits, thus reducing practice and geographic variations in care and unnecessary expenditure (Coulter 2011; Légaré 2014).

Preferences for an active, collaborative or passive role in decision making vary among populations, but patient roles are more often passive (Caress 2005; Sleath 2011), and many patients report a desire to be more involved (Caress 2005). Patient preferences for involvement in decision-making is related to education level, perceptions of the healthcare provider, cost barriers of care and psychosocial factors (Adams 2001), but preferences have not been strongly associated with demography or asthma severity (Caress 2005). Nonetheless, there is a lack of evidence regarding how best to achieve SDM in practice, especially in paediatric asthma with regards to the child-parent relationship and adapting the emphasis of SDM as the child matures (Rivera-Spoljaric 2014).

Organisational factors have been highlighted as a barrier to patients or families feeling satisfied with the role they played in their asthma care, especially quality and duration of consultations (Caress 2005), which will vary substantially across healthcare contexts. A narrative synthesis of the fast-growing field of patient involvement in medicine has identified the preparedness of service systems as an enabler to successful SDM, alongside empowerment, patient education, communication for involvement, and staff training (Snyder 2016). It is possible that engaging in SDM may cause unintended harms, for example by allowing a patient to choose an option without proper discussion of the harms and benefits, so it is important that staff are appropriately trained and that decision aids are used correctly (Coulter 2011).

Why it is important to do this review

SDM may improve clinical outcomes and quality of life by educating and empowering patients to be actively involved in their own health (Butz 2007; Wilson 2010). These interventions may be particularly beneficial in people with asthma as self-management behaviours are important (Gibson 2002; Guevara 2003), and make SDM particularly relevant to a population with asthma. The US Institute of Medicine has prioritised SDM (Institute of Medicine 2009), and Asthma UK identified methods to "empower and enable people to take control of their own asthma" as a research priority (Asthma UK 2011).

A recent Cochrane review found 43 studies that tested the effects of interventions to encourage patient-centred care in clinical consultations, and found mixed results in terms of patient satisfaction, health behaviour and health status (Dwamena 2012). The authors suggest complex interventions with condition-specific materials aimed at both providers and patients might be promising, but evidence was limited at this time. Similarly, Légaré 2014 focuses on interventions aimed at improving uptake of SDM by healthcare professionals with a primary focus on how well it is adopted in practice. Reviewing evidence for SDM in asthma will allow us to conduct wider searches in the asthma literature to find additional studies and to focus on important condition-specific outcomes. The growth of SDM research means it is likely that new evidence will have been published since the existing reviews.

O B J E C T I V E S

To assess the benefits and potential harms of shared decision-making for asthma.

M E T H O D S

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs). We will include studies that use individual or cluster randomisation, but we will exclude crossover studies due to the likelihood of carry-over effects. We will exclude non-randomised studies because they will restrict our ability to imply causation of intervention effects, and are more likely to be subject to selection biases and confounders. However, we will summarise narratively any non-randomised evidence identified by the searches and will contrast them with our results in the discussion, particularly with regards to potential harms. We will include studies reported as full-text articles, those published as abstract only, and unpublished data.

Types of participants

We will include studies of adults and children with a diagnosis of asthma, either confirmed by a physician or with spirometry according to guidelines (e.g. GINA 2016). We will exclude studies that include participants with other long-term conditions, in particular chronic obstructive pulmonary disease (COPD), unless separate results are presented for those with asthma. We will also exclude studies looking at shared decision-making (SDM) in asthma specifically for people with cognitive impairments, as the interventions are likely to have a different focus. If a study includes a subset of eligible participants (e.g. a mixed population that includes participants with other health conditions), we will only include it if we can analyse the disaggregated data for the eligible participants separately.

Types of interventions

We will include studies that assess SDM interventions for people with asthma. We will include interventions aimed at health professionals (specialist, general practitioner, nurse, pharmacist etc.), patients and their families or carers, or both. We will include studies that compare the intervention to usual care or a minimal control intervention separately from those comparing a SDM intervention to another active intervention. We will exclude studies of interventions that involve multiple components other than the SDM intervention unless the control group also received them.

Types of outcome measures

Primary outcomes

1. Asthma-related quality of life (on a validated scale e.g. Asthma Quality of Life Questionnaire (AQLQ)).
2. Patient/parent satisfaction.
3. Medication adherence.

Secondary outcomes

1. Exacerbations of asthma (leading to a course of oral corticosteroids or unscheduled visit to a health professional).
2. Asthma control (e.g. Asthma Control Questionnaire (ACQ)).
3. Acceptability/feasibility from the perspective of healthcare professionals.
4. Adverse events (all).

Reporting one or more of the outcomes listed here in the study will not be an inclusion criterion for the review.

We will prioritise any validated measures of patient/parent satisfaction, medication adherence, asthma control and acceptability/feasibility, but have not predefined accepted measures in advance so as not to restrict the analyses unnecessarily. If the study authors use non-validated measures, or there is a mixture of validated and non-validated measures across studies, we will assess which are sufficiently similar for pooling to make sense.

We will extract and analyse data from both the parent and child perspective in paediatric studies.

Search methods for identification of studies

Electronic searches

We will identify studies from the Cochrane Airways Group's Specialised Register (CAGR), which is maintained by the Information Specialist for the Cochrane Airways Group. The CAGR contains trial reports identified through systematic searches of multiple bibliographic databases and handsearches of respiratory journals and meeting abstracts (please see Appendix 1 for further details). We will search all records in the CAGR using the search strategy in Appendix 2. We have based our search terms for 'shared decision making' on those used in a Cochrane Review by Légaré 2014.

We will also conduct a search of ClinicalTrials.gov (http://ClinicalTrials.gov) and the WHO International Clinical Trials Registry Platform (ICTRP; http://who.int/ictrp/en/). We will search all databases from their inception to the present, and we will impose no restriction on language of publication.

Searching other resources

We will check reference lists of all primary studies and review articles for additional references.

We will search for errata or retractions from included studies published in full-text on PubMed (http://ncbi.nlm.nih.gov/pubmed) and we will report the date of the search within the review.

Data collection and analysis

Selection of studies

Two review authors (KK and PM) will independently screen titles and abstracts for inclusion of all the potential studies we identify as a result of the search and will code them as either 'retrieve' (eligible or potentially eligible/unclear) or 'do not retrieve'. We will retrieve the full-text study reports/publications of studies in the 'retrieve' category. Two review authors (KK and PM) will independently screen the full-text articles and identify studies for inclusion, and identify and record reasons for exclusion of the ineligible studies. We will resolve any disagreement through discussion or, if required, we will consult a third person. We will identify and exclude duplicates and collate multiple reports of the same study so that each study, rather than each report, is the unit of interest in

the review. We will record the selection process in sufficient detail to complete a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram and a 'Characteristics of excluded studies' table (Moher 2009).

Data extraction and management

We will use a data collection form for study characteristics and outcome data which we will pilot on at least one included study in the review. Both review authors (KK and PM) will extract study characteristics from the included studies. We will extract the following study characteristics.

1. Methods: study design, total duration of study, details of any 'run in' period, number of study centres and location, study setting, withdrawals and the date of study.

2. Participants: N, mean age, age range, gender, severity of condition, diagnostic criteria, baseline lung function, smoking history, inclusion criteria and exclusion criteria.

3. Interventions: intervention, comparison, concomitant medications and excluded medications.

4. Outcomes: primary and secondary outcomes specified and collected and time points reported.

5. Notes: funding for trial and notable conflicts of interest of trial authors.

Two review authors (KK and PM) will independently extract outcome data from included studies. We will note in the 'Characteristics of included studies' table if a study reports outcome data that are not usable in an analysis. We will resolve disagreements by consensus or by involving a third person. One review author (KK) will transfer data into the Review Manager (RevMan) file (RevMan 2014). We will double-check that data is entered correctly by comparing the data presented in the systematic review with the study reports.

Assessment of risk of bias in included studies

Two review authors (KK and PM) will independently assess the risk of bias for each included study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We will resolve any disagreements by discussion or by involving a third person. We will assess the risk of bias of each included study according to the following domains.

1. Random sequence generation.
2. Allocation concealment.
3. Blinding of participants and personnel.
4. Blinding of outcome assessment.
5. Incomplete outcome data.
6. Selective outcome reporting.
7. Other bias.

We will grade each potential source of bias as high, low or unclear and provide a quote from the study report together with a justification for our judgment in the 'Risk of bias' table. We will summarise

the 'Risk of bias' judgements across different studies for each of the domains listed. We will consider blinding separately for different key outcomes where necessary (e.g. for unblinded outcome assessment, risk of bias for all-cause mortality may be very different than for a patient-reported pain scale). Where information on risk of bias relates to unpublished data or correspondence with a trial author, we will note this in the 'Risk of bias' table.

When considering treatment effects, we will take into account the risk of bias for the studies that contribute to that outcome.

Assessment of bias in conducting the systematic review

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

Measures of treatment effect

We will analyse dichotomous data as odds ratios and continuous data as mean difference or standardised mean difference values. We will enter data presented as a scale with a consistent direction of effect.

We will undertake meta-analyses only where this is meaningful i.e. if the treatments, participants and the underlying clinical question are similar enough for pooling to make sense.

We will narratively describe skewed data reported as medians and interquartile ranges.

Where multiple trial arms are reported in a single study, we will include only the relevant arms. If we combine two comparisons (e.g. two types of SDM versus usual care) in the same meta-analysis, we will halve the control group to avoid double-counting.

If both change from baseline and endpoint scores are available for continuous data, we will use change from baseline unless most studies report endpoint scores. If a study reports outcomes at multiple time points, we will use the end-of-study measurement.

When both an analysis that includes only participants who completed the trial and an analysis that imputed data for participants who were randomly assigned but did not provide endpoint data (e.g. last observation carried forward) are available, we will use the latter.

Unit of analysis issues

For dichotomous outcomes, we will use participants, rather than events, as the unit of analysis (i.e. number of people admitted to hospital, rather than number of admissions per person). We will only meta-analyse data from cluster RCTs if the available data have been adjusted to account for the clustering.

Dealing with missing data

We will contact investigators or study sponsors in order to verify key study characteristics and obtain missing numerical outcome data where possible (e.g. when we identify a study as an abstract only). Where this is not possible, and we consider that the missing data may introduce serious bias, we will explore the impact of including such studies in the overall assessment of results by a sensitivity analysis.

Assessment of heterogeneity

We will use the I² statistic to measure heterogeneity among the studies in each analysis. If we identify substantial heterogeneity we will report it and explore possible causes by prespecified subgroup analysis.

Assessment of reporting biases

If we are able to pool more than 10 studies, we will create and examine a funnel plot to explore possible small study and publication biases.

Data synthesis

We will use a random-effects model and perform a sensitivity analysis with a fixed-effect model.

'Summary of findings' table

We will create a 'Summary of findings' table using the outcomes listed in this protocol. We will use the five Grading of Recommendations Assessment, Development and Evaluation (GRADE) considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of a body of evidence as it relates to the studies that contribute data to the meta-analyses for the prespecified outcomes. We will use methods and recommendations described in Section 8.5 and Chapter 12 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011), and will use GRADEpro Guideline Development Tool (GRADEpro GDT). We will justify all decisions to downgrade or upgrade the quality of the evidence using footnotes and we will make comments to aid the reader's understanding of the review where necessary.

Subgroup analysis and investigation of heterogeneity

We plan to perform the following subgroup analyses[1] for the primary outcomes.

1. Age of the asthma population (children less than 12 years of age, 12 to 18 years of age, adults over 18 years of age).

2. Focus of the intervention (i.e. population randomised to the intervention: healthcare providers versus patient/parent).

3. Duration/extensiveness of intervention (e.g. one-off or simple intervention versus ongoing SDM sessions).

[1]Children, adolescents and adults may have quite different needs and preferences with respect to SDM, so interventions may have different focuses and effects across age-groups. We also expect study effects to vary regarding the focus and extent of the intervention, which we will try to assess in the other two subgroup analyses. However, since a subgroup analysis can only look at one of these effect modifiers at a time and do not imply causation, we will interpret the results cautiously. We will present these and other possible effect modifiers in an additional table in the full review.

We will use the formal test for subgroup interactions in RevMan (RevMan 2014).

Sensitivity analysis

We plan to carry out the following sensitivity analyses by removing the following from the primary analyses.

1. Unpublished data.
2. Studies at high risk in either selection bias domain.

ACKNOWLEDGEMENTS

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* *Indicates the major publication for the study*

A P P E N D I C E S

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

Electronic searches: core databases

Database	Frequency of search
MEDLINE (Ovid)	Weekly
EMBASE (Ovid)	Weekly
CENTRAL (*The Cochrane Library*)	Monthly
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

Condition 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$)).mp.
16. or/1-15
17. exp Aspergillosis, Allergic Bronchopulmonary/
18. lung diseases, fungal/
19. aspergillosis/
20. 18 and 19
21. (bronchopulmonar$ adj3 aspergillosis).mp.
22. 17 or 20 or 21
23. 16 or 22
24. Lung Diseases, Obstructive/
25. exp Pulmonary Disease, Chronic Obstructive/
26. emphysema$.mp.

27. (chronic$ adj3 bronchiti$).mp.
28. (obstruct$ adj3 (pulmonary or lung$ or airway$ or airflow$ or bronch$ or respirat$)).mp.
29. COPD.mp.
30. COAD.mp.
31. COBD.mp.
32. AECB.mp.
33. or/24-32
34. exp Bronchiectasis/
35. bronchiect$.mp.
36. bronchoect$.mp.
37. kartagener$.mp.
38. (ciliary adj3 dyskinesia).mp.
39. (bronchial$ adj3 dilat$).mp.
40. or/34-39
41. exp Sleep Apnea Syndromes/
42. (sleep$ adj3 (apnea$ or apnoea$)).mp.
43. (hypopnoea$ or hypopnoea$).mp.
44. OSA.mp.
45. SHS.mp.
46. OSAHS.mp.
47. or/41-46
48. Lung Diseases, Interstitial/
49. Pulmonary Fibrosis/
50. Sarcoidosis, Pulmonary/
51. (interstitial$ adj3 (lung$ or disease$ or pneumon$)).mp.
52. ((pulmonary$ or lung$ or alveoli$) adj3 (fibros$ or fibrot$)).mp.
53. ((pulmonary$ or lung$) adj3 (sarcoid$ or granulom$)).mp.
54. or/48-53
55. 23 or 33 or 40 or 47 or 54

Filter to identify randomised controlled trials (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

#1 AST:MISC1
#2 MeSH DESCRIPTOR Asthma Explode All
#3 asthma*:ti,ab
#4 #1 or #2 or #3
#5 shared* NEAR decision*:ti,ab
#6 sharing* NEAR decision*:ti,ab
#7 informed* NEAR decision*:ti,ab
#8 informed* NEAR choice*:ti,ab
#9 decision* NEAR aid*:ti,ab
#10 ((share* or sharing* or informed*) AND (decision* or deciding* or choice*)):ti
#11 MeSH DESCRIPTOR Decision Making
#12 MeSH DESCRIPTOR Decision Support Techniques
#13 MeSH DESCRIPTOR Decision Support Systems, Clinical
#14 MeSH DESCRIPTOR Choice Behavior
#15 decision* NEAR making*:ti,ab
#16 decision* NEAR support*:ti,ab
#17 choice* NEAR behavio?r*:ti,ab
#18 ((decision* or choice*) AND (making* or support* or behavior* or behaviour*)):ti
#19 MeSH DESCRIPTOR Patient Participation
#20 patient* NEAR participation*:ti,ab
#21 consumer* NEAR participation*:ti,ab
#22 patient* NEAR involvement*:ti,ab
#23 consumer* NEAR involvement*:ti,ab
#24 ((patient* or consumer*) AND (involvement* or involving* or participation* or participating*)):ti
#25 MeSH DESCRIPTOR Professional-Patient Relations
#26 MeSH DESCRIPTOR Physician-Patient Relations
#27 MeSH DESCRIPTOR Patient-Centered Care
#28 ((patient* or person* or client* or consumer*) NEAR (centred or centered or focussed or oriented)):ti,ab
#29 #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28
#30 #4 AND #29
(Note: In search line #1, MISC1 denotes the field in the record where the reference has been coded for condition, in this case, asthma).

CONTRIBUTIONS OF AUTHORS

KK wrote the Background and Methods of this protocol with support from PM.

For the full review, KK and PM will both screen the search results, select studies for inclusion, extract data and assess the risk of bias in the included studies. KK will conduct the analyses and write up the results, and both review authors will assess the quality of the evidence using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach, interpret the findings and prepare the manuscript for submission.

DECLARATIONS OF INTEREST

KK: none known.

PM: none known.

SOURCES OF SUPPORT

Internal sources

External sources