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Personalised asthma action plans for adults with asthma (Review)

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[Intervention Review]

Personalised asthma action plans for adults with asthma

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ABSTRACT

Background

A key aim of asthma care is to empower each person to take control of his or her own condition. A personalised asthma action plan (PAAP), also known as a written action plan, an individualised action plan, or a self-management action plan, contributes to this endeavour. A PAAP includes individualised self-management instructions devised collaboratively with the patient to help maintain asthma control and regain control in the event of an exacerbation. A PAAP includes baseline characteristics (such as lung function), maintenance medication and instructions on how to respond to increasing symptoms and when to seek medical help.

Objectives

To evaluate the effectiveness of PAAPs used alone or in combination with education, for patient-reported outcomes, resource use and safety among adults with asthma.

Search methods

We searched the Cochrane Airways Group Specialised Register of trials, clinical trial registers, reference lists of included studies and review articles, and relevant manufacturers' websites up to 14 September 2016.

Selection criteria

We included parallel randomised controlled trials (RCTs), both blinded and unblinded, that evaluated written PAAPs in adults with asthma. Included studies compared PAAP alone versus no PAAP, and/or PAAP plus education versus education alone.

Data collection and analysis

Two review authors independently extracted study characteristics and outcome data and assessed risk of bias for each included study. Primary outcomes were number of participants reporting at least one exacerbation requiring an emergency department (ED) visit or hospitalisation, asthma symptom scores on a validated scale and adverse events (all causes). Secondary outcomes were quality of life measured on a validated scale, number of participants reporting at least one exacerbation requiring systemic corticosteroids, respiratory function and days lost from work or study. We used a random-effects model for all analyses and standard Cochrane methods throughout.

Main results

We identified 15 studies described in 27 articles that met our inclusion criteria. These 15 included studies randomised a total of 3062 participants (PAAP vs no PAAP: 2602 participants; PAAP plus education vs education alone: 460 participants). Ten studies (eight PAAP vs no PAAP; two PAAP plus education vs education alone) provided outcome data that contributed to quantitative analyses. The overall quality of evidence was rated as low or very low.

Fourteen studies lasted six months or longer, and the remaining study lasted for 14 weeks. When reported, mean age ranged from 22 to 49 years and asthma severity ranged from mild to severe/high risk.

PAAP alone compared with no PAAP

Results showed no clear benefit or harm associated with PAAPs in terms of the number of participants requiring an ED visit or hospitalisation for an exacerbation (odds ratio (OR) 0.75, 95% confidence interval (CI) 0.45 to 1.24; 1385 participants; five studies; low-quality evidence), change from baseline in asthma symptoms (mean difference (MD) -0.16, 95% CI -0.25 to - 0.07; 141 participants; one study; low-quality evidence) or the number of serious adverse events, including death (OR 3.26, 95% CI 0.33 to 32.21; 125 participants; one study; very low-quality evidence). Data revealed a statistically significant improvement in quality of life scores for those receiving PAAP compared with no PAAP (MD 0.18, 95% CI 0.05 to 0.30; 441 participants; three studies; low-quality evidence), but this was below the threshold for a minimum clinically important difference (MCID). Results also showed no clear benefit or harm associated with PAAPs on the number of participants reporting at least one exacerbation requiring oral corticosteroids (OR 1.45, 95% CI 0.84 to 2.48; 1136 participants; three studies; very low-quality evidence) nor on respiratory function (change from baseline forced expiratory volume in one second (FEV_1): MD -0.04 L, 95% CI -0.25L to 0.17 L; 392 participants; three studies; low-quality evidence). In one study, PAAPs were associated with significantly fewer days lost from work or study (MD -6.20, 95% CI -7.32 to - 5.08; 74 participants; low-quality evidence).

PAAP plus education compared with education alone

Results showed no clear benefit or harm associated with adding a PAAP to education in terms of the number of participants requiring an ED visit or hospitalisation for an exacerbation (OR 1.08, 95% CI 0.27 to 4.32; 70 participants; one study; very low-quality evidence), change from baseline in asthma symptoms (MD -0.10, 95% CI -0.54 to 0.34; 70 participants; one study; low-quality evidence), change in quality of life scores from baseline (MD 0.13, 95% CI -0.13 to 0.39; 174 participants; one study; low-quality evidence) and number of participants requiring oral corticosteroids for an exacerbation (OR 0.28, 95% CI 0.07 to 1.12; 70 participants; one study; very low-quality evidence). No studies reported serious adverse events, respiratory function or days lost from work or study.

Authors' conclusions

Analysis of available studies was limited by variable reporting of primary and secondary outcomes; therefore, it is difficult to draw firm conclusions related to the effectiveness of PAAPs in the management of adult asthma. We found no evidence from randomised controlled trials of additional benefit or harm associated with use of PAAP versus no PAAP, or PAAP plus education versus education alone, but we considered the quality of the evidence to be low or very low, meaning that we cannot be confident in the magnitude or direction of reported treatment effects. In the context of this caveat, we found no observable effect on the primary outcomes of hospital attendance with an asthma exacerbation, asthma symptom scores or adverse events. We recommend further research with a particular focus on key patient-relevant outcomes, including exacerbation frequency and quality of life, in a broad spectrum of adults, including those over 60 years of age.

PLAIN LANGUAGE SUMMARY

Written and personalised action plans to help adults manage their asthma

Review question

People with asthma may be given a written personalised action plan for managing their asthma. This plan provides information on which medicines they should take and when. Other people may be given education on how they should look after their asthma. This review set out to see if using a plan on its own or with education helps improve outcomes for people with asthma.

Background

Asthma is a disease that affects the lungs, which can make it difficult for people to breathe. Some people can manage their asthma very well, and it does not affect them very much, but for other people, asthma can change and sometimes can get worse very quickly and often. When this happens, people may go to see their doctor or may go to the hospital. When their asthma gets worse, people can take medicines or can change the amount of medicine they take to make their asthma better. To know when and how they should change their medicines, adults with asthma can be given a written plan that is designed just for them. This is called a personalised asthma action plan (PAAP). The PAAP will tell people when they need to see their doctor and may include education on how they should manage their asthma.

Study characteristics

We searched for studies up to September 2016. We found 15 studies that provided the information we were looking for in conducting this review. A total of 3062 people had taken part in these studies; 2602 people took part in 11 studies looking at PAAP versus no PAAP, and 460 people were included in four studies looking at PAAP and education versus just education. Fourteen studies lasted six months or longer. The average age of people in these studies ranged from 22 to 49 years. Asthma severity ranged from mild to severe. We were able to use data from 10 of these 15 studies to inform our findings.

Key results

PAAP alone compared with no PAAP: People using a PAAP did not show any difference (good or bad) in terms of having to go to the hospital because their asthma worsened compared with people not using a PAAP. This result was the same for changes in asthma symptom scores and number of deaths due to asthma. People with a PAAP showed no improvement in their quality of life compared with those without a PAAP, but the difference was not large enough to be meaningful.

PAAP plus education compared with education alone: Review authors found no real difference - good or bad - between people using a PAAP and education and those just receiving education. This finding was the same for all outcomes, that is, having to go to the hospital because their asthma worsened and changes in symptom scores and quality of life.

Quality of the evidence

We rated the quality of the 15 included studies as low or very low because the few studies included in this review had problems with study design, including how to enrol people into the study and how to handle missing data for some people. Also, studies had problems with how outcome data for those who did not finish the study should be managed. This means that as future studies are completed and added to future versions of this review, the findings of the review may change.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

PAAP compared with no PAAP for adults with asthma

Patient or population: adults with asthma
Setting: primary care, secondary care, tertiary care, community
Intervention: PAAP
Comparison: no PAAP

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with no PAAP	Risk with PAAP				
Exacerbation requiring ED or hospitalisation. Follow-up: range 14 weeks to 6 months.	82 per 1000.	63 per 1000 (39 to 100)	OR 0.75 (0.45 to 1.24)	1385 (5 RCTs)	⊕⊕◯◯ LOW[a]	No clear benefit or harm of a PAAP (low-quality evidence).
Asthma control, change from baseline in ACQ.	Mean asthma control, change from baseline in ACQ was -0.29.	MD 0.16 lower (0.25 lower to 0.07 lower)	-	141 (1 RCT)	⊕⊕◯◯ LOW[b]	No clear benefit or harm of a PAAP (low-quality evidence); MCID for ACQ was 0.5
Serious adverse events (including deaths).	16 per 1000.	49 per 1000 (5 to 538)	OR 3.26 (0.33 to 32.21)	125 (1 RCT)	⊕◯◯◯ VERY LOW[c]	No clear benefit or harm of a PAAP (very low-quality evidence)
Quality of life, change from baseline in AQLQ.	Mean quality of life, change from baseline in AQLQ ranged from 0.1 to 0.91	MD 0.18 higher (0.05 higher to 0.3 higher)	-	441 (3 RCTs)	⊕⊕◯◯ LOW[d]	Mean between-group difference in improvement from baseline did not exceed the minimum clinically important difference (0.5 for AQLQ) and is unlikely to be clinically relevant

Exacerbation requiring OCS.	306 per 1000.	390 per 1000 (270 to 523)	OR 1.45 (0.84 to 2.48)	1136 (3 RCTs)	⊕○○○ VERY LOW[e]	No clear benefit or harm of a PAAP (low-quality evidence).
Lung function, change from baseline in FEV_1 (L).	Mean lung function, change from baseline in FEV_1 (L) was 0 L.	MD 0.04 L lower (0.25 lower to 0.17 higher)	-	392 (3 RCTs)	⊕⊕○○ LOW[f]	No clear benefit or harm of a PAAP (low-quality evidence).
Days lost from work or study.	Mean days lost from work or study was 0.	MD 6.2 lower (7.32 lower to 5.08 lower)	-	74 (1 RCT)	⊕⊕○○ LOW[g]	PAAP was associated with significantly fewer days lost from work or study

*__The risk in the intervention group__ (and its 95% confidence interval) is based on assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

ACQ, Asthma Control Questionnaire; AQLQ, Asthma Quality of Life Questionnaire; CI, confidence interval; ED, emergency department; FEV_1, forced expiratory volume in 1 second; GRADE, Grades of Recommendation, Assessment, Development and Evaluation Working Group; HR, hazard ratio; MCID, minimum clinically important difference; MD, mean difference; OCS, oral corticosteroid; OR, odds ratio; PAAP, personalised asthma action plan; RCT, randomised controlled trial; RR, risk ratio

GRADE Working Group grades of evidence.
High quality: We are very confident that the true effect lies close to the estimate of effect.
Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of effect but may be substantially different.
Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of effect.
Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[a]The quality of the evidence was downgraded once for risk of bias (3/5 studies at risk of attrition bias and baseline imbalance in morbidity reported by Hoskins (weight 48.8%)) and once for imprecision (small number of total events; insufficient sample size (optimal size > 4 K) and CI including null effect and chance of appreciable benefit).
[b]The quality of the evidence was downgraded once for risk of bias (high risk of performance, detection and attrition bias) and once for indirectness (based on only one study, thus reducing generalisability).
[c]The quality of the evidence was downgraded once for risk of bias (attrition bias), once for imprecision (small number of events, insufficient sample size and CI including null effect and appreciable risk of harm) and once for indirectness (single study limiting generalisability).
[d]The quality of the evidence was downgraded twice for risk of bias (performance, detection and attrition bias).

[e] The quality of the evidence was downgraded twice for risk of bias (attrition bias and baseline imbalance in morbidity reported by Hoskins (weight 54.9%); high risk of other bias based on reporting error in Thoonen 2001) and once for imprecision (CI including null effect and chance of appreciable benefit).

[f] The quality of the evidence was downgraded once for risk of detection bias and attrition bias) and once for inconsistency (opposite direction of effect observed in one study; heterogeneity I^2 = 51%).

[g] The quality of the evidence was downgraded twice for indirectness (single study limiting generalisability; study performed in tertiary care setting in Serbia).

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 affected people living in low- and middle-income countries (Global Asthma Report 2014); the total burden may be greater than reported owing to the high prevalence of asthma in 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 2016). 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 be characterised by repeated exacerbations requiring a change to normal maintenance therapy. Treatment of people with asthma includes avoidance of potential triggers (when possible), use of inhaled corticosteroids (ICSs) and leukotriene receptor antagonists (LTRAs) to reduce airway inflammation and use of inhaled long-acting beta$_2$-agonists (LABAs), short-acting beta$_2$-agonists (SABAs) and anticholinergic bronchodilators (i.e. long-acting muscarinic antagonists (LAMAs)) to relieve airflow limitation (BTS/SIGN 2016; GINA 2016; 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). Goals of asthma treatment include total control of daytime and nocturnal symptoms, normal exercise and functional capacity and prevention of exacerbations (GINA 2016). It is clear from studies including the national review of UK asthma deaths (NRAD 2014) that there remains widespread misunderstanding of appropriate asthma treatment on the part of both patients and healthcare professionals; this puts people at risk of potentially avoidable adverse outcomes. A key recommendation for enhancing asthma care includes empowering all individuals to take control of their own condition and equipping them to deal with deteriorating symptoms early and appropriately (BTS/SIGN 2016).

Therefore, an important concept in asthma management is supported self-management; a personalised asthma action plan (PAAP) is a potentially important component of that support (Pearce 2016). This plan should detail the person's baseline characteristics, including measures of control (e.g. peak expiratory flow (PEF) and/or symptoms, and should state the agreed maintenance medication. Such plans should 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 by 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 2016; GINA 2016; NICE 2013). Although the format and design of action plans may 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). For adults, PAAPs may be based on symptoms, on peak flow monitoring or on both, whereas symptom-based plans generally are preferable for children (BTS/SIGN 2016). 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 therapy, along with 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 of the plan 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 2016) to record agreements made between clinician and patient. The modifiable nature of PAAPs is intended to avoid 'prescribing' of static care plans and to 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 promote 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 his or her asthma symptoms. PAAPs also function as an important communication tool for patients and healthcare professionals, representing both a record and a reminder of discussions between patient and clinician (Bhogal 2006; Welsh 2011). They are individualised, enabling the under-

lying nature of the person's asthma to be taken into consideration and reviewed on at least an annual basis (BTS/SIGN 2016).

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 death from asthma (NRAD 2014). PAAPs are associated with better asthma control in that they help reduce the risk of an exacerbation; 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 2016) and British Thoracic Society (BTS)/Scottish Intercollegiate Guidelines Network (SIGN) (BTS/SIGN 2016) 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, BTS/SIGN guidelines identify gaps in the evidence on which these guidelines were based. For example, data are insufficient for evaluation of the effectiveness of certain specific components of written PAAPs related to corticosteroid use (BTS/SIGN 2016). Furthermore, debate continues as to the effectiveness of written PAAPs in specific clinical settings (Khan 2014; Sheares 2015a), or when used alone or alongside education on self-management (Toelle 2011). Therefore, it is important that evidence for the effectiveness of PAAPs is re-evaluated systematically to ensure that guidelines accurately reflect an up-to-date evidence base. As PAAPs represent one component of multi-faceted self-management education, and given that provision of health education generally represents a significant cost for hospitals and clinics, it is important to confirm the effectiveness of PAAPs plus education to ensure efficient use of limited resources.

OBJECTIVES

To evaluate the effectiveness of PAAPs used alone or in combination with education, for patient-reported outcomes, resource use and safety among adults with asthma.

METHODS

Criteria for considering studies for this review

Types of studies

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

Types of participants

We included adults (aged 18 years or older) with asthma of any severity. We required that the diagnosis of asthma be determined by a clinician in accordance with validated national or international guidelines (e.g. BTS/SIGN 2016; GINA 2016). We required that studies that did not cite a specific guideline for diagnostic purposes must provide adequate information to allow diagnosis by review authors as per one of the validated guidelines. We excluded participants with other respiratory comorbidities (e.g. bronchiectasis, chronic obstructive pulmonary disease). If a study included only a subset of relevant participants, we included that study only if study authors could provide disaggregated data for participants who meet review inclusion criteria.

Types of interventions

We noted significant variability in the content and format of action plans (MacGillivray 2014). We defined a PAAP as any written plan that enables people with asthma (or their carers) to recognise when symptoms are worse, and that sets out actions to be taken if asthma control should deteriorate. As per GINA 2016 guidelines, we required that PAAPs must include specific instructions for patients (or their carers) regarding changes to reliever and controller medications, ways that oral corticosteroids (OCSs) should be used if needed and when and how healthcare services can be accessed (GINA 2016). Thresholds for action as defined in these plans could be based on symptoms or on peak flow. We assessed the following comparisons.

1. PAAP alone versus no PAAP.
2. PAAP plus education intervention (defined per GINA 2016 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, patient-reported outcomes and safety.

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 was not an inclusion criterion for this review.

Search methods for identification of studies

Electronic searches

We identified trials from the Cochrane Airways Trials Register, which is maintained by the Information Specialist for the Group. The Cochrane Airways Trials Register contains studies identified from several sources.

1. Monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL), through the Cochrane Register of Studies Online (crso.cochrane.org).
2. Weekly searches of MEDLINE Ovid SP (1946 to date).
3. Weekly searches of Embase Ovid SP (1974 to date).
4. Monthly searches of PsycINFO Ovid SP.
5. Monthly searches of the Cumulative Index to Nursing and Allied Health Literature (CINAHL) EBSCO.
6. Monthly searches of the Allied and Complementary Medicine Database (AMED) EBSCO.
7. Handsearches of the proceedings of major respiratory conferences.

Studies contained in the Trials Register are identified through search strategies based on the scope of Cochrane Airways. We have provided details of these strategies, as well as a list of handsearched conference proceedings, in Appendix 1. See Appendix 2 for search terms used to identify studies for this review.

We searched the following trials registries.

1. US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov).
2. World Health Organization International Clinical Trials Registry Platform (apps.who.int/trialsearch).

We searched the Cochrane Airways Trials Register and additional sources from their inception to 14 September 2016 with no restriction on language of publication.

Searching other resources

We checked reference lists of all primary studies and review articles for additional references. We searched relevant manufacturers' websites for trial information.

We searched for errata or retractions from included studies published in full text on PubMed (www.ncbi.nlm.nih.gov/pubmed) on 7 December 2016.

Data collection and analysis

Selection of studies

Two review authors (TG, AR or DE) independently screened titles and abstracts of all studies identified for potential inclusion as a result of the search, and coded them as 'retrieve' (eligible or potentially eligible/unclear) or 'do not retrieve'. We retrieved full-text study reports/publications; two review authors (TG, AR, CM or DE) independently screened the full text and identified studies for inclusion. We identified and recorded reasons for exclusion of ineligible studies. We resolved disagreements through discussion or, if required, through consultation with a third review author. We identified and excluded duplicates and collated multiple reports of the same study so that each study, rather than each report, was the unit of interest in the review. We recorded the selection process in sufficient detail to complete a PRISMA (Prefered Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram and a Characteristics of excluded studies table.

Data extraction and management

We used a data collection form for study characteristics and outcome data that was piloted on at least one study in the review. Two review authors (AR, DE or CM) independently extracted the following study characteristics from each of the included studies.

1. Methods: study design, total duration of study, details of any 'run-in' period, number of study centres and locations, 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 (AR, DE, CM or TG) independently extracted outcome data from each of the included studies. We noted in the Characteristics of included studies table if outcome data were not reported in a useable way. We resolved disagreements by consensus or by consultation with a third review author. One review author (DE) transferred data into Review Manager 5 (RevMan 2014). We double-checked that data were entered correctly by comparing data presented in the systematic review against the study reports. A second review author (CM) performed a spot-check of study characteristics against the trial report for accuracy.

Assessment of risk of bias in included studies

Two review authors (AR, CM, DE or TG) independently assessed the risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We resolved disagreements by discussion or by consultation with a third review author. We assessed 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 graded each potential source of bias as high, low or unclear and provided a quote from the study report together with a justification for our judgement in the 'Risk of bias' table. We summarised risk of bias judgements across different studies for each of the domains listed. We considered blinding separately for different key outcomes when necessary (e.g. for unblinded outcome assessment, risk of bias for all-cause mortality may be very different from a participant-reported pain scale). When information on risk of bias was related to unpublished data or to correspondence with a trialist, we noted this in the 'Risk of bias' table.

When considering treatment effects, we took into account the risk of bias for studies that contributed to those outcomes.

Assessment of bias in conducting the systematic review

We conducted the review according to the published protocol and reported deviations from it in the Differences between protocol and review section of the systematic review.

Measures of treatment effect

We analysed dichotomous data as odds ratios and as 95% confidence intervals (CIs). We analysed continuous data as mean differences and 95% CIs. We entered data presented as a scale with a consistent direction of effect. We used change from baseline scores when possible.

We undertook meta-analyses only when this was meaningful (i.e. if treatments, participants and the underlying clinical question were similar enough for pooling to make sense).

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

When multiple trial arms were reported in a single trial, we included only the relevant arms. If two comparisons (e.g. intervention A vs placebo and intervention B vs placebo) were combined in the same meta-analysis, we halved the control group to avoid double-counting. If trials reported outcomes at multiple time points, we used the end of treatment time point.

Unit of analysis issues

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

Dealing with missing data

We contacted investigators or study sponsors to verify key study characteristics and to obtain missing numerical outcome data when possible (e.g. when a study was identified as abstract only). When this was not possible, and when missing data were thought to introduce serious bias, we explored the impact of including such studies in the overall assessment of results by performing a sensitivity analysis.

Assessment of heterogeneity

We used the I^2 statistic to measure heterogeneity among the trials in each analysis. If we identified substantial heterogeneity (i.e. I^2 > 50%), we reported this and explored possible causes by performing prespecified subgroup analysis.

Assessment of reporting biases

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

Data synthesis

We used a random-effects model for all analyses, as we expected variation in effects due to differences in study populations and methods. We performed sensitivity analyses using a fixed-effect model.

'Summary of findings' table

We created a 'Summary of findings' table using data from all seven outcomes. We used 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 studies that contributed data to the meta-analyses for prespecified outcomes. We used methods and recommendations as described in Section 8.5 and Chapter 12 of the *Cochrane Handbook for Systematic Reviews of Interventions* and used GRADEpro software (Higgins 2011). We justified all decisions to downgrade or upgrade the quality of studies by using footnotes, and we made comments to aid the reader's understanding of the review when necessary.

Subgroup analysis and investigation of heterogeneity

When possible, we planned 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. subanalysis of the duration, format or frequency of education).
8. Provider of self-management education (e.g. physician-led vs nurse-led education).

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

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

Sensitivity analysis

We planned to carry out 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.

RESULTS

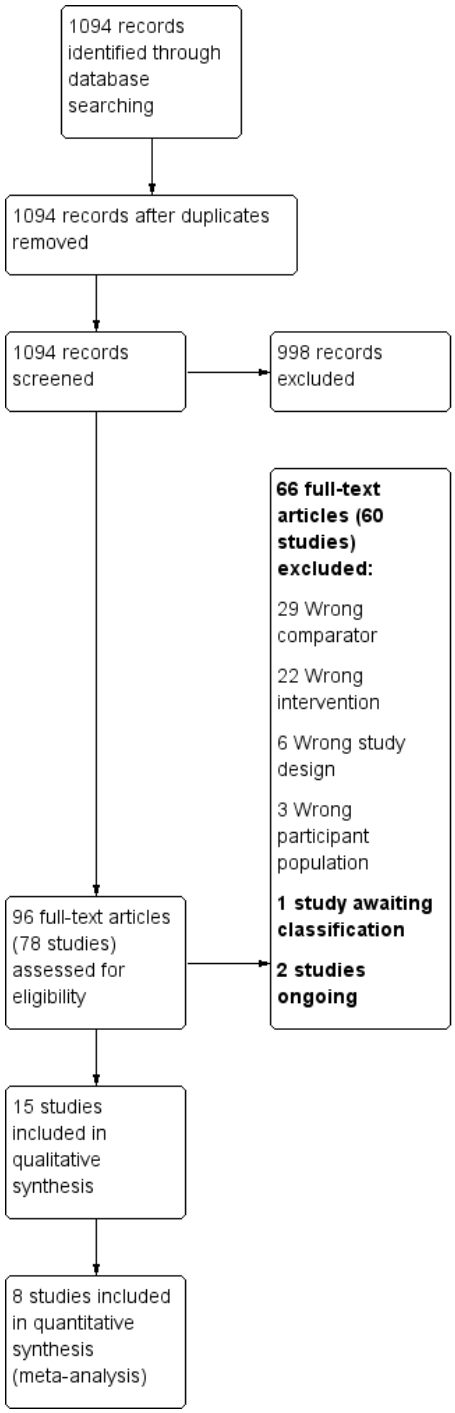
Description of studies

We have reported details of included studies in the Characteristics of included studies table and have provided a list of excluded studies (with reasons for exclusion) in the Characteristics of excluded studies table.

Results of the search

Through searches of databases, we identified 1094 references (Figure 1). After screening titles and abstracts, we excluded 998 references and sought full-text copies for the remaining 96 references describing 78 studies. Of these, we excluded 66 full-text articles describing 60 studies (see Excluded studies). The remaining 30 articles reported findings from the 18 studies included in this review (15 included studies, 2 ongoing studies, 1 study awaiting classification). We last updated all searches on 14 September 2016.

Figure 1. Study flow diagram.



Included studies

We included in the review 15 studies described in 27 articles. Four of these studies are reported in multiple articles. Thus, for example, three additional articles describe the study reported in Evans 2005. These 15 included studies randomised a total of 3062 participants (PAAP vs no PAAP: n = 2602 participants; PAAP plus education vs education alone: n = 460). Eleven studies were relevant to the first comparison (PAAP vs no PAAP); eight studies contributed data to the analyses (Ayres 1996; Cowie 1997; Sheares 2015; Hoskins 1996; Jones 1995; Milenković 2007; Nokela 2010; Thoonen 2001), and three provided no data of relevance to this review (Baldwin 1995; Griffiths 2004; Wang 2004). We received a communication just before submission indicating that relevant data from Griffiths 2004 are now available; if successfully sourced, we will include these data in a subsequent update of the review. Four studies were relevant to the second comparison (PAAP plus education vs education alone); two studies contributed data to the analyses (Charrois 2006; Klein 1998), and two provided no data of relevance to this review (McArdle 1997; Sangha 2004).

Methods

Most (11) included studies were parallel-group randomised controlled trials; four were cluster randomised trials for which the primary care centre, rather than the participant, was the unit of randomisation (Griffiths 2004; Hoskins 1996; Nokela 2010; Thoonen 2001). Fourteen of the fifteen included studies were of six months' duration or longer (range six months to two years), and one study had a duration of 14 weeks (Nokela 2010). Most trials did not blind participants or personnel to treatment allocation, although blinding is not feasible with this intervention, and assessor blinding was clearly reported in only two trials (Cowie 1997; Jones 1995). Studies were based in primary care (n = 7; Baldwin 1995; Charrois 2006; Griffiths 2004; Hoskins 1996; Jones 1995; Nokela 2010; Thoonen 2001), secondary care (n = 3; Cowie 1997; McArdle 1997; Sheares 2015), tertiary care (n = 3; Klein 1998; Milenković 2007; Wang 2004) or both primary and secondary care (Ayres 1996), or study setting was not reported (Sangha 2004). Trials were conducted in eight countries including UK (Ayres 1996; Baldwin 1995; Griffiths 2004; Hoskins 1996; Jones 1995), USA (Sheares 2015), Canada (Charrois 2006; Cowie 1997), the Netherlands (Klein 1998; Thoonen 2001), Serbia (Milenković 2007), Hong Kong (Wang 2004), Australia (McArdle 1997) and Sweden (Nokela 2010), or study location was not reported (Sangha 2004).

Participants

We included studies that recruited adults aged 18 years of age and older, or from which data for the adult population could be obtained (Sheares 2015). Individual studies rarely reported the age range of participants, but mean participant age ranged from 22 (Griffiths 2004) to 49 years (Milenković 2007), when reported. Review authors classified asthma severity using a range of definitions across the included studies and assigned participants across the spectrum from mild to severe/high risk. Concomitant medications were infrequently reported.

Interventions

PAAP versus no PAAP

Nine studies assessed PAAPs that had components based on peak flow (Ayres 1996; Baldwin 1995; Cowie 1997; Griffiths 2004; Hoskins 1996; Jones 1995; Milenković 2007; Sheares 2015; Thoonen 2001), one study assessed a PAAP based on symptoms alone (Nokela 2010) and it was not possible to determine the nature of the PAAP for one study that was reported only as an abstract (Wang 2004).

PAAP plus education versus education alone

Three studies assessed PAAPs that had components based on peak flow (Klein 1998; McArdle 1997; Sangha 2004), and the remaining study (Charrois 2006) did not report the nature of the PAAP. Educational components comprised 'generalised asthma education' (McArdle 1997); three consecutive weekly 90-minute sessions provided by a specially trained asthma nurse covering the pathophysiology of asthma, the role and side effects of medication, allergic and non-allergic triggers and symptoms indicating an impending exacerbation (Klein 1998); a 45-minute discussion with visual aids provided by the treating physician on the topic of asthma pathophysiology (Sangha 2004); and an educational component on the topic of 'all asthma medications' (Charrois 2006).

Outcomes

Outcomes were not consistently reported across trials. Five studies that met the review inclusion criteria did not report relevant outcomes (Baldwin 1995; Griffiths 2004; McArdle 1997; Sangha 2004; Wang 2004); when it was reasonable that relevant data may have been collected, we requested data from the trial authors (Griffiths 2004; McArdle 1997; Sangha 2004; Wang 2004); in all cases but one (Griffiths 2004), study authors were not able to provide additional data or we received no response. For the primary outcomes, six studies reported the proportion of participants who

experienced an exacerbation requiring an emergency department visit or hospitalisation (Ayres 1996; Charrois 2006; Cowie 1997; Hoskins 1996; Milenkovic 2007; Nokela 2010); two studies reported asthma control measured on a validated scale (Charrois 2006; Nokela 2010); and two studies reported serious adverse effects (Ayres 1996; Hoskins 1996). For the secondary outcomes, four studies reported quality of life using the Asthma Quality of Life Questionnaire (Klein 1998; Nokela 2010; Sheares 2015; Thoonen 2001); four studies reported the number of participants who experienced an exacerbation requiring treatment with OCSs (Charrois 2006; Hoskins 1996; Jones 1995; Thoonen 2001); four studies reported various measures of lung function (Ayres 1996; Jones 1995; Milenkovic 2007; Thoonen 2001); and one study reported days lost from work or study (Milenkovic 2007).

Excluded studies

We excluded 66 full-text articles related to 60 studies. We attributed the high number of exclusions at full-text evaluation to the fact that many abstracts/titles alluded to self-management programmes, but without consulting the full-text reports, it was difficult for review authors to ascertain whether these studies included a PAAP. Of the 60 excluded studies, 29 did not include our selected comparator (PAAP + education, or no PAAP and no education), 22 did not fulfil our definition of the intervention, six used a study design that did not meet our inclusion criteria (i.e. non-randomised or pseudo-randomised) and three did not meet our population criteria (i.e. children only). We have provided additional details in the Characteristics of excluded studies table.

Risk of bias in included studies

We have presented details of the risk of bias associated with each study along with supporting evidence in the Characteristics of included studies tables. Figure 2 presents a summary of risk of bias judgements according to study and domain, and Figure 3 depicts the risk of bias for each domain (see also following subsections) across all included studies.

Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

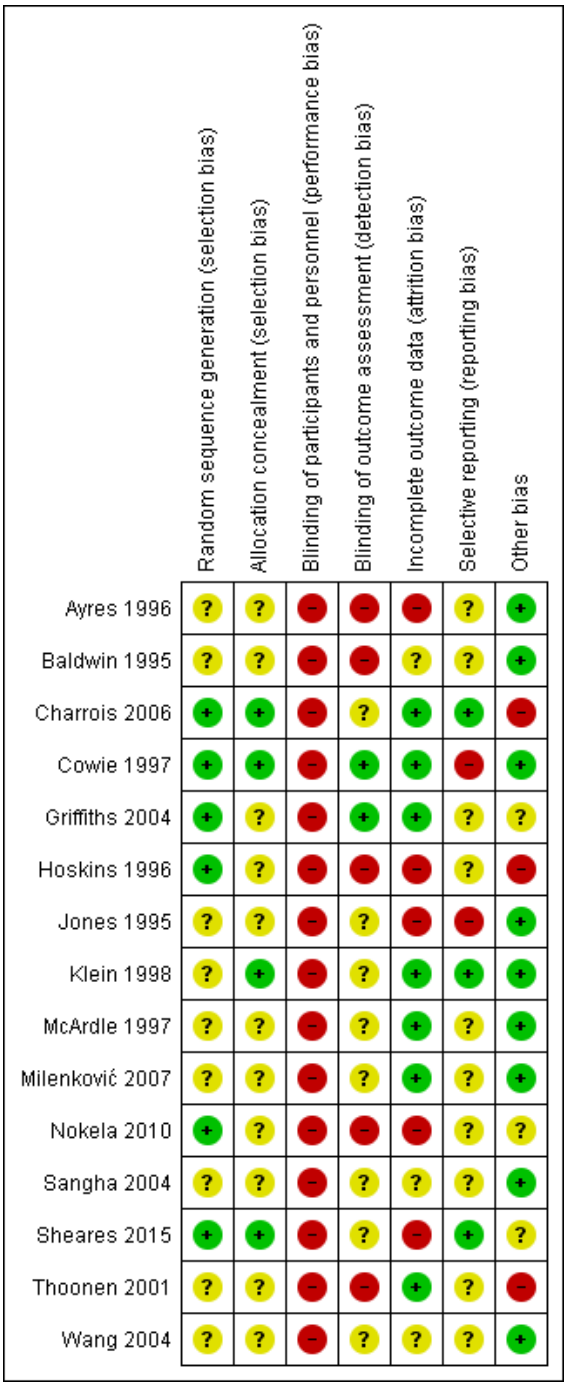
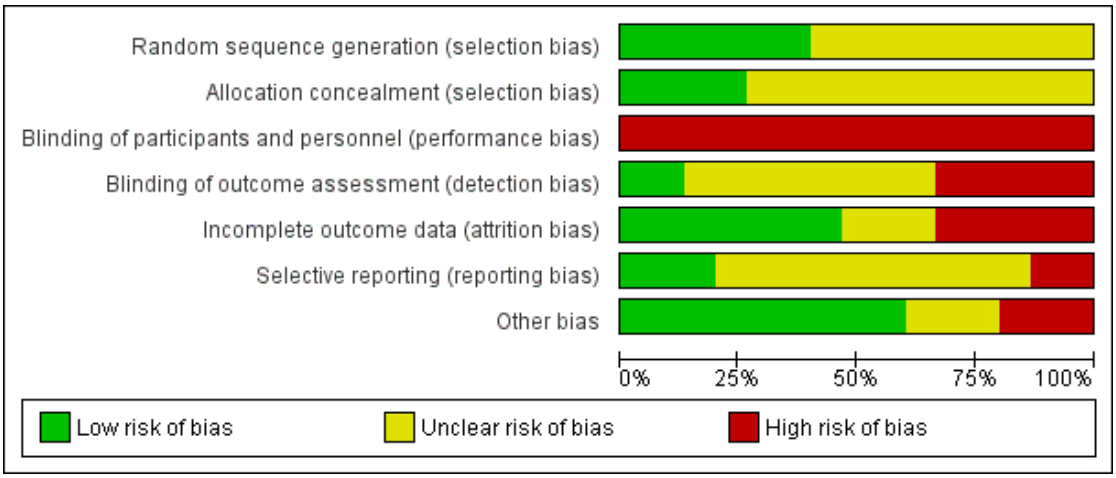


Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.



Allocation

All studies had low or unknown risk of selection bias. Six of the 15 included studies were associated with low risk of bias for random sequence generation (Charrois 2006; Cowie 1997; Griffiths 2004; Hoskins 1996; Nokela 2010; Sheares 2015), but the remaining studies provided insufficient information. Four studies were associated with low risk of bias in the allocation concealment process (Charrois 2006; Cowie 1997; Klein 1998; Sheares 2015) but the remaining studies did not provide sufficient information to inform a rating. We considered no studies to be at high risk of selection bias.

Blinding

We considered all included studies to be at high risk of performance bias, but this was not a consequence of poor design, as blinding of participants and personnel was not feasible for this intervention. Performance-related outcome measures, such as peak flow, asthma control and quality of life, may have been susceptible to detection bias. Outcomes such as exacerbations and serious adverse events were less likely to be influenced by participants' or investigators' knowledge of the intervention. We considered two trials that blinded outcome assessment to be at low risk of potential detection bias (Cowie 1997; Griffiths 2004); eight studies provided insufficient information (detection bias unknown), and we considered the remaining five studies to be at high risk of detection bias (Ayres 1996; Baldwin 1995; Hoskins 1996; Nokela 2010; Thoonen 2001).

Incomplete outcome data

Seven studies had low risk of attrition bias; three others provided insufficient information and we judged their risk of bias as unknown. Five studies had high risk of attrition bias owing to incomplete outcome data (Ayres 1996; Hoskins 1996; Jones 1995; Nokela 2010; Sheares 2015).

Selective reporting

Three studies were at low risk of reporting bias (Charrois 2006; Klein 1998; Sheares 2015). A publicly provided protocol was not available for most studies, resulting in a judgement of 'unknown' risk of reporting bias. We considered two studies to be at high risk of reporting bias (Cowie 1997; Jones 1995).

Other potential sources of bias

We considered three studies to be at high risk of 'other' bias. Pharmacist compliance with the intervention was poor in Charrois 2006. This meant that only three-quarters of the intervention group received a written asthma action plan (WAAP), and less than half of participants received education about WAAP at each pharmacy visit. Hoskins 1996 reported a between-group imbalance in

morbidity at baseline. Although these investigators reported some outcome measures as changes from baseline, this was not the case for all outcomes, and the magnitude or direction of treatment effect may have been affected. Thoonen and colleagues noted that participants who received PAAPs were provided with an oral course of prednisolone, and that this prescription may have been incorrectly interpreted as evidence of use of prednisolone during an exacerbation; thus data on exacerbations requiring treatment with an OCS may overestimate the number of participants with an exacerbation requiring an OCS in the PAAP group compared with the control group (Thoonen 2001). We considered three studies to have unknown risk of 'other' bias because it was not clear whether imbalance in baseline characteristics between groups would affect outcomes (Griffiths 2004; Nokela 2010; Sheares 2015). We considered the remaining included studies to have low risk of 'other' bias.

Effects of interventions

See: **Summary of findings for the main comparison** PAAP compared with no PAAP for adults with asthma; **Summary of findings 2** PAAP plus education compared with education alone for adults with asthma

PAAP versus no PAAP

Primary outcomes

Number of participants reporting at least one exacerbation requiring emergency department visit or hospitalisation

Five studies involving 1385 participants found no statistically significant difference in the number of exacerbations requiring an emergency department (ED) visit or hospitalisation between those participants receiving PAAP and those not receiving PAAP (odds ratio (OR) 0.75, 95% confidence interval (CI) 0.45 to 1.24) (Analysis 1.1). Among those who used a PAAP (vs no PAAP), we estimated that 19 fewer people per 1000 would have an exacerbation requiring an ED visit/hospitalisation, but confidence intervals ranged from 43 fewer to 18 more. We observed a low level of heterogeneity for this outcome (I^2 = 17%). Three studies measured this outcome at six months, and the remaining two studies measured this outcome at three months and 12 months. The quality of the evidence was low, as we had downgraded it once for risk of bias (3/5 studies at risk of attrition bias and baseline imbalance in morbidity as reported by Hoskins 1996 (weight 48.8%) and once for imprecision (small total number of events; sample size insufficient (optimal size > 4K) and confidence intervals include null effect and chance of appreciable benefit).

Asthma symptom scores

One study of 141 participants assessed change from baseline on the Asthma Control Questionnaire and reported a mean difference (MD) of -0.16 (95% CI -0.25 to -0.07) (Analysis 1.2). The quality of the evidence was low, as we had downgraded it once for risk of bias (high risk of performance, detection and attrition bias) and once for indirectness (based on only one study, therefore limiting generalisability).

Serious adverse events (including death)

Two studies contributed data on serious adverse events (SAEs), including deaths (Ayres 1996; Hoskins 1996). However, the SAEs reported in Hoskins 1996 comprised deaths that were considered unrelated to asthma. Therefore, we did not combine these events with data on SAEs from Ayres 1996. Results showed no statistically significant differences in SAEs between participants receiving a PAAP and those not receiving a PAAP (OR 3.26, 95% CI 0.33 to 32.21; 125 participants; one study) (Analysis 1.3). Among those who used a PAAP (vs no PAAP), we estimated that 33 more people per 1000 would have an SAE; confidence intervals ranged from 11 fewer to 522 more. We considered the quality of the evidence to be very low, as we had downgraded it once for risk of bias (attrition bias), once for imprecision (few events, insufficient sample size and CI, including null effect and appreciable risk of harm) and once for indirectness (limited generalisability of single study).

Secondary outcomes

Quality of life

We analysed data from three studies with 441 participants that assessed change in score from baseline on the Asthma Quality of Life Questionnaire (AQLQ) and found statistically significant improvement in quality of life scores for those receiving a PAAP compared with those not receiving a PAAP (mean difference (MD) 0.18, 95% CI 0.05 to 0.30) (Analysis 1.4). However, the magnitude of the MD was lower than the established minimum clinically important difference (MCID 0.5) and is thus unlikely to be of clinical relevance. We noted a moderate level of heterogeneity (I^2 = 61%). Each study measured outcomes at a different time point, namely, three months, 12 months and 24 months post recruitment. The quality of the evidence was low, as we had downgraded it twice for risk of bias (performance, detection and attrition bias).

Number of participants reporting at least one exacerbation requiring systemic corticosteroids

We analysed data from three studies involving 1136 participants and found that use of PAAP had no significant effect on the number of participants reporting at least one exacerbation requiring

oral systemic corticosteroids (OR 1.45, 95% CI 0.84 to 2.48) (Analysis 1.5). We observed a moderate level of heterogeneity (I^2 = 50%). We considered the quality of the evidence to be very low, as we had downgraded it twice for risk of bias (attrition bias and baseline imbalance in morbidity as reported by Hoskins 1996 (weight 54.9%); other risk of bias based on a reporting error in the study reported by Thoonen 2001) and once for imprecision (CI including null effect and chance of appreciable benefit).

Measures of respiratory function

Results showed no statistically significant difference in change in FEV_1 from baseline when groups receiving PAAP were compared with those not receiving PAAP (MD -0.04, 95% CI -0.25 to 0.17); we noted moderate heterogeneity (I^2 = 50%) (Analysis 1.6). Three studies with a total of 392 participants assessed this outcome. The quality of the evidence was low, as we had downgraded it once for risk of bias (detection bias and attrition bias) and once for inconsistency (opposite direction of effect observed in one study).
Data from two studies (146 participants) showed no statistically significant difference in the change from baseline of % predicted FEV_1 when the PAAP group was compared with the non-PAAP group (MD 0.40, 95% CI -6.05 to 6.85) (Analysis 1.7). Findings show no heterogeneity (I^2 = 0%), and the quality of the evidence was low, as we had downgraded it once for risk of bias (attrition and reporting bias) and once for inconsistency (opposite direction of effect).
One study of 72 participants assessed change from baseline in % predicted PEF and found no difference between the two groups (MD 1.20, 95% CI -5.67 to 8.07) (Analysis 1.8). The quality of the evidence was low, as we had downgraded it once for risk of bias (performance, attrition and reporting) and once for indirectness (limited generalisability of single study).
Similarly, one study measured change from baseline in PEF among a total of 125 participants and found no difference between the group receiving PAAP and the group not receiving PAAP (MD -18.00, 95% CI -54.03 to 18.03) (Analysis 1.9). The quality of the evidence was very low, as we had downgraded it once for risk of bias (attrition bias), once for indirectness (limited generalisability of single study) and once for imprecision (wide confidence intervals encompassing 72 L/min).

Days lost from work or study

One study counted days lost from work or study and found that the 37 participants receiving PAAP had a significant reduction in the number of days lost compared with the 37 participants who did not receive PAAP (MD -6.20, 95% CI -7.32 to -5.08) (Analysis 1.10). The quality of the evidence was low, as we had downgraded it twice for indirectness (limited generalisability of single study; study performed in tertiary care setting in Serbia).

Subgroup analyses

As per the protocol, we intended to perform prespecified subgroup analyses on the primary outcomes. The outcome 'number of participants reporting at least one exacerbation requiring emergency department visit or hospitalisation' was the only primary outcome for which a sufficient number of studies contributed data to permit subgroup analysis. The following subgroup analyses were not feasible because insufficient information was provided in published reports or reporting of key variables was inconsistent: people with recent unscheduled hospitalisation versus people without (information not reported by all contributing studies); symptom-based versus peak flow-based plans (all studies used peak flow-based plans or the type of plan was not reported); use of single-inhaler therapy (not reported by any included study); treatment instructions individualised using OCS/ICS/participant-specific triggers (inconsistently reported across included studies). The final two planned subgroup analyses (format of concurrent self-management education; provider of concurrent self-management education) were not relevant to this comparison.

Sensitivity analyses

The outcome 'number of participants reporting at least one exacerbation requiring emergency department visit or hospitalisation' was the only outcome with a sufficient number of contributing studies to permit the prespecified sensitivity analyses. However, no prespecified sensitivity analyses were feasible because unpublished data did not contribute to this outcome, all studies contributing data to this outcome were assessed as having high risk of performance bias and only one study was assessed as having low risk of detection bias (Cowie 1997).

PAAP plus education intervention (defined per GINA 2015 guidelines) versus education intervention alone

Primary outcomes

Number of participants reporting at least one exacerbation requiring emergency department visit or hospitalisation

One study assessed exacerbations requiring an emergency department visit or hospitalisation and found no difference between the group receiving PAAP and group receiving education alone (OR 1.08, 95% CI 0.27 to 4.32; 70 participants; one study) (Analysis 2.1). For people who used a PAAP plus education (vs education alone), we estimated that 15 more people per 1000 would have an exacerbation requiring an emergency department visit/hospitalisation, but confidence intervals ranged from 176 fewer to 344 more. The quality of the evidence was very low, as we had downgraded it once for risk of bias ('other': participants did not receive

the intervention as planned), once for indirectness (limited generalisability of single study) and once for imprecision (CI including null effect and risk of appreciable harm or benefit).

Asthma symptom scores

One study of 70 participants evaluated change in score on the Asthma Control Questionnaire from baseline and found no difference between the group receiving PAAP with an educational intervention and the group receiving education alone (MD -0.10, 95% CI -0.54 to 0.34; 70 participants; one study) (Analysis 2.2). The quality of the evidence was low, as we had downgraded it once for risk of bias ('other': participants did not receive the intervention as planned) and once for indirectness (limited generalisability of single study).

Serious adverse events (including death)

No studies reported data for this outcome.

Secondary outcomes

Quality of life

No difference was found in changes in score from baseline on the Asthma Quality of Life Questionnaire between a group of 84 participants receiving PAAP and education and a group of 90 participants in the same study receiving education alone (MD 0.13, 95% CI -0.13 to 0.39; 174 participants; one study) (Analysis 2.3). The quality of the evidence was low, as we had downgraded it once for risk of bias ('performance bias) and once for indirectness (limited generalisability of single study).

Number of participants reporting at least one exacerbation requiring systemic corticosteroids

One study that assessed use of PAAP and education compared with education alone found no statistically significant differences between groups in terms of the number of participants reporting at least one exacerbation requiring oral systemic corticosteroids (OR 0.28, 95% CI 0.07 to 1.12; 70 participants; one study) (Analysis 2.4). The quality of the evidence was very low, as we had downgraded it once for risk of bias ('other': participants did not receive the intervention as planned), once for indirectness (limited generalisability of single study) and once for imprecision (CI including null effect and risk of appreciable benefit).

Measures of respiratory function

No studies reported data for this outcome.

Days lost from work or study

No studies reported data for this outcome.

Subgroup and sensitivity analyses

For this comparison, the number of studies contributing data to any of the primary outcomes was insufficient to permit subgroup or sensitivity analyses.

ADDITIONAL SUMMARY OF FINDINGS [Explanation]

PAAP plus education compared with education alone for adults with asthma

Patient or population: adults with asthma
Setting: Community, secondary care, tertiary care
Intervention: PAAP plus education
Comparison: education alone

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Number of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with education alone	Risk with PAAP plus education				
Exacerbation requiring ED or hospitalisation.	265 per 1000.	280 per 1000 (89 to 609)	OR 1.08 (0.27 to 4.32)	70 (1 RCT)	⊕◯◯◯ VERY LOW[a]	No clear benefit or harm of PAAP plus education (very low-quality evidence). Risk with education alone based on 12 months before study start
Asthma control, change from baseline in ACQ score.	Mean asthma control, change from baseline in ACQ score was -0.29	MD 0.1 lower (0.54 lower to 0.34 higher)	-	70 (1 RCT)	⊕⊕◯◯ LOW[b]	No clear benefit or harm of PAAP plus education (low-quality evidence). MCID for ACQ (0.5) not reached
Serious adverse events (including death).	Included studies reported no data for this outcome.					
Quality of life, change from baseline in AQLQ score.	Mean quality of life, change from baseline in AQLQ score was 0.3	MD 0.13 higher (0.13 lower to 0.39 higher)	-	174 (1 RCT)	⊕⊕◯◯ LOW[c]	No clear benefit or harm of PAAP plus education (low-quality evidence). MCID for AQLQ (0.5) not reached

Exacerbation requiring OCS.	324 per 1000.	118 per 1000 (32 to 349)	OR 0.28 (0.07 to 1.12)	70 (1 RCT)	⊕○○○ VERY LOW[d]	No clear benefit or harm of PAAP plus education (very low-quality evidence). Risk with education alone based on 12 months before study start
Lung function.	Included studies reported no data for this outcome.					
Days lost from work or study.	Included studies reported no data for this outcome.					

*__The risk in the intervention group__ (and its 95% confidence interval) is based on assumed risk in the comparison group and the __relative effect__ of the intervention (and its 95% CI).

ACQ, Asthma Control Questionnaire; AQLQ, Asthma Quality of Life Questionnaire; CI, confidence interval; ED, emergency department; GRADE, Grades of Recommendation, Assessment, Development and Evaluation Working Group; HR, hazard ratio; MCID, minimum clinically important difference; MD, mean difference; OCS, oral corticosteroid; OR, odds ratio; PAAP, personalised asthma action plan; RCT, randomised controlled trial; RR, risk ratio

GRADE Working Group grades of evidence.
High quality: We are very confident that the true effect lies close to the estimate of effect
Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of effect but may be substantially different.
Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of effect.
Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[a]The quality of the evidence was downgraded once for risk of bias ('other': Participants did not receive the intervention as planned), once for indirectness (single study reducing generalisability) and once for imprecision (CI including null effect and risk of appreciable harm or benefit).
[b]The quality of the evidence was downgraded once for risk of bias ('other': Participants did not receive the intervention as planned) and once for indirectness (single study reducing generalisability).
[c]The quality of the evidence was downgraded once for risk of bias (performance bias) and once for indirectness (single study reducing generalisability).
[d]The quality of the evidence was downgraded once for risk of bias ('other': Participants did not receive the intervention as planned), once for indirectness (single study reducing generalisability) and once for imprecision (CI including null effect and risk of appreciable benefit).

DISCUSSION

Summary of main results

Of the 15 studies included in this review, 10 provided data relevant for analyses. Of these 10, eight studies compared a personalised asthma action plan (PAAP) versus no PAAP, and two studies compared PAAP plus education versus education alone. For both comparisons, our primary outcomes were the number of participants reporting at least one exacerbation requiring an emergency department visit or hospitalisation, change in asthma symptom scores and serious adverse events, including death. Secondary outcome measures were change in quality of life scores, number of exacerbations requiring oral corticosteroids, change in respiratory function tests and number of days lost from work or study.

PAAP versus no PAAP

Data on exacerbations requiring emergency department attendance or hospitalisation were available for five studies with 1385 participants. The meta-analysis did not show a statistically significant effect of the PAAP intervention on exacerbations, but this is not considered strong evidence of no effect, as follow-up measurement intervals were inconsistent (3 to 12 months), event frequencies were very low in three trials and overall methodological quality was relatively low.

Data from a validated asthma symptom score was available from only one study with 141 participants, which reported a statistically significant mean difference (MD) of -0.16 (95% confidence interval (CI) -0.25 to -0.07) in scores from the Asthma Control Questionnaire, although this is below the 0.5 threshold for a minimum clinically important difference and we considered the overall quality of the evidence to be low.

Adverse events data were available from two studies with 441 participants, but we excluded one from the analyses, as reported deaths were not asthma related (Hoskins 1996). Results showed no significant difference in serious adverse events reported in Ayres 1996, but this finding was based on a very low event frequency (four), making it difficult for review authors to draw firm conclusions.

Three studies contributed data on quality of life from the Asthma Quality of Life Questionnaire (AQLQ). PAAP was associated with a statistically significant improvement in quality of life, but the mean difference in score of 0.18 was below the minimum threshold of 0.5 considered clinically relevant (low-quality evidence).

Three studies contributed data on exacerbations requiring oral corticosteroids, but the effect was not statistically significant (very low-quality evidence). Four studies provided data on measures of respiratory function including forced expiratory volume in one second (FEV_1), FEV_1 % predicted, peak expiratory flow (PEF) and PEF % predicted, but effects were not statistically or clinically significant (low-quality evidence). One study with 74 participants showed a significant reduction in days lost from work with the intervention (MD -6.2 days, 95% CI -7.32 to -5.08) but the quality of evidence was low. The low or very low quality of evidence limits our capacity to draw firm conclusions based on secondary outcomes.

PAAP plus education versus education intervention alone

Only one study provided data on exacerbations requiring an emergency department visit or hospitalisation (Charrois 2006) and found no evidence of a significant difference. This same study reported no significant difference in AQLQ scores, although we considered the quality of evidence from this study to be low. No studies reported data on adverse events.

One study reported no significant differences in change in AQLQ scores (low-quality evidence), and one study reported no significant differences in exacerbations requiring oral corticosteroids, although again, this finding was based on low-quality evidence. No data were available for measures of respiratory function nor for days lost from work or study.

In summary, our analyses were unable to demonstrate significant benefit or harm associated with use of a PAAP, with or without an educational component, for our primary outcomes. However, the overall low quality of the evidence precludes robust conclusions on the role of PAAP in adult asthma.

Overall completeness and applicability of evidence

Although 15 studies met the inclusion criteria, only 10 included outcomes relevant to the review and half of these were considered to have high risk bias owing to incomplete outcome data (Ayres 1996; Hoskins 1996; Jones 1995; Nokela 2010; Sheares 2015). For studies that contributed data, of the 2497 randomised participants (n = 2152 PAAP vs no PAAP; n = 315 PAAP plus education vs education alone), 284 did not complete the trial (n = 257 PAAP vs no PAAP; n = 27 PAAP plus education vs education alone). In studies for which details of withdrawal were given for each study group (PAAP vs no PAAP) (Ayres 1996; Cowie 1997; Hoskins 1996; Milenkovi¿ 2007; Nokela 2010; Sheares 2015; Thoonen 2001), rates tended to be higher in the intervention arms. Study duration appeared to have no effect. Data from Hoskins 1996 showed that when general practitioners (GPs) were randomised to intervention and comparison arms (i.e. a cluster randomised trial), a much higher percentage of GPs in the comparator arm compared with those issuing PAAPs returned data on participants with asthma (83% vs 51%). The newly updated British Thoracic Society (BTS)/Scottish Intercollegiate Guidelines Network (SIGN) guidelines (BTS/SIGN 2016) and evidence presented in Ring 2011 and Pinnock 2015 highlight that successful implementation of effective self-management interventions is associated with empowered patients and knowledgeable staff work-

ing within an organisational culture that promotes asthma self-management; this can be particularly challenging in primary care. Hoskins 1996 may indicate that GP/patient compliance with the intervention was poor.

The BTS/SIGN asthma guidelines issued since 2008 and the National Institute for Clinical Excellence (NICE) Quality Standard for Asthma (NICE 2013) recommend provision of PAAPs (as opposed to verbal instructions alone) along with structured education, yet most studies contributing data to this review (n = 10), including the most recent study (Nokela 2010), did not include education as a comparator (n = 8). This suggests that recent empirical research has not addressed guideline recommendations. For the two older studies that featured education as a comparator (Charrois 2006; Klein 1998), data could not be pooled owing to lack of homogeneity in outcome measures.

Powell 2002 reported significant improvement in outcomes with self-monitoring based on peak expiratory flow or symptom control plus regular review, but only two studies in this review used a symptom-based PAAP and evidence may be insufficient to show effectiveness. Heterogeneity was considerable with respect to the structure/format of the PAAP used across studies, although we were generally satisfied that the PAAPs used in the included studies conformed to the key features described in BTS/SIGN guidelines (BTS/SIGN 2016). As further discussed later, whether participants were provided with a course of oral corticosteroids (OCSs) for self-administration on the basis of a predefined threshold of symptoms or lung function potentially confounds our findings, and included studies varied as to whether OCSs were provided for self-administration, or whether participants were required to seek medical consultation for OCS treatment.

Studies reported considerable variation in methods used to assess asthma severity during recruitment that may have influenced differences between study arms and between trials, owing to unequal distribution of asthma severity among participants, which in turn may have offered greater opportunity for improvement in more severe cases. In Ayres 1996, participants who were self-managed had better lung function and asthma severity scores at baseline than those managed by their physician. Furthermore, a predefined criterion required that we should exclude studies that enrolled patients with respiratory comorbidities (e.g. chronic obstructive pulmonary disease (COPD)); thus the applicability of current findings must be considered in this context.

All studies reported the mean age of participants (one reported age range), suggesting that adults 60 years of age and older are underrepresented, although this is a common feature of asthma research (BTS/SIGN 2016).

Finally, it is important to acknowledge that the outcomes examined in this review included elements commonly specified in PAAPs (e.g. use of OCS, visit to the emergency department). This potentially confounds the findings of included studies and could result in an underestimation of the efficacy of PAAPs, because individuals who received a PAAP would be more likely to experience a given event (e.g. exacerbation requiring OCS use) compared with individuals in the control group if the related intervention (e.g. OCS) was prespecified in the action plan. In this respect, it is possible that the outcome 'exacerbations requiring treatment with OCS' functions as a measure of self-management, whereby participants take action to treat an exacerbation, rather than relying on inhaled medicines or going to the emergency department. Additionally, we noted heterogeneity between studies with respect to provision of an 'OCS rescue pack' (intended to be taken as laid out in the personalised plan). For these reasons, we have elected to refrain from presenting results for the OCS-related outcome in terms of absolute numbers, which could be misleading. However, despite these limitations, the selected outcomes examined in this review represent commonly used measures of efficacy and safety in randomised controlled trials of participants with asthma, and it may be difficult to assess the effectiveness of PAAPs without using these outcomes.

Quality of the evidence

We judged that three of the 15 included studies had low risk of selection bias (Charrois 2006; Cowie 1997; Griffiths 2004) and that all other studies poorly documented some aspect of the selection process, leading to our determination that risk of bias for these studies was unclear. Risk of performance bias for all 15 studies was high owing to study design and the self-management intervention. We judged two studies to have low risk of detection bias and five to have high risk, and risk was unclear in the remaining eight studies. We also judged five studies to be at high risk of attrition bias, three others to be at unclear risk and the remaining seven studies to be at low risk. We judged two studies to be at high risk of reporting bias, three studies at low risk and 10 studies at unclear risk. We had significant concerns about other forms of bias in three studies. In summary, risk of bias was highly variable between studies.

We rated the overall quality of the evidence as low or very low in our GRADE assessment, which takes into account risk of bias (study limitations), as well as indirectness, imprecision, consistency of effect and risk of publication bias. This rating was largely due to high risk of bias as well as issues related to imprecision and indirectness. It was not clear whether publication bias was an issue because studies were insufficient for a formal assessment.

Potential biases in the review process

We conducted the review according to guidelines provided in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). The Cochrane Airways Group Trials Search Co-ordinator designed and performed the search process, and two review authors with expert clinical knowledge independently screened search results. We are confident that we identified all potentially

relevant randomised trials. Similarly, two review authors independently performed each step in the systematic review process requiring a subjective decision (e.g. extraction of data, assessment of risk of bias, GRADE assessment) and, if necessary, resolved disagreements by consulting a third review author. A potential sample bias could result from the selective use of disaggregated data; however, this approach is a pragmatic necessity. This review has undergone editorial and peer review to ensure that the opinion of external experts has been considered. Therefore, we are confident that our conclusions fairly represent the current evidence base for this clinical question.

Agreements and disagreements with other studies or reviews

More than a decade ago, Le Fevre 2002 conducted a systematic review of randomised controlled trials in adults and children that compared written action plans versus no plan (five studies) and peak flow monitoring without a plan versus peak flow monitoring with a plan (two studies). Heterogeneity of included studies precluded meta-analysis, and a narrative review of findings suggested that most studies did not report improved outcomes with addition of an action plan. However, review authors suggested that all included studies were of low quality, limiting confidence in the findings, and stated that evidence available at the time did not permit firm conclusions. The current review includes more recent studies, although our finding that many studies are of low quality and our limited confidence in findings of little evidence of benefit (or harm) are similar.

Bhogal 2006 reviewed the effect of providing PAAPs for children specifically and found no studies that compared provision of a PAAP versus no PAAP. A later paper (Zemek 2008) updated the search and included one extra study, which did look at the comparison of PAAP versus no PAAP. Review authors reported that this one study (with 68 children) suggested that an action plan reduced the mean number of acute care visits, symptoms and nocturnal awakenings and reduced time lost from school, but again could offer no firm conclusions on the effectiveness of a PAAP on the basis of this single study. Individual non-randomised studies also support benefit for PAAPs. For example, among patients with moderate to severe asthma, not possessing a written asthma action plan was associated with increased acute use of healthcare services (Adams 2009).

PAAPs are often included as part of self-management programmes, and Powell 2002 examined different aspects of self-management programmes for adults (over 16 years of age), including PAAPs. Six studies compared self-adjustment of medications according to a PAAP versus adjustment by a doctor and found no differences in outcomes including hospitalisation, emergency department visits, unscheduled doctor visits and incidence of nocturnal asthma; therefore, study authors concluded that the two approaches were equally effective. Only one study compared written plans versus verbal instruction and found no difference in healthcare use or lung function, but study authors suggested that this finding needed further corroboration in future studies. Gibson 2003 reviewed 36 trials comparing self-management education approaches for adults (over 16 years of age) versus usual care; 18 included a written PAAP. In general, review authors found that self-management reduced hospitalisations, ED visits, unscheduled doctor visits, days off work or school and incidence of nocturnal asthma, and that it improved quality of life (but not lung function). In subgroup analyses of studies implementing optimal self-management education (which involved a written plan, self-monitoring and regular review), many positive outcomes remained (reduced hospitalisations, ED visits, unscheduled doctor visits and incidence of nocturnal asthma). Study evidence led review authors to conclude that self-management was effective, and in particular that optimal self-management education should be offered to adults with asthma. However, it was not possible to discern from this review the contributions of action plans specifically. Furthermore, findings from this review are now over a decade old.

Tapp 2007 focused on adults who had attended an ED for an asthma exacerbation and examined whether asthma education (including written PAAPs) improved health outcomes. The investigators found that education reduced hospital (re)admission (high-quality evidence) but did not appear to reduce re-presentation at an ED (low-quality evidence). Education also led to improved symptoms but not to improvement in peak flow, quality of life or days of work/study lost (but these null outcomes involved few studies and large variation across studies). In addition, the education provided revealed considerable heterogeneity across all studies reviewed, for example, only nine of the 13 included studies provided a PAAP, and again, the effectiveness of the PAAP specifically could not be ascertained.

More recently, Peytremann-Bridevaux 2015 evaluated the effectiveness of chronic disease self-management programmes for asthma in 20 included studies (12 provided action plans as part of the programme). In addition to self-management, these programmes included an organisational component targeting patients and one targeting professionals, as well as at least two healthcare professionals involved in the patient's care. Given the complexity of these programmes, it was not possible to determine the effect of action plans alone. Indeed as the review authors note, in some studies, participants in both intervention and usual care arms had action plans; in other studies, the proportion of participants using action plans changed throughout the study; and in other studies, the proportion of participants with plans was not reported.

AUTHORS' CONCLUSIONS

Implications for practice

Development of a PAAP and structured education for patients

are endorsed by BTS and NICE guidelines (BTS/SIGN 2016; NICE 2013). Our findings are based on a small number of studies of poor quality, so results of this review should be interpreted with caution. Furthermore, we have identified multiple confounding factors that would make it difficult to demonstrate efficacy for a single component of a multi-component self-management strategy (Pinnock 2015; Ring 2011). With consideration of these caveats, this systematic review, which considered evidence from randomised controlled trials, did not find additional benefit from the use of PAAPs, with or without education, across key asthma outcomes including exacerbation frequency, hospitalisation and measures of asthma control. Equally, there was no indication from the included studies of adverse outcomes with the use of PAAPs.

Implications for research

Review conclusions are based on a relatively small number of studies of poor quality, and interpretation is limited by lack of consistency in terms of design, populations, interventions and outcomes. Further high-quality research is required to determine whether PAAPs alone, or in combination with education, have an impact on important outcomes such as symptom control and indirect costs such as days lost from work. Future studies should reflect a broad population demographic, including older adults and people from different ethnic groups. The format of PAAPs used in future research should be consistent with BTS/SIGN guidelines (BTS/SIGN 2016), that is, they "should include specific advice about recognising loss of asthma control, assessed by symptoms or peak flows or both; and actions, summarised as two or three action points, to take if asthma deteriorates, including seeking emergency help, starting oral steroids (which may include provision of an emergency course of steroid tablets), restarting or temporarily increasing (as opposed to just doubling) ICS, as appropriate to clinical severity". Furthermore, careful consideration should be given to whether selected outcomes could confound study findings as the result of overlap with measures instructed by PAAPs.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Ayres 1996

Methods	**Study design:** randomised, open-label, parallel-group: 2 groups, self-management plan (SM) and doctor-managed (DM) **Total duration of study:** 24 ± 2 weeks. **Details of any 'run-in' period:** not reported. **Number of centres and locations:** hospitals and general practice centres, UK; no further details **Study setting:** primary and secondary care. **Withdrawals:** 1 did not receive treatment following randomisation. 32 discontinued treatment and were withdrawn (22 in SM group, 10 in DM group). Participants were withdrawn for the following reasons: non-compliance (SM 8; DM 4); asthma deterioration (SM 3; DM 3); pregnancy/lack of contraception (SM 2); excluded medication (SM 2); adverse events (SM 5; DM 1); and other (SM 2; DM 2) **Date of study:** not reported.
Participants	**Number of participants:** 126. Full analysis SM 61, DM 64. Per-protocol analysis SM 21, DM 29 **Mean age:** in years. Full analysis SM 44 ± 2, DM 47 ± 2. Per-protocol analysis SM 42 ± 3, DM 50 ± 3 **Age range:** not reported. **Gender:** full analysis SM M/F 23/38, DM M/F 28/36. Per-protocol analysis SM M/F 7/14, DM M/F 13/16 **Severity of condition:** nocturnal awakening despite use of inhaled prophylactic therapy (inhaled corticosteroids 400 to 1600 μg·day-1, sodium cromoglycate or nedocromil sodium) for a minimum of 3 months **Diagnostic criteria:** documented increase ($\geq$ 15%) in FEV_1 following inhalation of a β_2-agonist and/or documented diurnal variation in PEF ($\geq$ 15%). **Baseline lung function (% potential normal PEF on prophylaxis):** full analysis self-managed 79%; full analysis doctor-managed 72% **Smoking history:** not reported. **Study inclusion criteria:** aged 17 years or older, with a documented increase ($\geq$ 15%) in FEV_1 following inhalation of a β_2-agonist and/or documented diurnal variation in PEF ($\geq$ 15%) plus $\geq$ 1 documented exacerbation of asthma in the previous 6 months that required contact with a doctor/nurse. Patients had disturbed sleep (which included early morning awakening due to asthma) on at least 3 nights in the week before enrolment into the study despite use of inhaled prophylactic therapy (inhaled corticosteroids 400 to 1600 µg·day-1, sodium cromoglycate or nedocromil sodium) for a minimum of 3 months **Study exclusion criteria:** use of LABA, anticholinergics, corticosteroids (other than by the inhaled route) within the past 4 weeks; routine/regular use of a Turbohaler® in the 6 months before entry; respiratory tract infection at, or within 2 weeks of, entry; significant disease that could have interfered with the study; pregnancy, lactation or lack of adequate contraception; and previous participation in the study or participation in any other clinical study in the 6 months before entry

Ayres 1996 (*Continued*)

Interventions	**Intervention:** written guidelines on how to adjust budesonide dose on the basis of morning PEF measurements (best of 3 attempts before terbutaline use) as a percentage of their "normal" PEF **Comparison:** dose adjusted by investigator at clinic. **Concomitant medications and excluded medications:** Participants received budesonide (Turbohaler® 200; Astra: 200, 400 or 800 μg BID)
Outcomes	**Primary outcomes:** number of sleep-disturbed nights due to asthma. **Secondary outcomes:** lung function (PEF); asthma symptom scores and activity assessments; hospitalisation due to exacerbations; 4 visits to clinic at 6 ± 1 weekly intervals.
Notes	**Funding for trial:** Astra Pharmaceuticals Ltd, UK. **Notable conflicts of interest of trial authors:** not reported. **Correspondence with trial authors:** none.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient details provided.
Allocation concealment (selection bias)	Unclear risk	Insufficient details provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind participants (self-management of budesonide vs doctor-managed). Not possible to blind personnel (but sleep disturbance, daytime symptoms and activity scores unlikely to be influenced by lack of blinding)
Blinding of outcome assessment (detection bias) All outcomes	High risk	Self-reported outcomes and lung function and medication usage likely to be influenced by lack of blinding
Incomplete outcome data (attrition bias) All outcomes	High risk	One hundred twenty-six participants were randomised into the study. One hundred twenty-five participants received treatment and were included in the analysis. Fifty participants completed the study without violating the protocol and were included in the per-protocol analysis. Demographic characteristics of participants for both analyses are presented in Table 1. Thirty-two participants discontinued treatment and were withdrawn from the study - 22 in the SM group and 10 in the DM group

Ayres 1996 (*Continued*)

Selective reporting (reporting bias)	Unclear risk	Protocol not available.
Other bias	Low risk	Appears to be free of other sources of bias.

Baldwin 1995

Methods	**Study design:** randomised, parallel-group, open-label. **Total duration of study:** approximately 9 months. **Details of any 'run-in' period:** not reported. **Number of centres and location:** 1 urban general practice in North Staffordshire, UK. **Study setting:** general practice/primary care. **Withdrawals:** none. **Date of study:** not reported.
Participants	**Number of participants:** 50 (25 in each group). **Mean age:** not reported (aged 17 to 39 years: 26 (verbal 11, written 15); aged 40 to 59 years: 16 (verbal 9, written 7); aged 60 to 70 years: 8 (verbal 5, written 3)) **Age range:** 17 to 74 years. **Gender:** M 23, F 37 (verbal M 10, F 15; written M 13, F 12). **Severity of condition:** PEF less than 75% of predicted value. **Diagnostic criteria:** diagnosis of asthma based on detailed history and presence of PEF below 75% of predicted value **Baseline lung function:** verbal: highest PEF 350 L/min; written: highest PEF 335 L/min **Smoking history:** current smokers: 7 (verbal 4, written 3); ex-smokers: 15 (verbal 6, written 9); non-smokers: 28 (verbal 15, written 13) **Study inclusion criteria:** patients registered with the practice with a diagnosis of asthma and PEF less than 75% of predicted value **Study exclusion criteria:** illiteracy, pregnancy, history of occupational asthma, chronic lung disease other than asthma and heart disease
Interventions	**Intervention:** written instructions on asthma management in the form of a management plan, instruction in the use of Mini-Wright® peak flow meters **Comparison:** verbal instructions on asthma management, instruction in the use of Mini-Wright® peak flow meters **Concomitant medications and excluded medications:** not reported.
Outcomes	**Primary outcomes:** lung function measured on 3 occasions in clinic at 3-month intervals; objective assessment of inhaler technique via a 5-point scoring system (based on highest PEF score, PEF variability score, bronchodilator use, nocturnal symptoms, lifestyle, additional medication); number of home visits, emergency admissions or attendances at hospital for exacerbations of asthma (12 months before the study and for subsequent 12 months) noted but not reported; medication recorded at start and finish of the study period (primary outcome not stated) **Secondary outcomes:** Distinction between primary and secondary outcomes was not made/reported

Notes	**Funding for trial:** not reported. **Notable conflicts of interest of trial authors:** not reported. **Correspondence with trial authors:** requested data on number of participants requiring admission/ED visit, reported by group (verbal or written). Pending response

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Participants assigned to study groups by random number generation. No further information provided
Allocation concealment (selection bias)	Unclear risk	Insufficient details provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding of personnel and participants not performed (not practical/feasible)
Blinding of outcome assessment (detection bias) All outcomes	High risk	"assessment was made by another doctor, instructions given and PEF recorded. To avoid bias, the assessor was unaware of scores given at successive visits". However, doctor would be aware of the group to which a participant was assigned
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Study does not report drop-outs or number of participants on whom the data were based
Selective reporting (reporting bias)	Unclear risk	Study protocol not available. It would appear that all intended outcomes have been reported, apart from the second clinic visit assessment interval
Other bias	Low risk	The 2 groups were imbalanced in terms of the severity of asthma at baseline. This study was used to test the validity of the Midland Thoracic Society measure of morbidity scale (BMJ 1995;310:255). Although this scale features objective measures such as drug use and peak flow, it also features subjective measures such as "nocturnal symptoms in the week before the clinic visit (seven items); symptoms affecting lifestyle since the last clinic visit (six items)". Participant recall since last clinic visit, 3 months before, may have influenced

		scores, as participants were not asked to keep diaries. However, this study did not contribute outcome data to the review

Charrois 2006

Methods	**Study design:** randomised, parallel-group, open-label. **Total duration of study:** 6 months. **Details of any 'run-in' period:** no run-in period. **Number of centres and locations:** 4 Hinton pharmacies and 1 pharmacy in Edson, Canada. **Study setting:** Pharmacy/community. **Withdrawals:** 7 withdrawals; 2 lost to follow-up; 9 incomplete data; 1 protocol violation **Date of study:** not reported.
Participants	**Number of participants:** 70. **Mean (SD) age, years:** Intervention: 35.7 (10.2); control: 38.7 (10.7). **Age range:** not reported. **Gender, n female/male:** intervention: 19/17; control: 18/16. **Severity of condition:** high risk (see inclusion criteria). **Diagnostic criteria:** Canadian National Guidelines. **Baseline lung function:** not reported. **Smoking history, % current smoker:** intervention: 30.6; control: 29.4. **Study inclusion criteria:** self-reported diagnosis of asthma; 17 to 54 years of age and considered at high risk (ED visit or hospital admission due to asthma in the previous 12 months or use of more than 2 canisters of inhaled beta2-agonist in the previous 6 months, which far exceeds the definition for asthma control as outlined by the Canadian guidelines) **Study exclusion criteria:** patients not responsible for administering their own asthma medications, unable to understand English, unavailable for 6-month follow-up, did not provide written informed consent
Interventions	**Intervention:** education on asthma,assessment, optimisation of drug therapy by the pharmacist and referral to an RT and/or physician as needed. Education component included instruction on all asthma medications, with focus on the development of a written action plan (PEF- and symptom-based) **Comparison:** The usual care group was given an asthma education booklet and general advice as needed **Concomitant medications and excluded medications:** not reported.
Outcomes	**Primary outcomes:** comparison of the difference between intervention and usual care groups in terms of change in ACQ scores from baseline to 6 months; score 0 to 6 (0 indicating the best level of control, 6 indicating the poorest level of control); improvement of 0.5 or more points considered clinically significant **Secondary outcomes:** comparisons between intervention and usual care groups in terms of numbers of ED visits and hospital admissions, use of inhaled corticosteroid (at baseline and at 6 months), number of courses of oral steroid, FEV_1 (at baseline and at 2 and 6 months).

Notes	**Funding for trial:** Financial support was provided by Canadian Institutes of Health Research, Institute of Health Economics, University Hospital Foundation and ASTHMA Study (Alberta Strategy to Help Manage Asthma) **Notable conflicts of interest of trial authors:** not reported. **Correspondence with trial authors:** not required.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Randomisation accomplished through an internet randomisation service (EPICORE)
Allocation concealment (selection bias)	Low risk	Randomisation accomplished through an internet randomisation service (EPICORE)
Blinding of participants and personnel (performance bias) All outcomes	High risk	No participant blinding evident; pharmacists providing PAAPs not blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear whether respiratory technicians, who performed the assessments, were blinded to the group
Incomplete outcome data (attrition bias) All outcomes	Low risk	All participants except 1 (protocol deviation) in the intervention group included in the analyses
Selective reporting (reporting bias)	Low risk	All outcomes listed in the protocol reported.
Other bias	High risk	Study authors state that pharmacist compliance with the intervention was poor. Only 3/4 in the intervention group received a WAAP. Less than half of participants received education about WAAP at each pharmacy visit. Education provided for intervention and comparator groups may have been subtly different

Cowie 1997

Methods	**Study design:** randomised, parallel-group (3), single-blind (assessor blinded) **Total duration of study:** 6 months. **Details of any 'run-in' period:** no run-in period. **Number of centres and location:** Calgary, Canada. **Study setting:** secondary care. **Withdrawals:** 11 withdrew or were lost to follow-up. **Date of study:** not reported.
Participants	**Number of participants:** 151 (139 completed the study). **Mean (SD) age, years:** peak flow plan: 39.1 (14.41); symptom plan: 36.8 (16.50); no plan: 36.4 (12.76) **Age range:** not reported. **Gender, n M/F:** peak flow plan: 29/17; symptom plan: 25/20; no plan: 29/19. **Severity of condition:** patients who had received urgent treatment for asthma in the previous 12 months; moderate to severe **Diagnostic criteria:** not reported. **Baseline lung function - % predicted FEV_1 (SD):** peak flow plan: 82 (20.5); symptom plan: 79 (18); no plan: 78 (21.3) **Smoking history:** not reported. **Study inclusion criteria:** history of receiving urgent treatment for asthma in the previous 12 months **Study exclusion criteria:** patients with written asthma plans.
Interventions	**Intervention:** symptom-based action plan or peak flow-based action plan. **Comparison:** no action plan. **Concomitant medications and excluded medications:** not reported.
Outcomes	**Primary outcomes:** attendance for urgent treatment of asthma. **Secondary outcomes:** asthma control.
Notes	**Funding for trial:** not reported. **Notable conflicts of interest of trial authors:** not reported. **Correspondence with trial authors:** not required.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation achieved by use of 3 lists of random numbers, combined in database and indexed in ascending order
Allocation concealment (selection bias)	Low risk	Allocation concealed using 150 sequentially numbered sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind participants and personnel owing to the nature of the intervention

Cowie 1997 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Baseline interview, spirometry and education performed before consent and randomisation. Research assistants who performed telephone interview 6 months after enrolment blinded to participant allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Only 11 of 150 participants lost to follow-up and loss to follow-up equally distributed across groups
Selective reporting (reporting bias)	High risk	Primary outcome - comparison between groups regarding degree of asthma control and attendance for urgent treatment of asthma. Latter reported. However, data regarding asthma control not presented: night-time waking, reliever use, self-rating of asthma severity, daily dose of IHC or prednisolone course
Other bias	Low risk	None identified.

Griffiths 2004

Methods	**Study design:** cluster randomised controlled trial, open-label (analysis blinded) **Total duration of study:** 1 year. **Details of any 'run-in' period:** no run-in period. **Number of centres and locations:** 44 general practices in 2 boroughs in east London. **Study setting:** primary care. **Withdrawals:** primary outcome data available for 319/324 (98%) participants **Date of study:** not reported.
Participants	**Number of participants:** 324. **Mean (SD) age:** intervention: 22.9 (17.4); control: 22.2 (18.1). **Age range:** aged 4 to 60 years. **Gender, n male (%):** intervention: 85 (49); control: 76 (51). **Severity of condition:** acute asthma requiring attendance at hospital or general practitioner out of hours service **Diagnostic criteria:** not reported. **Baseline lung function:** not reported. **Smoking history (in patients > 16 years only), n smoker (%):** intervention: 26 (31); control: 24 (35). **Study inclusion criteria:** patients who attended hospital or GP practice for acute asthma and with sufficient understanding to follow a self-management plan **Study exclusion criteria:** not reported.

Interventions	**Intervention:** participant review in a nurse-led clinic and liaison with general practitioners and practice nurses comprising educational outreach, promotion of guidelines for high-risk asthma and ongoing clinical support; participants with sufficient understanding provided with a peak flow meter, a supply of rescue oral corticosteroids for future use and a written plan produced by the National Asthma Campaign with standard thresholds for peak flow and symptoms **Comparison:** Control practices received a visit promoting standard asthma guidelines; control participants were checked for inhaler technique **Concomitant medications and excluded medications:** not reported.
Outcomes	**Primary outcomes:** percentage of participants receiving unscheduled care for acute asthma over 1 year **Secondary outcomes:** rates of attendance for unscheduled care and review, self-management behaviour, quality of life, assessed by generic (EQ-5D) and respiratory-specific (AQ20 and north of England) scales.
Notes	Study authors contacted for disaggregated data. Study author (Dr. Griffiths) replied just before submission of the review to say that the data could potentially become available pending a data sharing agreement that was being set up. Data to be included in subsequent update of review if available owing to lack of time remaining on the grant

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Forty-four GP practices randomised via a minimisation programme - stratifying by partnership size and other criteria
Allocation concealment (selection bias)	Unclear risk	Insufficient details provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Cluster randomised trial. Blinding not feasible.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Researchers blinded to randomisation status of each practice extracted data from written and computerised participant records from both primary and secondary care. A research officer removed any specialist nurse letters to maintain blinding. Completeness and accuracy of extraction was validated by another blinded researcher, who checked 10 sets of records, using random numbers

Griffiths 2004 (*Continued*)

Incomplete outcome data (attrition bias) All outcomes	Low risk	Researchers were able to extract health record data for most participants recruited (98%)
Selective reporting (reporting bias)	Unclear risk	Abstract only. Protocol not available.
Other bias	Unclear risk	Control group included a higher percentage of participants who were fluent in English (89% vs 81%). Although randomisation resulted in equal groups at a practice level, this resulted in more participants recruited from intervention practices than from control (n = 175 vs n = 149)

Hoskins 1996

Methods	**Study design:** cluster randomised controlled trial. **Total duration of study:** 6 months. **Details of any 'run-in' period:** no run-in period. **Number of centres and locations:** 290 GP practices in the UK that participated in the second national audit on asthma attacks (1991-1992) **Study setting:** primary care. **Withdrawals:** NA. **Date of study:** 1993.
Participants	**Number of participants:** 290 GP practices randomised; data from 906 participants useable **Mean age:** not reported. **Age range:** not reported. **Gender:** not reported. **Severity of condition:** exacerbation in previous 3 months. **Diagnostic criteria:** not reported. **Baseline lung function:** not reported. **Smoking history:** not reported. **Study inclusion criteria:** asthma exacerbation in previous 3 months. **Study exclusion criteria:** not reported.
Interventions	**Intervention:** 3-step self-management plan consistent with BTS guidelines. **Comparison:** usual care; no plan. **Concomitant medications and excluded medications:** not reported.
Outcomes	**Outcomes:** exacerbation resulting in hospital admission; exacerbation resulting in emergency department visit; patient-initiated GP consultation for asthma; GP asthma review consultation; course of oral steroids or use of emergency nebulised bronchodilator for asthma (each assessed at 6 months)

Notes	**Funding for trial:** an educational grant from Allen and Hanburys Limited. **Notable conflicts of interest of trial authors:** not reported. **Correspondence with trial authors:** not required.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	General practitioners in the UK who had participated in the second national audit of asthma attacks in 1992-1993 were randomised (1:1) into intervention and control groups through a predetermined random numbers sequence; however, study authors do not say how random number sequence was generated
Allocation concealment (selection bias)	Unclear risk	Insufficient details provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	GP not blinded to which group his/her patients were allocated; participants knew which group they were in (if made aware of the study)
Blinding of outcome assessment (detection bias) All outcomes	High risk	General practitioners who participated in this study were a self-selected group with an interest in audit. Participants were likely to have shown enthusiasm and commitment and encouraged their patients to follow plans in an attempt to reduce morbidity. Six months later, both groups of doctors were invited to complete a morbidity questionnaire for each patient recruited. GP completed questionnaire on outcomes
Incomplete outcome data (attrition bias) All outcomes	High risk	Data were reported for only 51% of GPs in the intervention group vs 83% of those in the comparator group
Selective reporting (reporting bias)	Unclear risk	Study protocol not available. All outcomes listed in Methods section reported in Results section
Other bias	High risk	Despite randomisation, measures of patient morbidity in the intervention group before the issue of self-management plans were much higher than in the control group. A plausible explanation is that gen-

Hoskins 1996 (*Continued*)

		eral practitioners in the intervention group elected to issue plans to patients with uncontrolled asthma, rather than to all patients who were eligible to receive them. No data on number of patients that GPs enrolled into the study, only data on number of patients for whom GPs returned questionnaires and how many of these were useable

Jones 1995

Methods	**Study design:** randomised, parallel-group (2), open-label (analysis blinded) **Total duration of study:** 6 months. **Details of any 'run-in' period:** no run-in period. **Number of centres and locations:** 25 general practices in the Wessex region (UK). **Study setting:** primary care. **Withdrawals:** 55 participants failed to complete the study. **Date of study:** August 1990 to February 1992.
Participants	**Number of participants:** 127 randomised; 72 completed the study. **Mean (SD) age, years:** intervention: 30.4 (11.5); control: 28.6 (7.0). **Age range:** not reported. **Gender, n M/F:** intervention: 14/19; control: 13/26. **Severity of condition:** not stated. **Diagnostic criteria:** not stated. **Baseline lung function - % predicted FEV_1 (SD):** intervention: 85.1 (20.8); control: 80.2 (19.9). **Smoking history, % non/passive/smoker:** intervention: 55/15/30; control: 36/26/38. **Study inclusion criteria:** aged 15 to 40 years; use of metered dose steroid inhaler (dose < 1001 micrograms per day, or dry powder equivalent) **Study exclusion criteria:** patients on regular oral steroids; patients already possessing and regularly using a peak flow meter
Interventions	**Intervention:** written self-management plan, peak flow-based. **Comparison:** usual care. **Concomitant medications and excluded medications:** not reported.
Outcomes	**Primary outcomes:** lung function, quality of life (at 6 months vs baseline). **Secondary outcomes:** days lost from work or school (comparing 4 weeks before baseline and visits at 6 months); interference with daily life; symptom scores; bronchodilator use
Notes	**Funding for trial:** The study was funded by a grant from Allen and Hanburys. **Notable conflicts of interest of trial authors:** not reported. **Correspondence with trial authors:** not required.
Risk of bias	

Jones 1995 (*Continued*)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation to a self-management group or a planned visit group stratified by centre in blocks of 6. Insufficient details
Allocation concealment (selection bias)	Unclear risk	No details of allocation sequence concealment given.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind participants or practice staff.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information on who extracted data on medical resource use and prescribing data from medical records. However, personnel undertaking analysis blinded to group allocation
Incomplete outcome data (attrition bias) All outcomes	High risk	Mean group symptom scores not presented for each of the review intervals. No patient flow diagram presented - 127 recruited, 72 completed. 30% dropped out but not clear how many were lost to each group nor losses at each review point. Quality of life data not clearly presented
Selective reporting (reporting bias)	High risk	Mean symptom scores at measurement intervals not presented. Uncertain what the "Time to first symptom" equates to. Very little reference made to quality of life data
Other bias	Low risk	Appears to be free of other bias.

Klein 1998

Methods	**Study design:** randomised, parallel-group (2), open-label. **Total duration of study:** 2 years. **Details of any 'run-in' period:** no run-in period. **Number of centres and location:** Department of Pulmonary Medicine of a teaching hospital (1100 beds) in Enschede, the Netherlands **Study setting:** tertiary care. **Withdrawals:** year 1: 6 lost to follow-up, 1 death; year 2: 1 death. **Date of study:** August 1995 to April 1996.
Participants	**Number of participants:** 245 randomised. **Mean (SD) age, years:** intervention: 43.5 (11.7); control: 45.2 (12.0). **Age range:** not reported.

Klein 1998 (*Continued*)

	Gender, n M/F: intervention: 51/72; control: 60/62. **Severity of condition:** stable asthma with continuous use of inhaled steroids (> 200 micrograms per day metered dose inhaler) **Diagnostic criteria:** European Respiratory Society. **Baseline lung function, % predicted FEV_1 (SD):** intervention: 76 (20); control: 76.9 (20.1). **Smoking history, % non/ex/current:** intervention: 54.4/35.8/9.8; control: 51.7/35.2/13.1. **Study inclusion criteria:** between the ages of 18 and 65;continuous use of inhaled steroids (≥ 200 mg/d by metered dose inhaler (MDI) or400 mg/d by dry powder inhaler) for ≥ 3 months; in a stable phase of disease during last 6 weeks, defined as no use of short courses of oral steroids or no increase in maintenance dose of oral steroids; ability to speak and read the Dutch language **Study exclusion criteria:** not stated.
Interventions	**Intervention:** asthma nurse-led education plus written self-management plan (peak flow- and symptom-based) **Comparison:** asthma nurse-led education, no plan. **Concomitant medications and excluded medications:** not reported.
Outcomes	**Primary outcomes:** pulmonary function at baseline and at 4, 8, 12, 18 and 24 months after entry (pre-bronchodilator FEV_1 (% predicted) and from 2-week diaries mean morning pre-bronchodilator PEF and mean diurnal PEF variability together with PC20 histamine at baseline and at 12 months); asthma morbidity parameters (frequency of exacerbations at baseline and at 4, 8, 12, 18 and 24 months; use of healthcare facilities during the year before and the first and second years after the intervention (numbers of outpatient visits, hospitalisations and hospital days)
Notes	**Funding for trial:** Netherlands Asthma Foundation (Grant 94-52), GlaxoWellcome, the "StichtingAstmabestrijding" and Amicon Health Care Insurance Fund **Notable conflicts of interest of trial authors:** not reported. **Correspondence with trial authors:** not required.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information provided.
Allocation concealment (selection bias)	Low risk	Remaining 245 participants randomised into a self-treatment group (group S) and a control group (group C) by a closed envelope method
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding not possible and outcomes possibly influenced by lack of blinding

Klein 1998 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information provided to make a judgement.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Few drop-outs baseline to 12 months, greater number of drop-outs 12 months to 24 months. However, 12-month data can be examined separately from 24-month data. Study extended from original 1-year plan to 2 years after commencing. High drop-out rates going into year 2 - mainly younger people. Potential to skew data
Selective reporting (reporting bias)	Low risk	Appears that all prespecified outcomes in Methods section have been reported in Results section. Some outcomes (e.g. perceived control of asthma, self-confidence) reported only for the 1-year interval - not at 2 years
Other bias	Low risk	Appears to be free of other sources of bias.

McArdle 1997

Methods	**Study design:** randomised, parallel-group (2), open-label. **Total duration of study:** 6 months. **Details of any 'run-in' period:** no run-in period. **Number of centres and location:** single outpatient clinic of large inner city hospital, Australia **Study setting:** secondary care. **Withdrawals:** data reported for 41/45 randomised participants; reasons for loss not reported **Date of study:** not reported.
Participants	**Number of participants:** 45 participants randomised. **Mean age:** not reported (abstract only). **Age range:** not reported (abstract only). **Gender:** not reported (abstract only). **Severity of condition:** not reported (abstract only). **Diagnostic criteria:** not reported (abstract only). **Baseline lung function:** not reported (abstract only). **Smoking history:** not reported (abstract only). **Study inclusion criteria:** patients with a diagnosis of asthma . **Study exclusion criteria:** not reported (abstract only).
Interventions	**Intervention:** generalised asthma education plus written asthma action plan (peak flow-based) **Comparison:** generalised asthma education only.

	Concomitant medications and excluded medications: not stated (abstract only).
Outcomes	**Primary outcomes:** adherence to plan. **Secondary outcomes:** symptom score.
Notes	**Funding for trial:** not reported (abstract only). **Notable conflicts of interest of trial authors:** not reported (abstract only). **Correspondence with trial authors:** trial authors contacted for more detailed data not presented in the abstract. Trial authors agreed to search for data on return to office; no further contact

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient details provided.
Allocation concealment (selection bias)	Unclear risk	Insufficient details provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding would not be feasible.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient details provided.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data reported for 91% of participants.
Selective reporting (reporting bias)	Unclear risk	Study protocol not available.
Other bias	Low risk	None identified.

Milenkovic 2007

Methods	**Study design:** prospective, randomised, parallel-group (2), open-label trial **Total duration of study:** 12 months (additional follow-up at 5 years). **Details of any 'run-in' period:** 2 weeks; ability of participants in the self-management group to measure peak expiratory values evaluated **Number of centres and locations:** outpatient departments of 2 tertiary reference clinics in Serbia **Study setting:** tertiary care (outpatient). **Withdrawals:** 6 participants dropped out (3 from each group). **Date of study:** Patients entered the trial at staggered intervals from September 1999 to September 2000
Participants	**Number of participants:** 80 randomised participants. **Mean (SD) age, years:** intervention: 49.1 (14.4); control: 44.9 (11.7). **Age range:** not reported. **Gender, n M/F:** intervention: 17/20; control: 18/19. **Severity of condition, % mild/moderate/severe:** intervention: 51/35/14; control: 54/35/16. **Diagnostic criteria:** "The diagnosis was confirmed and treatment prescribed according to the national and international asthma guidelines" **Baseline lung function - mean (SD) FEV_1, L:** intervention: 2.47 (0.78); control: 2.48 (0.55). **Smoking history, % never/ex/current:** intervention: 75/25/0; control: 70/30/0. **Study inclusion criteria:** age between 18 and 60 years; continuous use of inhaled steroids for at least last 1 year; stable phase of disease during last 3 months **Study exclusion criteria:** smoking history of 15 or more pack-years; other diseases that could influence bronchial symptoms and/or lung function
Interventions	**Intervention:** individual written action plan based on peak flow measurements **Comparison:** usual care; no peak flow meter. Participants were instructed to take reliever medication if their asthma symptoms deteriorated and to seek advice from their primary care physician regarding controller medication **Concomitant medications and excluded medications:** not reported.
Outcomes	**Outcomes:** lung function; number of asthma exacerbations; number of hospital admissions; number of unscheduled visits (including visits to emergency department, general practitioner or pulmonologist); treatment requirements during asthma exacerbations (courses of doubling dose of inhaled corticosteroids, use of oral prednisolone and antibiotics); days off work because of asthma exacerbations and asthma symptoms
Notes	**Funding for trial:** not reported. **Notable conflicts of interest of trial authors:** not reported. **Correspondence with trial authors:** none required.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient details provided.

Milenković 2007 (*Continued*)

Allocation concealment (selection bias)	Unclear risk	Insufficient details provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Unlikely that blinding possible.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Outpatient visits scheduled every 6 months - clinical state and course of treatment evaluated by a physician as per routine clinical practice. Insufficient information provided to make a judgement
Incomplete outcome data (attrition bias) All outcomes	Low risk	40 participants randomised to each group. Attrition of 3 participants per group by 1-year interval (37 vs 37)
Selective reporting (reporting bias)	Unclear risk	Study protocol not available.
Other bias	Low risk	None identified.

Nokela 2010

Methods	**Study design:** cluster randomised trial. **Total duration of study:** 14 weeks. **Details of any 'run-in' period:** none. **Number of centres and locations:** 19 primary healthcare centres in the Stockholm area. **Study setting:** primary health care. **Withdrawals:** 11 participants in the control group and 10 in the intervention group were lost to follow-up for unknown reasons. One participant in the intervention group did not meet the age inclusion criteria and was therefore excluded. Three controls and 2 participants in the intervention group completed the second visit much later than planned in the protocol (20 to 32 weeks overdue) and were therefore excluded. Thus, 64 participants in the intervention group and 77 in the control group completed the study **Date of study:** From October 2003 until December 2004.
Participants	**Number of participants:** 141. **Mean age (range), years:** intervention: 48 (19 to 87); control: 52.5 (18 to 79). **Age range:** 18 to 87 years. **Gender, n F/M:** 98/43. **Severity of condition:** not reported. **Diagnostic criteria:** 'asthma diagnosis'. **Baseline lung function - mean (min, max) % predicted FEV_1, L:** intervention: 89 (33, 127); control:82.6 (5, 118). **Smoking history - current/ex/never, %:** intervention: 14/45/41; control: 18/40.3/40.3 (1.3% missing data) **Study inclusion criteria:** Centres were instructed to consecutively invite all eligible patients with an asthma diagnosis who sought medical attention (for any condition) to participate

	Study exclusion criteria: age < 18 years; poor understanding of written Swedish; malignant disease; severe psychiatric disease and dementia
Interventions	**Intervention:** provision of additional structured written and oral information (symptom-based plan), follow-up using an asthma diary **Comparison:** according to local treatment routine. **Concomitant medications and excluded medications:** not reported.
Outcomes	**Primary outcomes:** change in score on the asthma control questionnaire (ACQ) between the 2 visits in the study. (Minimum important difference ~0.5.) **Secondary outcomes:** lung function measurements (FEV_1 or PEF), number of self-reported emergency visits caused by asthma, number of participants with additional/unanswered questions about their asthma or its management, prescribed changes in drug treatment, patient-perceived benefit of asthma medications, costs of asthma medications, changes in disease-specific quality of life. Disease-specific quality of life was measured using the validated Swedish version of the Mini Asthma Quality of Life Questionnaire (Mini-AQLQ; MCID 0.5), which yields a total score between 1 and 7, where 7 is the best and 1 is very poor
Notes	**Funding for trial:** Study was supported and funded by drug and therapeutics committees in Stockholm and Sörmland, the Stockholm County Council, the Vårdal Foundation and the Karolinska Institutet **Notable conflicts of interest of trial authors:** none reported. **Correspondence with trial authors:** not required.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was performed with a computer programme that generated random numbers
Allocation concealment (selection bias)	Unclear risk	Insufficient details provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding not possible owing to the nature of the intervention
Blinding of outcome assessment (detection bias) All outcomes	High risk	Assessors aware of allocation throughout.
Incomplete outcome data (attrition bias) All outcomes	High risk	> 85% follow-up. 11 control, 10 intervention participants lost to follow-up - reasons unknown. Lung function reported in records for 100% of Intervention participants (64) and only 91% of control participants (77). Also, study authors reported

Nokela 2010 (*Continued*)

		mean (SD) point change in outcome measure between first and second visits - actual data not presented
Selective reporting (reporting bias)	Unclear risk	Study protocol not available.
Other bias	Unclear risk	More smokers in control group (14 vs 9).

Sangha 2004

Methods	**Study design:** randomised, parallel-group (2), open-label. **Total duration of study:** 6 months. **Details of any 'run-in' period:** not reported (abstract only). **Number of centres and locations:** not reported (abstract only). **Study setting:** not reported (abstract only). **Withdrawals:** not reported (abstract only). **Date of study:** not reported (abstract only).
Participants	**Number of participants:** 100. **Mean age:** not reported (abstract only). **Age range:** not reported (abstract only). **Gender:** not reported (abstract only). **Severity of condition:** not reported (abstract only). **Diagnostic criteria:** not reported (abstract only). **Baseline lung function:** not reported (abstract only). **Smoking history:** not reported (abstract only). **Study inclusion criteria:** diagnosis of bronchial asthma. **Study exclusion criteria:** not reported (abstract only).
Interventions	**Intervention:** education plus peak flow-based written action plan. **Comparison:** education. **Concomitant medications and excluded medications:** not reported (abstract only).
Outcomes	**Primary outcomes:** lung function parameters at 6 months. **Secondary outcomes:** 'morbidity data'.
Notes	**Funding for trial:** not reported (abstract only). **Notable conflicts of interest of trial authors:** not reported (abstract only). **Correspondence with trial authors:** study authors contacted for further data/information. No response at time of submission

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Insufficient details provided.

Sangha 2004 (*Continued*)

Allocation concealment (selection bias)	Unclear risk	Insufficient details provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding not feasible.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient details provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient details provided.
Selective reporting (reporting bias)	Unclear risk	Protocol not available.
Other bias	Low risk	None identified (abstract only).

Sheares 2015

Methods	**Study design:** randomised, parallel-group (2), open-label. **Total duration of study:** 12 months. **Details of any 'run-in' period:** no run-in period. **Number of centres and locations:** 7 pulmonary and allergy practices at 4 urban medical centres **Study setting:** secondary care. **Withdrawals:** 7 withdrawals; 10 relocations; 67 lost-to follow-up. **Dates of study:** 2006-2009.
Participants	**Number of participants:** 407 participants randomised. 135 adults (33%) and 272 children (67%) **Mean age:** not reported. **Age range:** not reported. **Gender, n female (%):** intervention: 188 (92); control: 175 (86). **Severity of condition:** persistent asthma as defined by NAEPP guidelines. **Diagnostic criteria:** NAEPP guidelines. **Baseline lung function:** not reported. **Smoking history:** not reported. **Study inclusion criteria:** children and adults aged 5 to 80 years with a physician diagnosis of persistent asthma (as defined by NAEPP guidelines) **Study exclusion criteria:** diagnosis of a comorbid condition affecting lung health.
Interventions	**Intervention:** written asthma action plan. **Comparison:** usual care (no written asthma action plans). **Concomitant medications and excluded medications:** not reported.
Outcomes	**Primary outcomes:** asthma symptom frequency, emergency visits, asthma quality of life (mini-AQLQ score); each at 12 months **Secondary outcomes:** participant use of WAAP.

Notes	**Funding for trial:** supported by the NIH/NHLBI (grant R01HL73955) and the National Center for Advancing Translational Sciences, NIH (UL1 TR000040), formerly the National Center for Research Resources (UL1 RR024156) **Notable conflicts of interest of trial authors:** none. **Correspondence with trial authors:** trial authors contacted with request for mean age of cohort. No response at time of submission

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random number sequence was used for randomisation. "we used a randomised block, mixed-effects factorial design"..."Blocks were of variable sizes to eliminate predictability"
Allocation concealment (selection bias)	Low risk	Allocation was concealed in sealed numbered envelopes.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Double-blinding was not possible. However, a randomised block design with physician as a random factor was used to minimise variability due to physician. "The intervention group had a blank WAAP form inserted into their charts and the control group had no WAAP form, but a sticker was applied to the outside of the chart to remind physicians to provide their usual instructions without giving any written materials other than prescriptions"
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information provided to make a judgement. Presumably, research staff interviewed participant following physician appointment. Unclear whether staff were blinded to participant group allocation. "After the initial visit, participants were interviewed via telephone by staff from the New England Research Institute (Watertown, MA) every 3 months during the 12-month follow-up period". Presumed research institute staff blinded to group allocation but study authors do not state this
Incomplete outcome data (attrition bias) All outcomes	High risk	No one was excluded from the analysis other than for reason of missing data. A relatively high percentage of randomised par-

Sheares 2015 (*Continued*)

		ticipants were excluded from analyses for missing data; inverse proportions of adults/ children were recruited to intervention and control groups. More children in the Intervention group. More participants lost to follow-up in the intervention group (24%) compared with the control group (18%)
Selective reporting (reporting bias)	Low risk	Comparison with NCT website demonstrates that all comparisons were reported
Other bias	Unclear risk	Study included both adults and children, so we need to seek disaggregated data. More children in the intervention group

Thoonen 2001

Methods	**Study design:** cluster randomised controlled trial. **Total duration of study:** 2 years. **Details of any 'run-in' period:** none. **Number of centres and locations:** 19 general practices were recruited from 2 pools; the first were in and around the city of Eindhoven, and the second included practices from our department's academic research network; Netherlands **Study setting:** primary care. **Withdrawals:** 43. **Date of study:** not reported.
Participants	**Number of participants:** 214. **Mean (SD) age, years:** intervention: 39.6 (11.2); control: 39.3 (12.0). **Age range:** not reported. **Gender, n M/F:** intervention: 34/64; control: 40/56. **Severity of condition:** FEV_1 > 40% predicted and > 55% predicted 15 minutes after salbutamol **Diagnostic criteria:** not reported. **Baseline lung function - mean (SD) % predicted FEV_1 pre-BD, L:** intervention: 84.0 (13.1); control: 86.9 (14.2). **Smoking history, % never/former/current:** intervention: 46/32/22; control: 56/22/22. **Study inclusion criteria:** treated for asthma by GP; age 16 to 60 years; FEV_1 > 40% of predicted value and > 55% of predicted value 15 minutes after inhalation of 800 µg salbutamol or 6 weeks after inhalation of 800 µg budesonide twice daily; FEV_1 reversibility (after bronchodilation with 800 µg salbutamol metered dose inhaler or 8 weeks treatment with 800 µg budesonide twice daily) of at least 10% of predicted value or PC20 histamine of 8 mg/mL **Study exclusion criteria:** smoking history of 15 or more pack-years; serious diseases other than asthma with low survival rates; exacerbations during the month before the start of the study; other diseases that influence bronchial symptoms and/or lung function such as heart failure, sarcoidosis; inability to inhale medication correctly or to measure

Thoonen 2001 (*Continued*)

	and record peak flow adequately and unlikely that this can be taught
Interventions	**Intervention:** written personalised asthma action plan. **Comparison:** usual care according to national guidelines. **Concomitant medications and excluded medications:** not reported.
Outcomes	**Primary outcomes:** asthma control, asthma-specific quality of life, lost activity days **Secondary outcomes:** number of puffs of budesonide, number of dose equivalents of short-acting bronchodilators, number of short courses of oral prednisolone and antibiotics, number of GP-diagnosed exacerbations
Notes	**Funding for trial:** This research project has been made possible by research grants from The Netherlands Organization for Scientific Research (NWO) and ASTRAZeneca Pharmaceutica BV **Notable conflicts of interest of trial authors:** reported as 'none'. **Correspondence with trial authors:** not required.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information provided.
Allocation concealment (selection bias)	Unclear risk	Insufficient information provided.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Owing to the nature of the intervention and GP practice rather than participant randomisation, it is not possible to blind personnel and participants
Blinding of outcome assessment (detection bias) All outcomes	High risk	"Assessors were not blinded to study group allocation".
Incomplete outcome data (attrition bias) All outcomes	Low risk	104 usual care (UC) and 110 self-management (SM) recruited - 95 UC and 98 ITT analyses. 18 participants did not complete UC arm, 25 did not complete SM arm
Selective reporting (reporting bias)	Unclear risk	Protocol not available. All defined outcomes appear to have been reported
Other bias	High risk	Study authors noted that participants who received PAAPs were provided with an oral course of prednisolone, and that the prescription may have been incorrectly interpreted as evidence of use of prednisolone

Thoonen 2001 (*Continued*)

		during an exacerbation

Wang 2004

Methods	**Study design:** randomised, parallel-group (2), open-label. **Total duration of study:** 12 months. **Details of any 'run-in' period:** none. **Number of centres and location:** Queen Mary Hospital, Hong Kong. **Study setting:** tertiary care. **Withdrawals:** 13% lost to follow-up. **Date of study:** not reported (abstract only).
Participants	**Number of participants:** 76. **Mean age:** not reported (abstract only). **Age range:** not reported (abstract only). **Gender:** not reported (abstract only). **Severity of condition:** "acute asthma". **Diagnostic criteria:** not reported (abstract only). **Baseline lung function:** not reported (abstract only). **Smoking history:** not reported (abstract only). **Study inclusion criteria:** acute asthma. **Study exclusion criteria:** not reported (abstract only).
Interventions	**Intervention:** asthma self-management programme with a written self-action plan and usual care **Comparison:** usual care only. **Concomitant medications and excluded medications:** not reported (abstract only).
Outcomes	**Outcomes:** ratio of asthma-related hospitalisation, A&E visits, visits to general practitioners, days off work, asthma symptoms, use of medications, lung function; all outcomes measured at 12 months
Notes	**Funding for trial:** not reported (abstract only). **Notable conflicts of interest of trial authors:** not reported (abstract only). **Correspondence with study authors:** study authors contacted via email with request for published data or associated peer-reviewed paper. No response at time of submission

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Insufficient details provided.
Allocation concealment (selection bias)	Unclear risk	Insufficient details provided.

Wang 2004 (*Continued*)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding not feasible.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient details provided.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient details provided.
Selective reporting (reporting bias)	Unclear risk	Protocol not available.
Other bias	Low risk	None identified (note abstract only).

Abbreviations: ACQ, Asthma Control Questionnaire; A&E, accident and emergency; AQ20, Airways Questionnaire 20; AQLQ, Asthma Quality of Life Questionnaire; BTS, British Thoracic Society; DM, doctor-managed; ED, emergency department; EQ-5D, Euro quality of life five dimensions questionnaire; F, female; FEV_1, forced expiratory volume in one second; GP, general practitioner; ITT, intention-to-treat; LABA, long-acting beta-agonist; M, male; MCID, minimum clinically important difference; MDI, metered-dose inhaler; Mini-AQLQ, Mini Asthma Quality of Life Questionnaire; NCT, national clinical trial; NHLBI, National Heart, Lung and Blood Institute; NIH, National Institutes of Health; NAEPP, National Asthma Education and Prevention Program; PAAP, personalised asthma action plan; PC20, provocation concentration causing a 20% fall in FEV_1; PEF, peak expiratory flow; RT, respiratory technician; SD, standard deviation; SM, self-managed; UC, usual care; WAAP, written asthma action plan.

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Adams 2001	Wrong comparator: Study compared peak-flow- vs symptom-based plans; no control group that received no PAAP
Araújo 2012	Wrong comparator: Participants were randomly assigned to a sequence of Web-based and paper-based diary and action plan; no control group that received no PAAP
Arguel 2013	Wrong intervention: evaluation of a Web-based personally controlled health management system (PCHMS) called Healthy.me
Bailey 1990	Wrong intervention: evaluation of a workbook with 1-to-1 counselling and adherence-promoting strategies
Bailey 1999	Wrong intervention: Self-management plans did not appear to include a written action plan
Behera 2006	Wrong comparator: self-care manual, which appeared to involve an educational component (interviews), vs no manual and no education. Pilot study for Behera 2008.

(*Continued*)

Behera 2008	Wrong comparator: self-care manual, which appeared to involve an educational component (interviews), vs no manual and no education. Pilot study was Behera 2006.
Berg 1996	Wrong intervention: 6-week self-management programme. No specific mention of written asthma plan
Boath 1998	Wrong comparator: peak-flow-based plan vs symptom-based plan; no control group that did not receive any plan
Breysse 2011	Wrong participant population: 'asthmatic children'.
Buist 2001	Wrong intervention: compares different shared decision-making models
Calhoun 2012	Wrong intervention: Participants in the intervention groups did not appear to receive a personalised written action plan
Chenu 2000	Wrong comparator: education plus PAAP vs no education and no PAAP
Clark 2005	Wrong intervention: a multiple-component behavioural education programme delivered by a nurse health educator through telephone counselling
Cleland 2004	Wrong intervention: an interactive seminar delivered at practice level
Couturaud 2002	Wrong comparator: education plus PAAP vs no education and no PAAP
Côté 2001	Wrong comparator: limited education plus PAAP vs structured education plus PAAP vs 'usual care' (no PAAP plus no education)
Espinosa 1998	Wrong intervention: 'personal education for one year'.
Fernandes 2011	Wrong intervention: education on inhaler technique by trained respiratory technician
Fonseca 2006	Wrong study design: participant diary vs no participant diary
Ford 1996	Wrong intervention: education vs no education; self-management group does not specify use of PAAP. Pilot study for Ford 1997.
Ford 1997	Wrong intervention: education vs no education; self-management group does not specify use of PAAP. Piloted in Ford 1996.
Gaga 2004	Wrong comparator: Usual care comprised specialist-directed adjustments to therapy
Gallefoss 2001	Wrong comparator: structured education plus PAAP vs no PAAP and no education
Goeman 2013	Wrong intervention: No PAAP was issued (the intervention included advice to discuss obtaining a PAAP from physician)
GRASSIC 1994	Wrong comparator: self-management education plus PAAP vs no PAAP and no self-management education

(*Continued*)

Haniotou 2012	Wrong comparator: PAAP plus education/training around breathing technique vs no PAAP and no education
Ignacio 1995	Wrong comparator: Control group received PAAP.
Janson 2009	Wrong comparator: education plus PAAP vs no education and no PAAP
Kelso 1996	Wrong study design: non-randomised.
Kemple 2002a	Wrong study design: Randomisation occurred after group allocation
Kim 2016	Wrong intervention: Intervention includes possibility of investigators directly intervening as they monitored data entered by participants into the mobile-based plan
Kokubu 2000	Wrong comparator: Both groups received a PAAP.
Kotses 1996	Wrong study design: appears to be pseudo-randomised (participants randomised but with the restriction that groups were balanced for numbers)
Lahdensuo 1994	Wrong intervention: Plan was not personalised.
Lahdensuo 1996	Wrong comparator: PAAP plus education (therapeutic counselling by specialist nurses and relaxation/breathing techniques by physiotherapist) vs general asthma advice by specialist nurse and no PAAP
Levy 1995	Wrong comparator: PAAP plus education provided by secondary care specialist nurses at arranged consultations vs usual care in primary care setting
Lincicome 2001	Wrong participant population: paediatric participants aged 3 to 15 years
Magar 2005	Wrong comparator: PAAP plus education vs no PAAP and no education
McLean 2003	Wrong comparator: PAAP plus education vs no PAAP and no education
NCT00129662	Wrong study design: non-randomised study.
NCT00214669 2005	Wrong comparator: PAAP plus education vs no PAAP and no education
NCT01070095	Wrong study design: non-randomised, single group assignment.
NCT01079000 2012	Wrong comparator: Control group received PAAP.
NCT01282359	Wrong comparator: PAAP plus education vs no PAAP and no education
NCT02046759	Wrong comparator: PAAP plus education vs no PAAP and no education
NCT02091869 2014	Wrong participant population: paediatric patients aged 12 to 17 years

(*Continued*)

Olivera 2016	Wrong comparator: education (and possibly PAAP) vs no education and no PAAP
Osman 2001	Wrong comparator: 30% of control group also received a PAAP.
Parkes 2012	Wrong study design: non-randomised (study authors contacted and confirmed that randomised portion of study will not go ahead)
Patel 2015	Wrong comparator: PAAP plus education vs no PAAP and no education
Put 2001	Wrong intervention: workbook to re-enforce education (not PAAP)
Ross 2012	Wrong intervention: no reference to use of a PAAP.
Sittipunt 2008	Wrong comparator: PAAP plus education vs no PAAP and no education
Steurer-Stey 2010	Wrong comparator: Control group also received a PAAP.
Tousman 2009	Wrong intervention: daily tracking diary rather than a PAAP.
Tuazon 2000	Wrong comparator: comparison between 2 different education programmes. Unsure about inclusion of a PAAP
Urek 2005	Wrong intervention: comparison of 3 different education approaches
Wilson-Pessano 1987	Wrong intervention: no reference to PAAP.
Zairina 2015	Wrong intervention: tele-health application.

Characteristics of studies awaiting assessment *[ordered by study ID]*

Angelini 2010

Methods	**Study design:** randomised controlled trial with 3 parallel groups: control, education and self-management **Total duration of study:** 24 months. **Details of any 'run-in' period:** not reported. **Number of centres and locations:** not reported. **Study setting:** not reported. **Withdrawals:** not reported. **Date of study:** not reported.
Participants	**Number of participants:** 84. **Mean age:** not reported. **Age range:** not reported. **Gender:** not reported. **Severity of condition:** "moderate and severe persistent asthma". **Diagnostic criteria:** not reported.

Angelini 2010 (*Continued*)

	Baseline lung function: not reported. **Smoking history:** not reported. **Study inclusion criteria:** not reported. **Study exclusion criteria:** not reported.
Interventions	**Intervention:** educational programme consisting of lectures on pathophysiology and environmental control, asthma symptoms, treatment and training in the inhalation technique. Self-management group also received a symptoms diary card and a written personal asthma action plan **Comparison:** not reported. **Concomitant medications and excluded medications:** not reported.
Outcomes	**Primary outcomes:** Asthma Control Test (mean score). **Secondary outcomes:** Questionnaire Disease Knowledge (QDK), asthma quality of life (AQLQ-s), Hospital Anxiety and Depression Scale (HADS), functional literacy health test (s-TOFHLA). (Study authors do not distinguish between primary and secondary.)
Notes	**Funding for trial:** not reported. **Notable conflicts of interest of trial authors:** not reported. **Correspondence with trial authors:** none.

Characteristics of ongoing studies *[ordered by study ID]*

NCT02190617 2014

Trial name or title	Guidelines to Practice: Reducing Asthma Health Disparities Through Guideline Implementation
Methods	Randomised controlled trial, intervention study.
Participants	Aged 5 to 75 years with a diagnosis of uncontrolled asthma; estimated enrolment 550
Interventions	1. Enhanced clinic plus unified management plan; 2. Home visit option only; 3. Enhanced clinic plus unified management plan plus home visit option
Outcomes	Symptom-free days, asthma control, asthma-related quality of life, nocturnal awakening, asthma exacerbations, pulmonary function, fractional exhaled nitric oxide, beta-agonist use, oral steroid use, controller use, emergency healthcare utilisation, days of work or school missed, general health status
Starting date	December 2014.
Contact information	James Stout, MD (Washington University).
Notes	https://clinicaltrials.gov/show/NCT02190617

NCT02424409 2015

Trial name or title	Evaluation of the Relapse Rate One Month After Discharge From Emergency Department for Asthmatic Patients Given a Strict Formalized Follow up Protocol
Methods	Randomised controlled trial, intervention study.
Participants	Patients over 18 years, consulting to the emergency department for an acute asthma attack, who, after initial treatment are discharged directly from the emergency department after giving free and informed consent
Interventions	Personalised asthma action plan (PAAP) vs no PAAP.
Outcomes	Recurrence rate of any asthma attacks at 15 days and at 1 month, hospitalisation rate at 30 days, asthma control score, percentage of participants self-medicating, percentage of participants using peak flow meter, participant adherence to protocol
Starting date	August 2015.
Contact information	Jennifer Truchot, MD; jennifer.truchot@lrb.aphp.fr.
Notes	https://clinicaltrials.gov/ct2/show/NCT02424409

DATA AND ANALYSES

Comparison 1. PAAP versus no PAAP

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of participants reporting at least 1 exacerbation requiring emergency department visit or hospitalisation	5	1385	Odds Ratio (M-H, Random, 95% CI)	0.75 [0.45, 1.24]
2 Asthma symptom scores (change from baseline in ACQ)	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
3 Serious adverse events (including deaths)	1		Odds Ratio (M-H, Random, 95% CI)	Subtotals only
4 Quality of life (change from baseline in AQLQ)	3	441	Mean Difference (IV, Random, 95% CI)	0.18 [0.05, 0.30]
5 Number of participants reporting at least 1 exacerbation requiring systemic corticosteroids	3	1136	Odds Ratio (M-H, Random, 95% CI)	1.45 [0.84, 2.48]
6 Measure of respiratory function (change from baseline in FEV_1 (L))	3	392	Mean Difference (IV, Random, 95% CI)	-0.04 [-0.25, 0.17]
7 Measure of respiratory function (change from baseline in % predicted FEV_1)	2	146	Mean Difference (IV, Random, 95% CI)	0.40 [-6.05, 6.85]
8 Measure of respiratory function (change from baseline in % predicted PEF)	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
9 Measure of respiratory function (change from baseline in PEF (L/min))	1		Mean Difference (IV, Random, 95% CI)	Totals not selected
10 Days lost from work or study	1	74	Mean Difference (IV, Random, 95% CI)	-6.2 [-7.32, -5.08]

Comparison 2. PAAP plus education versus education alone

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Number of participants reporting at least 1 exacerbation requiring emergency department visit or hospitalisation	1		Odds Ratio (Fixed, 95% CI)	Subtotals only
2 Asthma symptom scores (change from baseline in ACQ score)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only
3 Quality of life (change from baseline in AQLQ score)	1		Mean Difference (IV, Random, 95% CI)	Subtotals only

4 Number of participants reporting at least 1 exacerbation requiring systemic corticosteroids	1	Odds Ratio (Random, 95% CI)	Subtotals only

WHAT'S NEW

Date	Event	Description
12 April 2017	Amended	AR affiliation and COI statement corrected.

CONTRIBUTIONS OF AUTHORS

All review authors contributed to 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: provides freelance medical writing services to medical communications agencies.

Alison Rushton: undertook 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 northwest of England. The project was completed in 2015 as part of a Clinical Academic Internship, funded by Health Education England and a northwest CCG. The intern received no payment for including individuals in the study.

Nathan Halcovitch: none.

Fiona Eccles: none.

Timothy Gatheral: none.

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

Gemma Whiteley: none.

Caroline Mulvaney: none.

SOURCES OF SUPPORT

Internal sources

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

External sources

- Alison Rushton, Nathan Halcovitch, Timothy Gatheral, Gemma Whiteley declare that no such funding was received for this review, Other.
- David Evans, UK.

National Institute for Health Research: Evidence to guide care in adults and children with asthma, 13/89/14

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

In the original protocol, we stated that "If a study uses more than one scale to report the same outcome, or if different scales were used across studies, we will analyse them together using the standardised mean difference." For quality of life outcomes reported on different scales across individual studies, we reported outcomes separately, as combining scales using the standardised mean difference would be clinically difficult to interpret.

INDEX TERMS

Medical Subject Headings (MeSH)

*Patient Education as Topic; Asthma [complications; *drug therapy; mortality]; Disease Progression; Emergency Medical Services [statistics & numerical data]; Hospitalization [statistics & numerical data]; Quality of Life; Randomized Controlled Trials as Topic; Self Care [adverse effects; *methods; mortality]

MeSH check words

Adult; Humans; Middle Aged