Personalised asthma action plans for adults with asthma (Protocol)

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[Intervention Protocol]

Personalised asthma action plans for adults with asthma

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ABSTRACT

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

To evaluate the effectiveness of PAAPs for adults with asthma, either alone or in combination with education on self management.

BACKGROUND

Description of the condition

Asthma is a common respiratory condition characterised by airway inflammation and oedema, bronchoconstriction and airflow limitation. World Health Organization (WHO) estimates suggest that up to 334 million people are affected worldwide, with the majority of people affected in low- and middle-income countries (Global Asthma Report 2014); the total burden may be greater than reported due to the high prevalence of asthma in these countries that lack adequate reporting mechanisms. The economic burden of asthma is considerable, with direct treatment costs and indirect costs of lost productivity among the highest for non-communicable diseases (Global Asthma Report 2014). Symptoms including cough and breathlessness may be intermittent or persistent (BTS/SIGN 2014). Triggers may be allergic (e.g. pollen, animal dander, dust mite) or non-allergic (e.g. exercise, smoking, cold air, smoke from fires in confined living spaces). The disease may also be characterised by repeated exacerbations requiring a change to normal maintenance therapy. Treatment of asthma includes avoidance of potential triggers (where possible), use of inhaled corticosteroids (ICS) and leukotriene receptor antagonists (LTRA) to reduce airway inflammation, and use of inhaled long-acting beta$_2$-agonists (LABA), short-acting beta$_2$-agonists (SABA) and anti-cholinergic bronchodilators (i.e. long-acting muscarinic antagonists (LAMAs)) to relieve airflow limitation (BTS/SIGN 2014; GINA 2015; NICE 2007; NICE 2013). Exacerbations may require the addition of oral or parenteral steroids. People with severe asthma may also benefit from immunomodulatory therapy targeted to key mediators of allergic airway inflammation, including immunoglobulin E (IgE) (Normansell 2014).

The goals of asthma treatment are total control of daytime and nocturnal symptoms, normal exercise and functional capacity, and the prevention of exacerbations (GINA 2015). It is clear from studies including the national review of UK asthma deaths (NRAD 2014) that there remains a widespread misunderstanding, by both patients and healthcare professionals, of appropriate asthma treat-

ment; this puts people at risk of potentially avoidable adverse outcomes. A key recommendation to enhance asthma care is to empower each person to take control of their own condition, and to equip them to deal with deteriorating symptoms early and appropriately (BTS/SIGN 2014).

Therefore, an important concept in asthma management is a personalised asthma action plan (PAAP) for each person. This plan should detail the person's baseline characteristics, including measures of airflow limitation in adults (e.g. peak expiratory flow (PEF)) and state the agreed maintenance medication. Such plans also provide clear instruction on how a person should respond to increasing symptoms, with the aim of improving overall asthma control and minimising the risk of exacerbations.

Description of the intervention

Historically, asthma action plans have been referred to using various terms including written action plans, individualised action plans and self management action plans (Bhogal 2006). As opposed to a discrete intervention (Toelle 2011), PAAPs are considered an essential component of multi-faceted, self management education (Bhogal 2006; BTS/SIGN 2014; GINA 2015; NICE 2013). Though the format and design of action plans vary (Charlton 1990; D'Souza 1996; Ducharme 2008; Jenkinson 1988; Kristiansen 2012; Marcano Belisario 2013; Turner 1998), they are inherently similar in that they convey individualised self management instructions to enable people to both attain control of asthma and regain control in the event of an acute exacerbation (Bhogal 2006). In adults, PAAPs may be based on symptoms or peak flow monitoring, or both, whereas symptom-based plans are generally preferable for children (BTS/SIGN 2014). Typically, content includes objective cues to promote early detection of deteriorating asthma symptoms, medications prescribed and action to take in the event of an acute episode, with particular reference to step-up and step-down of therapy, and health service access (Gibson 2004; Holt 2004; Partridge 2004; Toelle 2011). In principle, individuals are not passive recipients of PAAPs (NICE 2013) as a participatory process is intended to maximise engagement and ensure tailoring to a person's experience of asthma (Bauman 2003; Gibson 1995; Lahdensuo 1999; Ring 2011). PAAPs should be firmly embedded within the regular review process (BTS/SIGN 2014), to record the agreements made between clinician and patient. The modifiable nature of PAAPs is intended to avoid 'prescribing' of static care plans and ensure the co-production of contemporary self care advice in the context of the individual (Douglas 2002). In the present review, we will focus on written PAAPs.

How the intervention might work

PAAPs primarily serve to increase self management of asthma by reminding people of their treatment plan and offering the following directives: which triggers to avoid, when to increase treatment, how to increase treatment, how long to increase treatment and when to seek medical help (Gibson 2004). By promoting and increasing self management of asthma, PAAPs ultimately aim to improve a person's overall control of their asthma symptoms. PAAPs also function as an important communication tool for patients and healthcare professionals, representing both a record and reminder of discussions between patient and clinician (Bhogal 2006; Welsh 2011). They are individualised, enabling the underlying nature of the person's asthma to be taken into consideration and reviewed on at least an annual basis (BTS/SIGN 2014).

Why it is important to do this review

The national review of UK asthma deaths highlighted that there remain significant levels of avoidable morbidity (e.g. exacerbations requiring oral steroids or admission to hospital) and deaths from asthma (NRAD 2014). PAAPs are associated with better asthma control, helping to reduce the risk of catastrophic deterioration. For people who have had a recent acute exacerbation resulting in admission to hospital, PAAPs may reduce re-admission rates (NICE 2013). Although both the Global Initiative for Asthma (GINA; GINA 2015) and British Thoracic Society (BTS)/Scottish Intercollegiate Guidelines (SIGN) (BTS/SIGN 2014) guidelines recommend that people are offered self management education, which should include a written PAAP, these recommendations are based on evidence from over a decade ago (Gibson 2004). Moreover, the BTS/SIGN guidelines identify gaps in the evidence on which the guidelines were based. For example, there are insufficient data to evaluate the effectiveness of certain specific components of written PAAPs relating to corticosteroid use (BTS/SIGN 2014). Furthermore, there remains debate as to the effectiveness of written PAAPs in specific clinical settings (Khan 2014; Sheares 2015), or when used alone or alongside education on self management (Toelle 2011). Therefore, it is important to re-evaluate the evidence for the effectiveness of PAAPs systematically to ensure that the guidelines accurately reflect an up-to-date evidence base. As PAAPs represent one component of a multi-faceted self management education, and the provision of health education generally represents a significant cost for hospitals and clinics, it is also important to confirm the effectiveness of PAAPs plus education to ensure the efficient use of limited resources. Finally, as the use of a single combined LABA and ICS inhaler for both prevention and relief of asthma symptoms has been shown to be beneficial (Cates 2013; Kew 2013), it is important to examine whether the use of single inhaler therapy is a potential effect modifier for PAAPs.

OBJECTIVES

To evaluate the effectiveness of PAAPs for adults with asthma, either alone or in combination with education on self management.

METHODS

Criteria for considering studies for this review

Types of studies

We will include parallel randomised controlled trials (RCTs), both blinded and unblinded, of any duration that evaluate written PAAPs (for details, see Types of interventions). We will include studies reported as full-text, published as abstract only and unpublished data.

Types of participants

We will include adults (aged 18 years or over) with asthma of any severity. The diagnosis of asthma should be determined by a clinician in accordance with validated national or international guidelines (e.g. BTS/SIGN 2014; GINA 2015). Studies that do not cite a specific guideline for diagnostic purposes should provide adequate information to allow diagnosis by the review authors as per one of the validated guidelines. We will exclude participants with other respiratory co-morbidities (e.g. bronchiectasis, chronic obstructive pulmonary disease). If the search identifies studies that include only a subset of relevant participants, we will include them only if the study authors can provide disaggregated data for participants who meet the inclusion criteria.

Types of interventions

Significant variability exists in the content and format of action plans (MacGillivray 2014). We will define PAAPs as any written plan that 1. enables people with asthma (or their carer) to recognise when symptoms are worse and 2. sets out actions to be taken if asthma control deteriorates. As per GINA 2015 guidelines, PAAPs should include specific instructions for the patient (or their carer) about changes to reliever and controller medications, how to use OCS if needed, and when and how to access healthcare services (GINA 2015). Thresholds for action as defined in the plans can be based on symptoms or peak flow. We will assess the following comparisons:

1. PAAP alone versus no PAAP;
2. PAAP plus education intervention (defined as per GINA 2015 guidelines) versus education intervention alone.

Types of outcome measures

Primary outcomes

1. Number of participants reporting at least one exacerbation requiring emergency department visit or hospitalisation.
2. Asthma symptom scores* (measured on a validated scale, e.g. Asthma Control Questionnaire).
3. Adverse events (all-cause).

We selected the primary outcomes to represent an important measure of resource use, a patient-reported outcome and safety.

*If a study uses more than one scale to report the same outcome, or if different scales are used across studies, we will analyse them together using the standardised mean difference.

Secondary outcomes

1. Quality of life (QoL)* (measured on a validated scale, e.g. Asthma QoL Questionnaire).
2. Number of participants reporting at least one exacerbation requiring systemic corticosteroids.
3. Measure of respiratory function - forced expiratory volume in one second (FEV_1) or PEF.
4. Days lost from work or study.

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

Search methods for identification of studies

Electronic searches

We will identify trials from the Cochrane Airways Group's Specialised Register (CAGR), which the Trials Search Co-ordinator maintains for the Group. The Register contains trial reports identified through systematic searches of bibliographic databases including the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE, EMBASE, CINAHL, AMED and PsycINFO, and handsearching of respiratory journals and meeting abstracts (see Appendix 1 for further details). We will search all records in the CAGR using the search strategy in Appendix 2. We will also conduct a search of ClinicalTrials.gov (www.ClinicalTrials.gov) and the WHO trials portal (www.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 relevant manufacturers' websites for trial information.

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

Data collection and analysis

Selection of studies

Two review authors (TG, AR) will independently screen titles and abstracts for inclusion of all the potential studies that we identify as a result of the search and code them as 'retrieve' (eligible or potentially eligible/unclear) or 'do not retrieve'. We will retrieve the full-text study reports/publication and two review authors (TG, AR) will independently screen the full-text and identify studies for inclusion. We will identify and record reasons for the exclusion of the ineligible studies. We will resolve any disagreements through discussion or, if required, we will consult a third review author (DE). 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 PRISMA (Prefered Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram and 'Characteristics of excluded studies' table.

Data extraction and management

We will use a data collection form for study characteristics and outcome data that has been piloted on at least one study in the review. Two review authors (NH, DE) will independently extract study characteristics from 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 date of study.
2. Participants: number, 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 (NH, AR) will independently extract outcome data from included studies. We will note in the 'Characteristics of included studies' table if outcome data were not reported in a usable way. We will resolve disagreements by consensus or by involving a third review author (DE). One review author (NH) will transfer data into Review Manager 5 (RevMan 2014). We will double-check that data are entered correctly by comparing the data presented in the systematic review with the study reports. A second review author (DE) will spot-check study characteristics for accuracy against the trial report.

Assessment of risk of bias in included studies

Two review authors (NH, DE) will independently assess risk of bias for each 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 another review author (AR). We will assess the risk of bias 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 judgement 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 from a participant-reported pain scale). Where information on risk of bias relates to unpublished data or correspondence with a trialist, 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 from 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 95% confidence intervals (CI). We will analyse continuous data as mean difference or standardised mean difference and 95% CI. We will enter data presented as a scale with a consistent direction of effect.

We will use change from baseline scores when possible.

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 provide a narrative description of skewed data reported as medians and interquartile ranges.

When multiple trial arms are reported in a single trial, we will include only the relevant arms. If two comparisons (e.g. intervention A versus placebo and intervention B versus placebo) are combined in the same meta-analysis, we will halve the control group to avoid double-counting. If trials report outcomes at multiple time points, we will use the end of treatment time point.

Unit of analysis issues

For dichotomous outcomes, we will use participants, rather than events, as the unit of analysis (i.e. number of participants admitted to hospital at least once rather than the number of admissions per participant).

Dealing with missing data

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

Assessment of heterogeneity

We will use the I^2 statistic to measure heterogeneity among the trials in each analysis. If we identify substantial heterogeneity (i.e. I^2 > 50%), we will report it and explore possible causes by performing pre-specified subgroup analysis.

Assessment of reporting biases

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

Data synthesis

We will use a random-effect model for all analyses as we expect variation in effects due to differences in study populations and methods. We will perform sensitivity analyses using a fixed-effect model.

'Summary of findings' table

We will create a 'Summary of findings' table using data from all seven outcomes. We will use the five 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 pre-specified outcomes. We will use methods and recommendations described in Section 8.5 and Chapter 12 of the *Cochrane Handbook for Systematic Reviews of Interventions* using GRADEpro software (Higgins 2011). We will justify all decisions to downgrade or upgrade the quality of studies using footnotes and we will make comments to aid reader's understanding of the review where necessary.

Subgroup analysis and investigation of heterogeneity

When possible, we plan to carry out the following subgroup analyses for the primary outcomes.

1. People with recent unscheduled hospitalisation versus people without.
2. Symptom-based versus peak flow-based PAAPs.
3. Use of single inhaler therapy (e.g. a single inhaler containing LABA plus ICS used for both prevention and relief of symptoms).
4. Treatment instructions individualised* using OCS only versus not individualised by OCS only.
5. Treatment instructions individualised* using ICS versus not individualised by ICS.
6. Treatment instructions individualised* using participant-specific triggers versus not individualised by participant-specific triggers.
7. Format of concurrent self management education (if applicable; e.g. sub-analysis of the duration, format or frequency of the education).
8. Provider of self management education (e.g. physician-led versus nurse-led education).

*Individualisation of action plans will be determined based on whether plan templates include blank text boxes for participant-specific asthma treatment instructions or asthma trigger details (MacGillivray 2014).

We will use the formal test for subgroup interactions in Review Manager 5 (RevMan 2014).

Sensitivity analysis

We plan to carry out the following sensitivity analyses while excluding the following:

1. unpublished data (i.e. no peer-reviewed full-text paper available);
2. studies at high risk of bias for blinding.

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Sean Beggs was the Editor for this review and commented critically on the review.

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* *Indicates the major publication for the study*

APPENDICES

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

Electronic searches: core databases

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

(*Continued*)

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 (BTS) winter meeting	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 randomised controlled trials

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

We will adapt the MEDLINE strategy and RCT filter to identify trials in other electronic databases.

Appendix 2. Search strategy to identify relevant trials from the Cochrane Airways Group's Specialised Register (CAGR)

#1 AST:MISC1
#2 MeSH DESCRIPTOR Asthma Explode All
#3 asthma*:ti,ab
#4 #1 or #2 or #3
#5 MeSH DESCRIPTOR Individualized Medicine
#6 MeSH DESCRIPTOR Patient Education as Topic
#7 MeSH DESCRIPTOR Self Care
#8 MeSH DESCRIPTOR Patient Care Planning Explode All
#9 PAAP:ti,ab
#10 action-plan* or action* NEXT plan*
#11 written* NEAR3 plan*
#12 management* NEAR3 plan*
#13 self-management* or self* NEXT management*
#14 self-care* or self* NEXT care*
#15 self-action*
#16 medication* NEAR3 plan*
#17 tailored*
#18 individuali*ed
#19 personali*ed
#20 individual* NEAR plan*
#21 personal* NEAR plan*
#22 pictorial* NEAR plan*
#23 care* NEAR3 plan*
#24 *treatment* NEAR3 plan*
#25 goal* NEAR3 set*
#26 therapeutic* NEAR (plan* or strategy or educat* or management)
#27 #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
#28 #4 and #27

[In search line #1, MISC1 denotes the field in which the reference has been coded for condition, in this case, asthma]

CONTRIBUTIONS OF AUTHORS

All review authors contributed to the drafting of the protocol, reviewed it critically for intellectual content, provided final approval of the version to be published and are accountable for all aspects of the work.

DECLARATIONS OF INTEREST

David Evans: none.

Alison Rushton: currently undertaking a feasibility study to pilot a locally developed asthma self management plan for children and young people within a Clinical Commissioning Group (CCG) locality in the north west of England. The project is being undertaken as part of a Clinical Academic Internship, funded by Health Education England and a north west CCG. There is no payment to the intern for including individuals in the study.

Nathan Halcovitch: none.

Timothy Gatheral: none.

Sally Spencer: a co-investigator on the Cochrane Programme Grant supporting this review.

Gemma Whiteley: none.

SOURCES OF SUPPORT

Internal sources

- The review authors declare that no funding was received for this protocol, Other.

External sources

- Three review authors (Alison Rushton, Nathan Halcovitch, Timothy Gatheral, Gemma Whiteley) declare that no funding was received for this protocol, Other.
- David Evans: National Institute for Health Research, UK. Evidence to guide care in adults and children with asthma, 13/89/14, UK.