

NEW ZEALAND HEALTH TECHNOLOGY ASSESSMENT (NZHTA)  
THE CLEARING HOUSE FOR HEALTH OUTCOMES AND  
HEALTH TECHNOLOGY ASSESSMENT

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# Education and patient self-management of asthma

*A critical appraisal of the literature*

Peter Day

## **ACKNOWLEDGEMENTS**

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This review was commissioned by the Asthma Working Group of the New Zealand Guidelines Group.

The staff of NZHTA developed this review. It was prepared by Mr Peter Day (Researcher) and supported by Dr Ray Kirk (Director), Dr Robert Weir (Researcher), Ms Susan Bidwell (Information Specialist), Ms Cecilia Tolan (Administrator) and Dr Phil Hider (Researcher). Ms Tracey Smitheram, Miss Becky Mogridge, Mrs Carol Davison and Mrs Joan Downey provided additional administrative assistance.

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## **DISCLAIMER**

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## **CONTACT DETAILS**

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## LIST OF ABBREVIATIONS

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$\Delta$	=	change in
%PV	=	% of predicted value
ATS	=	American Thoracic Society
BTS	=	British Thoracic Society
c.f.	=	compared with
cntrl	=	control group
CRCT	=	randomised controlled trial, cluster design
COPD	=	Chronic Obstructive Pulmonary Disease
diff	=	difference
Dx	=	diagnosis
ED	=	Emergency Department
educ	=	education group
freq	=	frequency
FEV <sub>1</sub>	=	forced expiratory volume in one second
grp	=	group
inh	=	inhaler
ITT	=	intention to treat
LOS	=	length of stay (days)
MDI	=	metered dose inhaler
mg	=	milligrams
N	=	number
N/A	=	not applicable or not available
NNT	=	numbers needed to treat using the education program efficacy to achieve one favourable outcome over a period of time (study duration in this report)
n.s.	=	comparison difference not statistically significant ( $P > 0.05$ )
<i>P</i> -value	=	probability measure of uncertainty
PC <sub>20</sub>	=	challenge (usually methacholine or histamine) concentration that caused a 20% fall in FEV <sub>1</sub>
PEFR	=	peak expiratory flow rate

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QoL	=	quality of life
RCT	=	randomised controlled trial
sd	=	standard deviation
se	=	standard error
µg	=	micrograms

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# Scope of systematic review of asthma education and patient self-management

The development of this systematic review protocol involved consultation between the NZHTA and the asthma education and self-management sub-committee of the Asthma Working Group.

## SEARCH METHODOLOGY

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### *Search strategy*

Searches were restricted to information published from 1st January 1998 onwards, in all languages. Original searches were carried out in May 2001.

### *Principal sources of information*

The following databases were searched using the search strategies outlined in Appendix 1:

#### Bibliographic databases

- Medline
- Embase
- Current Contents
- Science Citation Index
- Cinahl
- Cochrane Library Controlled Trials Register
- Index New Zealand
- Psychinfo
- Eric

#### Review databases

- Cochrane Library Systematic Reviews & Protocols
- Database of Abstracts of Reviews of Effectiveness
- NHS Economic Evaluation Database
- Best Evidence

#### Library catalogues

- New Zealand Ministry of Health library
- New Zealand Bibliographic database - Te Puna
- US National Library of Medicine
- World Health Organisation

#### Websites

- Health Canada
  - US Centers for Disease Control
  - British Thoracic Society
  - EGuidelines (UK)
  - University of Dundee Asthma Research Unit
  - UK General Practice Airways Group
  - UK Department of Health publications
  - Meta-register of Controlled Trials
  - TRIP - Turning Research into Practice
  - Health Evidence Bulletins Wales
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- OMNI - Organised Medical Networked Information
- European Federation of Asthma and Allergy Associations
- GINA - Global Information Network on Asthma
- Canadian Office for Health Technology Assessment
- Canadian Network for Asthma Care
- Canadian Lung Association
- Canadian Thoracic Society
- Asthma Society of Canada
- ClinicalTrials.gov
- American Academy of Allergy Asthma and Immunology
- JAMA Asthma Information Center - Physicians Section
- US National Heart, Lung, and Blood Institute
- US Asthma Clinical Research Network
- US National Institute of Allergy and Infectious Diseases
- Thoracic Society of New Zealand and Australia
- Australian Department of Health & Aged Care
- Ministerial Asthma Working Party

Note: hand searching of journals, contacting of manufacturers, or contacting of authors for unpublished research was not undertaken during the search process.

### ***Major search terms used***

- Publication types searched on Medline (additional to above index terms) were randomized controlled trial, controlled clinical trial, meta-analysis, guideline
- Index terms from Embase: asthma, self care, patient education, health education, randomized controlled trial, clinical trial, randomization, meta-analysis, practice guideline
- Additional keywords used (not standard index terms) : systematic review, systematic overview, self care, self monitor\*, self manage\*, cluster, random\*, action plan, action plans
- Keywords used for exclusions: child\*, pediater\*, paediatr\* as title words when adult\* was *not also* in the title

Search filters used to identify randomized controlled trials, meta-analyses, and guidelines in the literature were adapted from those produced by the Center for Reviews and Dissemination at the University of York.

The complete search strategies are given in Appendix 1.

## **STUDY INCLUSION CRITERIA**

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Studies published in English, French and German language from 1998 onwards are included. The population of interest is defined as adults with acute or chronic asthma. A strict definition of adult based on age inclusion criteria has been avoided. Where both children and adults make up the study population these studies have been included.

Studies conducted in hospital, emergency department, outpatient clinic, general practitioner and community settings are included. Only randomised controlled trials are included. Systematic reviews and meta-analyses (as a subset of systematic reviews) of randomised controlled trials were to be included if the researchers searched Medline and at least one other database. No relevant reviews or meta-analyses were found.

The interventions of interest were:

- asthma education of all types
- patient self-management with written action plans using self-monitoring, regular review or optimal self-management
- patient self-management by PEFR monitoring compared with symptom monitoring

Asthma education intervention studies were not conducted using double blinding. Such blinding is difficult to achieve in educational settings. Instead single blinding was considered appropriate where

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outcome assessment was done blind to group allocation. True placebo comparison is also difficult to achieve in educational intervention study settings because of ethical considerations. In most studies usual care from a medical practitioner involving some limited level of education was used in the control group.

## **STUDY EXCLUSION CRITERIA**

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Studies were excluded if they included:

- only patients with Chronic obstructive pulmonary disease (COPD)
- only patient compliance (medication, device use) outcomes
- only children (classified as 12 years or younger or an article using the term 'child' or 'children' or 'paediatric' or 'pediatric')
- an economic evaluation/cost-benefit analysis alone
- small patient numbers ( $N < 30$ ), major methodological problems, non-RCT, significant absence of study methodology
- letters, non-systematic reviews, editorials and comments were also excluded

## **INTERVENTIONS**

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Following is a list of the main systematic review comparisons between different asthma education and self-management interventions:

- Asthma education with patient self-management (information only) compared with usual care
- Asthma education with patient self-management (self-monitoring and regular review) compared with usual care
- Asthma education with patient self-management (optimal self-management) compared with usual care
- Asthma education with patient self-management (self-monitoring only) compared with usual care
- Asthma education with patient self-management using PEFR monitoring compared with symptom monitoring
  
- These interventions have been subjected to Cochrane Reviews. Topics covered include written action plans, self-management using PEFR or symptoms, regular medical review, asthma education including information only interventions. The studies covered in these reviews have been excluded from individual appraisal, being pre 1998. The Cochrane systematic reviews themselves should be regarded as high quality appraised literature.

## **PATIENT OUTCOMES**

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Studies with all or some of the following outcome measures have been included:

- hospital admissions
- rescue medicine use
- symptom ratings/peak flow diary
- quality of life
- spirometric outcomes (e.g. FEV<sub>1</sub>, PEFR)
- ED visits
- days lost from school/work
- unscheduled doctors visits

## **STUDY SELECTION**

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Studies were selected for appraisal using a two-stage process. Initially the titles and abstracts (where available) identified from the search strategy were scanned and excluded as appropriate. The full text articles were retrieved for the remaining studies and these were appraised if they fulfilled the study selection criteria outlined above.

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There were 281 studies identified by the search strategy (see appendix 1). Thirty-nine full text articles were obtained after excluding studies based on examination of the search titles and abstracts. A further 21 of these full text articles did not fulfil the inclusion criteria. Therefore 18 articles were fully appraised and are included in this report.

## EVIDENCE TABLES

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Key information summaries include:

- study reference
- study design
- study grading
- study arm description
- patient inclusion and exclusion criteria
- number of patients randomised
- primary and secondary efficacy results with p-values and/or 95% confidence intervals
- comments on internal validity issues arising from the study appraisal

Number needed to treat (NNT) was calculated when sufficient information was presented to allow calculation of this statistic.

Unless otherwise stated the intervention(s) of efficacy are presented in the left-hand column of the results section. *P*-values unless otherwise stated relate to between group comparisons. Refer to Appendix 2 for a detailed description of table items.

All studies were appraised using modified SIGN (Scottish Intercollegiate Guidelines Network) methodology checklists (see Appendix 3). The evaluation criteria are defined by a series of questions covering study internal validity. These questions addressed:

- the quality of the study research question(s)
- randomisation methods
- study population demographics
- concealment and blinding methods
- type of outcome measures
- study group treatment regimens
- patient dropout rates and statistical power adequacy
- intention to treat (ITT) analysis methodology

The final grading (1++, 1+ or 1-) code was allocated based upon the study design and study quality.

For a study to receive a 1++ grading the following criteria needed to be fulfilled:

- clearly defined study question
- a clear description of an adequate randomisation design and process
- absence of baseline differences in demographic variables, markers of asthma severity and other potential confounding variables between intervention groups post-randomisation
- an adequate concealment method and use of single blinding in outcome assessment
- outcomes measured in a standard, valid and reliable way
- all study arms treated equally
- at least 80% of the sample randomised were included in the presented analyses
- adequate statistical power
- an ITT analysis was presented

Factors (4 or more) that consigned studies to a 1- grading included:

- open study
  - study groups were not treated equally
  - ITT analysis not presented, analysis not based on randomised allocation
  - baseline study differences
  - outcome assessment not blinded to allocation
-

- less than 80% of the participant's randomised were analysed
- inadequate method or description of randomisation and concealment
- significant omissions or errors in patient demographic information and outcome results

All other studies were graded as 1+.

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# Study limitations

In the review of asthma education and self-management the quality of the included articles was such that there were no studies graded as 1++. Thirteen of 18 (72%) were graded as 1+ and five of 18 (28%) as 1-. Ordinarily 1- studies would be excluded from a systematic review. They were included on this occasion so the education and self-management team of the asthma guidelines group could assess them for relevance to the development of the New Zealand based guideline. However, the results of these studies should be viewed with considerable caution.

Limitations to the study designs included:

- lack of description on the study methodology, especially randomisation and concealment
- differences between study groups post randomisation or a lack of comparison between key variables post randomisation
- outcome assessment not done blind to group allocation
- inadequate power
- not using an ITT analysis, analysis not based on originally randomised allocation
- limited study generalisability in a NZ context

Individual study limitations are described in the comment section of the evidence tables.

Limitations to the review methodology that need to be considered in developing an asthma education and patient self-management guideline include restriction to:

- articles published from 1998 onwards
- the published literature
- English, French and German language articles
- reviewing each study by one researcher only
- study evaluation criterion did not cover aspects of statistical methodology such as the appropriateness of the data collected and the statistical tests used to analyse this

In developing a guideline for asthma education and patient self-management consideration will need to be given to studies published pre 1998. The vast majority of articles of interest were published in the pre 1998 time period so methods should be developed by the guidelines group to assess whether the new evidence presented in this review is sufficient to alter any recommendations included in previous evidence based guidelines.

Restriction to the published literature is likely to lead to bias since the unpublished literature tends to consist of studies not identifying a significant result.

Restriction by language may result in study bias but the direction of this bias cannot be determined.

None of the articles appraised were set in New Zealand. Therefore, the generalisability of these studies to the New Zealand setting needs to be considered.

The studies were initially selected by examining the abstracts of these articles. Therefore, it is possible that some studies were inappropriately excluded prior to examination of the full text article.

There is a limitation on space in evidence tables, therefore, study details have been summarised.

This review was conducted over a limited time frame (May – June 2001).

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# Evidence Tables

## Asthma education and patient self-management:

Table 1: Asthma education with patient self-management (information only) compared with usual care

Study Source, design and evidence grading	Intervention comparison/ educator/setting and duration	Criteria for Inclusion/ Exclusion	N	Results/outcomes					Comments
(Shah, Peat et al. 2001)  CRCT  Grade 1+  Country: Australia	Education Intervention: Triple A (Adolescent Asthma Action) programme  3 x 45min asthma education (asthma and its management) presentations (videos, games, worksheets, discussions) led by peers to year 10 students Subsequent Year 10 student presentations (drama/songs) to year 7 students V Control group: No asthma education  <u>Educator</u> Trained student peers  <u>Setting</u> 6 rural High Schools  Evaluation of outcomes at 8 months (October c.f. February)	<u>Inclusion:</u> High School adolescents reporting wheeze	272	<u>QoL Questionnaire</u> % of students with clinically significant improvement (>0.5 units)	<u>Education Intervention Group</u>	<u>Control Group</u>	<u>P value</u>	<u>NNI</u>	<ul style="list-style-type: none"> <li>• Mean age 12.5 (year 7) and 15.5 (year 10) across both groups</li> <li>• Higher proportion of females (65%) within intervention group than control group (46%) due to school mix and cluster randomisation</li> <li>• Asthma diagnosed by a doctor reported in 189 (75%) of students with recent wheeze</li> <li>• Of 272 students participating, 124 in intervention group and 148 in control group, 251 completed study and included in analysis. Withdrawal rate 8%</li> <li>• Cluster RCT design and concealment (described) with appropriate statistical tests and adjustments to results for clustering effect. Power/sample size analysis not presented in paper</li> <li>• Likelihood of contamination between groups (program well known to community) and Type II error</li> <li>• Follow-up QoL responses c.f. baseline (symptoms and activities) likely to have been subject to seasonal influences</li> <li>• Unclear if outcome assessment blinded to allocation, NNT presented</li> </ul>
				Overall mean total QoL	28/113 (25%)	17/138 (12%)	<i>P</i> =.01	8	
				Activities	46/113 (41%)	38/138 (28%)	<i>P</i> =.028	8	
				Symptoms	25/113 (25%)	29/138 (12%)	n.s.	13	
				Emotions	27/113 (41%)	31/138 (28%)	n.s.	13	
				<u>Lung function</u> FEV <sub>1</sub> %PV and (95% CI) Before bronchodilator					
				Baseline	103.8 (101, 107)	102.4 (100, 105)			
				Follow-up After bronchodilator	105.3 (102, 109)	111.0 (108, 114)	n.s.	N/A	
				Baseline	108.5 (104, 112)	107.2 (105, 110)			
				Follow-up	110.2 (107, 114)	116.1 (113, 119)	n.s.	N/A	

Table 2: Asthma education with patient self-management (self-monitoring &amp; regular review) compared with usual care

Study source, design and evidence grading	Intervention Comparison/ Educator/setting and duration	Criteria for Inclusion/ Exclusion	N	Results/outcomes	Comments																																																																																
(Bailey, Kohler et al. 1999) RCT Grade 1+ Country: USA	<p>Education Intervention: Patient education on asthma self-management (One 1 hour individual session where skill-oriented self-help workbook provided giving information on asthma control, self-management using PEFR monitoring, general asthma information, symptom &amp; medication self-management)</p> <p>Two support group sessions (4-6 patients), telephone and letter follow-up to 1 month) V</p> <p>Education Intervention: Modified version of above education program with core elements only (shortened workbook, one 15-20 minute individual session with training for PEFR monitoring, inhaler use) Telephone and letter follow-up for 2 weeks) V</p> <p>Control Group: Usual care programme from GP</p> <p><u>Educator</u> Public health educator</p> <p><u>Setting</u> Hospital outpatient clinic</p> <p>Outcome assessment at 24 months</p>	<p><u>Inclusion:</u> Patients with recurrent episodes of dyspnea or wheezing</p> <p>Objective evidence of increased airflow resistance during episodes</p> <p>Mild to severe asthma as assessed by physician</p> <p><u>Exclusion:</u> Earlier participation in self-management study</p>	236	<p><u>Relative risk and 95% CI</u> Reference: baseline data in control group</p> <p><u>Asthma status measures</u></p> <p><u>Symptoms</u></p> <table border="1"> <thead> <tr> <th></th> <th>Full Education Intervention Group</th> <th>Core Education Intervention Group</th> <th>Control Group</th> </tr> </thead> <tbody> <tr> <td>6 months</td> <td>0.5 (0.2, 1.3)</td> <td>0.4 (0.1, 1.1)</td> <td>0.8 (0.4, 1.6)</td> </tr> <tr> <td>12 months</td> <td>0.9 (0.3, 2.4)</td> <td>0.5 (0.2, 1.4)</td> <td>0.5 (0.2, 1.1)</td> </tr> <tr> <td>18 months</td> <td>0.5 (0.2, 1.4)</td> <td>0.5 (0.2, 1.5)</td> <td>0.7 (0.3, 1.5)</td> </tr> <tr> <td>24 months</td> <td>1.1 (0.4, 3.2)</td> <td>0.7 (0.2, 2.2)</td> <td>0.4 (0.2, 1.1)</td> </tr> </tbody> </table> <p><u>Respiratory illness</u></p> <table border="1"> <thead> <tr> <th></th> 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<td>2.2 (1.0, 5.0)</td> <td>0.5 (0.3, 1.9)</td> <td>0.5 (0.3, 0.9)*</td> </tr> <tr> <td>24 months</td> <td>1.1 (0.5, 2.5)</td> <td>0.6 (0.2, 0.9)*</td> <td>0.6 (0.3, 1.0)</td> </tr> </tbody> </table> <p><u>Use of health care resources</u></p> <table border="1"> <thead> <tr> <th></th> <th>Full Education Intervention Group</th> <th>Core Education Intervention Group</th> <th>Control Group</th> </tr> </thead> <tbody> <tr> <td>6 months</td> <td>0.9 (0.4, 2.3)</td> <td>0.7 (0.3, 1.8)</td> <td>0.5 (0.2, 0.9)*</td> </tr> <tr> <td>12 months</td> <td>0.5 (0.2, 1.2)</td> <td>0.5 (0.2, 1.2)</td> <td>0.5 (0.3, 0.8)*</td> </tr> <tr> <td>18 months</td> <td>1.1 (0.4, 2.6)</td> <td>1.0 (0.4, 2.7)</td> <td>0.3 (0.1, 0.6)*</td> </tr> <tr> <td>24 months</td> <td>0.7 (0.3, 1.7)</td> <td>0.6 (0.2, 1.8)</td> <td>0.4 (0.2, 0.7)*</td> </tr> </tbody> </table> <p>* 95% CI excludes 1.0</p>		Full Education Intervention Group	Core Education Intervention Group	Control Group	6 months	0.5 (0.2, 1.3)	0.4 (0.1, 1.1)	0.8 (0.4, 1.6)	12 months	0.9 (0.3, 2.4)	0.5 (0.2, 1.4)	0.5 (0.2, 1.1)	18 months	0.5 (0.2, 1.4)	0.5 (0.2, 1.5)	0.7 (0.3, 1.5)	24 months	1.1 (0.4, 3.2)	0.7 (0.2, 2.2)	0.4 (0.2, 1.1)		Full Education Intervention Group	Core Education Intervention Group	Control Group	6 months	0.7 (0.3, 1.6)	0.6 (0.3, 1.5)	0.5 (0.3, 0.9)*	12 months	0.7 (0.3, 1.6)	0.5 (0.2, 1.2)	0.6 (0.3, 1.1)	18 months	1.0 (0.4, 2.1)	0.7 (0.3, 1.4)	0.6 (0.3, 0.9)*	24 months	1.0 (0.5, 2.2)	1.0 (0.4, 2.2)	0.5 (0.3, 0.8)*		Full Education Intervention Group	Core Education Intervention Group	Control Group	6 months	1.3 (0.6, 2.8)	0.6 (0.3, 1.3)	0.6 (0.3, 1.0)	12 months	1.2 (0.6, 2.6)	0.5 (0.3, 1.2)	0.5 (0.3, 1.0)	18 months	2.2 (1.0, 5.0)	0.5 (0.3, 1.9)	0.5 (0.3, 0.9)*	24 months	1.1 (0.5, 2.5)	0.6 (0.2, 0.9)*	0.6 (0.3, 1.0)		Full Education Intervention Group	Core Education Intervention Group	Control Group	6 months	0.9 (0.4, 2.3)	0.7 (0.3, 1.8)	0.5 (0.2, 0.9)*	12 months	0.5 (0.2, 1.2)	0.5 (0.2, 1.2)	0.5 (0.3, 0.8)*	18 months	1.1 (0.4, 2.6)	1.0 (0.4, 2.7)	0.3 (0.1, 0.6)*	24 months	0.7 (0.3, 1.7)	0.6 (0.2, 1.8)	0.4 (0.2, 0.7)*	<ul style="list-style-type: none"> <li>Full education group programme was a replication of a previous efficacious asthma self-management programme</li> <li>Mean age N/A, female 70%, and African American 36% in full-education grp; mean age N/A, female 68%, and African American 23% in core education grp; mean age N/A, female 70%, and African American 40% in control grp</li> <li>Limited generalisability of study given high minority and female study population</li> <li>Of 236 randomised patients, data and analysis for 221 patients over 2-year period. The attrition rate during study was 15/236 (7%)</li> <li>Adequate randomisation method, "closed-envelope technique". Adequate concealment at randomisation. Follow-up assessors blinded to allocation for outcome assessment</li> </ul>
	Full Education Intervention Group	Core Education Intervention Group	Control Group																																																																																		
6 months	0.5 (0.2, 1.3)	0.4 (0.1, 1.1)	0.8 (0.4, 1.6)																																																																																		
12 months	0.9 (0.3, 2.4)	0.5 (0.2, 1.4)	0.5 (0.2, 1.1)																																																																																		
18 months	0.5 (0.2, 1.4)	0.5 (0.2, 1.5)	0.7 (0.3, 1.5)																																																																																		
24 months	1.1 (0.4, 3.2)	0.7 (0.2, 2.2)	0.4 (0.2, 1.1)																																																																																		
	Full Education Intervention Group	Core Education Intervention Group	Control Group																																																																																		
6 months	0.7 (0.3, 1.6)	0.6 (0.3, 1.5)	0.5 (0.3, 0.9)*																																																																																		
12 months	0.7 (0.3, 1.6)	0.5 (0.2, 1.2)	0.6 (0.3, 1.1)																																																																																		
18 months	1.0 (0.4, 2.1)	0.7 (0.3, 1.4)	0.6 (0.3, 0.9)*																																																																																		
24 months	1.0 (0.5, 2.2)	1.0 (0.4, 2.2)	0.5 (0.3, 0.8)*																																																																																		
	Full Education Intervention Group	Core Education Intervention Group	Control Group																																																																																		
6 months	1.3 (0.6, 2.8)	0.6 (0.3, 1.3)	0.6 (0.3, 1.0)																																																																																		
12 months	1.2 (0.6, 2.6)	0.5 (0.3, 1.2)	0.5 (0.3, 1.0)																																																																																		
18 months	2.2 (1.0, 5.0)	0.5 (0.3, 1.9)	0.5 (0.3, 0.9)*																																																																																		
24 months	1.1 (0.5, 2.5)	0.6 (0.2, 0.9)*	0.6 (0.3, 1.0)																																																																																		
	Full Education Intervention Group	Core Education Intervention Group	Control Group																																																																																		
6 months	0.9 (0.4, 2.3)	0.7 (0.3, 1.8)	0.5 (0.2, 0.9)*																																																																																		
12 months	0.5 (0.2, 1.2)	0.5 (0.2, 1.2)	0.5 (0.3, 0.8)*																																																																																		
18 months	1.1 (0.4, 2.6)	1.0 (0.4, 2.7)	0.3 (0.1, 0.6)*																																																																																		
24 months	0.7 (0.3, 1.7)	0.6 (0.2, 1.8)	0.4 (0.2, 0.7)*																																																																																		

Table 2: Asthma education with patient self-management (self-monitoring & regular review) compared with usual care (*continued*)

Study Source, design and evidence grading	Intervention Comparison/ Educator/setting and duration	Criteria for Inclusion/ Exclusion	N	Results/outcomes					Comments
(Heard, Richards et al. 1999)  RCT  Grade 1+  Country: Australia	Education Intervention: General practice based asthma clinic of 3 hours, (individual asthma education on self-management strategies including a written plan, spirometry PEFr monitoring, inhaler and diary card use and consultation with GP)  Follow-up with 3 asthma clinic sessions within 6 months V Control Group: Usual care programme from GP  <u>Educator</u> Qualified nurse educators  <u>Setting</u> General practices (8)  Outcome assessment at 6 months	<u>Inclusion:</u> Patients with asthma attending general practice	195	<u>Proportions of patients, adjusted odds ratios and 95% CI over 6 month follow-up*</u>	<u>Education Intervention Group</u>	<u>Control Group</u>	<u>Odds Ratio</u>	<u>95% CI</u>	<ul style="list-style-type: none"> <li>• Mean age 28, female 58%, in education grp: mean age 26, female 57% in control grp</li> <li>• Patients mostly mild asthmatics given low rates of hospitalisations and ED visits</li> <li>• Of 195 randomised patients, data and analysis for 191 patients over 2-year period. The attrition rate during study was 4/195 (2%). ITT analysis, however only 67/98 (68%) of intervention group received the whole intervention (attended all sessions) as allocated</li> <li>• Randomisation method not described. Unclear if concealment adequate. Educators informed of allocation before baseline interview. Both groups often seen by same GP, outcome assessors and GP's not blinded to allocation</li> </ul>
				Proportion of patients reporting:					
				Time lost from work or school	0.35	0.38	0.92	0.48, 1.76	
				Taking relief medication	0.95	0.97	0.65	0.14, 2.97	
				Taking preventer medication	0.81	0.84	0.88	0.37, 2.09	
				AM waking weekly with asthma, wheeze, cough	0.22	0.33	0.65	0.32, 1.34	
				Waking at night weekly due to asthma	0.07	0.20	0.38	0.16, 0.91**	
				Doctor visit to home	0.01	0.01	0.97	0.06, 15.1	
				Emergency department visit	0.03	0.01	2.97	0.28, 32.0	
				Hospital admission	0.02	0.05	0.31	0.05, 1.75	
				* adjusted for baseline measures and clustering by doctor					
				** 95% CI does not include 1.00					

Table 2: Asthma education with patient self-management (self-monitoring & regular review) compared with usual care (*continued*)

Study source, design and evidence grading	Intervention Comparison/ Educator/setting and duration	Criteria for Inclusion/ Exclusion	N	Results/outcomes	Comments																																																																												
(Kauppinen, Sintonen et al. 1998) RCT Grade 1+ Country: Finland	Education Intervention: At baseline, individual conventional education programme on inhaled drugs, PEFR follow-up, treatment, guided self-management plan, video  Plus: at 3, 6, 9 months 30 min individual educational session with checks on plans, PEFR follow-ups, reiteration of treatment principles  Between 6-9 months one group (2-3 patients) 2 hour educational programme V Control group: (conventional education programme only)  <u>Educator</u> Qualified nurse, physiotherapist, chest physician educators  <u>Setting</u> Hospital outpatient clinic  Outcome assessment at 12 months	<u>Inclusion:</u> Age 18-76 years  New asthma patients (ATS definition)  FEV <sub>1</sub> ≥ 15% bronchodilator response	162	<p><u>Lung function</u> Mean lung function values (as %PV)</p> <table border="1"> <thead> <tr> <th></th> <th><u>Education Intervention Group</u></th> <th><u>Control Group</u></th> <th><u>P value</u></th> </tr> </thead> <tbody> <tr> <td>FVC</td> <td></td> <td></td> <td></td> </tr> <tr> <td>- baseline</td> <td>94.7</td> <td>92.5</td> <td></td> </tr> <tr> <td>- 12 months</td> <td>99.8</td> <td>94.7</td> <td>n.s.</td> </tr> <tr> <td>FEV<sub>1</sub></td> <td></td> <td></td> <td></td> </tr> <tr> <td>- baseline</td> <td>85.7</td> <td>82.8</td> <td></td> </tr> <tr> <td>- 12 months</td> <td>92.3</td> <td>84.7</td> <td>P=.02</td> </tr> <tr> <td>FEV%</td> <td></td> <td></td> <td></td> </tr> <tr> <td>- baseline</td> <td>90.0</td> <td>89.1</td> <td></td> </tr> <tr> <td>- 12 months</td> <td>91.9</td> <td>88.9</td> <td>n.s.</td> </tr> <tr> <td>PEFR</td> <td></td> <td></td> <td></td> </tr> <tr> <td>- baseline</td> <td>84.2</td> <td>83.4</td> <td></td> </tr> <tr> <td>- 12 months</td> <td>91.6</td> <td>87.1</td> <td>n.s.</td> </tr> <tr> <td>PC<sub>15</sub> mg ml<sup>-1</sup> (Histamine)</td> <td></td> <td></td> <td></td> </tr> <tr> <td>- baseline</td> <td>0.54</td> <td>0.58</td> <td></td> </tr> <tr> <td>12 months</td> <td>1.41</td> <td>1.23</td> <td>n.s.</td> </tr> <tr> <td>Self-reported questionnaire Mean HRQOL total score*</td> <td></td> <td></td> <td></td> </tr> <tr> <td>- baseline</td> <td>26.4</td> <td>27.9</td> <td></td> </tr> <tr> <td>- 12 months</td> <td>16.5</td> <td>20.5</td> <td>n.s.</td> </tr> </tbody> </table> <p>* all components had no significant difference between groups</p>		<u>Education Intervention Group</u>	<u>Control Group</u>	<u>P value</u>	FVC				- baseline	94.7	92.5		- 12 months	99.8	94.7	n.s.	FEV <sub>1</sub>				- baseline	85.7	82.8		- 12 months	92.3	84.7	P=.02	FEV%				- baseline	90.0	89.1		- 12 months	91.9	88.9	n.s.	PEFR				- baseline	84.2	83.4		- 12 months	91.6	87.1	n.s.	PC <sub>15</sub> mg ml <sup>-1</sup> (Histamine)				- baseline	0.54	0.58		12 months	1.41	1.23	n.s.	Self-reported questionnaire Mean HRQOL total score*				- baseline	26.4	27.9		- 12 months	16.5	20.5	n.s.	<ul style="list-style-type: none"> <li>Longer-term (3 and 5 year) outcomes of this trial reported in Kauppinen et al., 1999, and Kauppinen et al., 2001. Economic evaluation is excluded from evidence tables</li> <li>Mean age 43, female 69%, smokers 24% and FEV<sub>1</sub> 86%PV for intervention grp; mean age 44, female 57%, smokers 20% and FEV<sub>1</sub> 83 %PV in control grp</li> <li>Of 162 patients randomised, 80 and 82 per group, 157 assessed at 12 months. Withdrawal rate of 3% (accounted for), intervention grp 4%, control grp 2%</li> <li>Randomisation method described as using "computerized list with consecutive numbers". Unclear if adequate concealment and blinding for outcome assessment</li> <li>Withdrawals not included in analysis but small number of withdrawals are accounted for</li> </ul>
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Table 2: Asthma education with patient self-management (self-monitoring & regular review) compared with usual care (*continued*)

Study source, design and evidence grading	Intervention Comparison/ Educator/setting and duration	Criteria for Inclusion/ Exclusion	N	Results/outcomes				Comments
(Kauppinen, Sintonen et al. 1999) RCT Grade 1+ Country: Finland	<p>Education Intervention: At baseline, individual conventional education programme on inhaled drugs, PEFR follow-up, treatment, guided self-management plan, video Plus: at 3, 6, 9 months 30 min individual educational session with checks on plans, PEFR follow-ups, reiteration of treatment principles</p> <p>Between 6-9 months one group (2-3 patients) 2 hour educational programme</p> <p>Primary health care responsibility from one year, assessment at 12, 36 months V Control group: (conventional education programme only) Primary health care responsibility from one year, assessment at 12, 36 months</p> <p><u>Educator</u> Qualified nurse, physiotherapist, chest physician educators</p> <p><u>Setting</u> Hospital outpatient clinic</p> <p>Outcome assessment at 36 months</p>	<p><u>Inclusion:</u> Age 18-76 years</p> <p>New asthma patients (ATS definition)</p> <p>FEV<sub>1</sub> ≥ 15% bronchodilator response</p>	162	<p><u>Lung function</u> Mean lung function values (as %PV)</p> <p>FVC</p> <p>- baseline 95.1 92.5 - 36 months 94.8 91.4</p> <p>FEV<sub>1</sub></p> <p>- baseline 86.1 82.8 - 36 months 89.2 83.9</p> <p>FEV% - baseline 90.0 89.1 - 36 months 93.8 92.0</p> <p>PEFR</p> <p>- baseline 84.3 83.4 - 36 months 91.6 87.2</p> <p>PC<sub>15</sub> mg ml<sup>-1</sup> (Histamine)</p> <p>- baseline 0.54 0.58 - 36 months 1.57 1.26</p> <p>Self-reported questionnaire Mean HRQOL total score*</p> <p>- baseline 27.0 27.7 - 36 months 15.5 16.8</p> <p>* all components had no significant difference between groups</p>	<p><u>Education Intervention Group</u></p> <p><u>Control Group</u></p> <p><u>P value</u></p> <p>n.s.</p> <p>P&lt;.05</p> <p>n.s.</p> <p>P&lt;.05</p> <p>n.s.</p> <p>n.s.</p>	<ul style="list-style-type: none"> <li>1 year and 5 year outcomes of this trial reported in Kauppinen et al., 1998, and Kauppinen et al., 2001. Economic evaluation is excluded from evidence tables</li> <li>Mean age 43, female 69%, smokers 24% and FEV<sub>1</sub> 86%PV for intervention grp; mean age 44, female 57%, smokers 20% and FEV<sub>1</sub> 83 %PV in control grp</li> <li>Of 162 patients randomised, 80 and 82 per group, 150 assessed at 36 months. Withdrawal rate of 7% (accounted for), intervention grp 10%, control grp 5%</li> <li>Randomisation method described as using "computerized list with consecutive numbers". Unclear if adequate concealment and blinding for outcome assessment</li> <li>Withdrawals not included in analysis but small number of withdrawals are accounted for</li> </ul>		

Table 2: Asthma education with patient self-management (self-monitoring & regular review) compared with usual care (*continued*)

Study source, design and evidence grading	Intervention Comparison/ Educator/setting and duration	Criteria for Inclusion/ Exclusion	N	Results/outcomes				Comments
(Kauppinen, Vilkkka et al. 2001) RCT Grade 1+ Country: Finland	<p>Education Intervention: At baseline, individual conventional education programme on inhaled drugs, PEFr follow-up, treatment, guided self-management plan, video</p> <p>Plus: at 3, 6, 9 months 30 min individual educational session with checks on plans, PEFr follow-ups, reiteration of treatment principles</p> <p>Between 6-9 months one group (2-3 patients) 2 hour educational programme</p> <p>Primary health care responsibility from one year, assessment at 12, 36 and 60 months</p> <p>V</p> <p>Control group: (conventional education programme only) Primary health care responsibility from one year, assessment at 12, 36 and 60 months</p> <p><u>Educator</u> Qualified nurse, physiotherapist, chest physician educators</p> <p><u>Setting</u> Hospital outpatient clinic</p> <p>Outcome assessment at 60 months</p>	<p><u>Inclusion:</u> Age 18-76 years</p> <p>New asthma patients (ATS definition)</p> <p>FEV<sub>1</sub> ≥ 15% bronchodilator response</p>	162	<p><u>Lung function</u> Mean lung function values (as %PV)</p> <p>FVC</p> <p>- baseline 94.5 - 60 months 95.6</p> <p>FEV<sub>1</sub></p> <p>- baseline 85.0 - 60 months 92.5</p> <p>FEV%</p> <p>- baseline 89.4 - 60 months 92.5</p> <p>PEFR</p> <p>- baseline 83.7 - 60 months 90.8</p> <p>PC<sub>15</sub> mg ml<sup>-1</sup> (Histamine)</p> <p>- baseline 0.56 - 60 months 1.92</p> <p>Self-reported questionnaire Mean HRQOL total score*</p> <p>- baseline 27.0 - 60 months 15.0</p> <p>* all components had no significant difference between groups</p>	<p><u>Education Intervention Group</u></p> <p>94.5 95.6 85.0 92.5 89.4 92.5 83.7 90.8 0.56 1.92</p>	<p><u>Control Group</u></p> <p>92.5 94.7 82.8 84.7 89.1 88.9 83.4 87.1 0.58 1.23</p>	<p><u>P value</u></p> <p>n.s. n.s. n.s. n.s. n.s. n.s.</p>	<ul style="list-style-type: none"> <li>1 year and 3 year outcomes of this trial reported in Kauppinen et al., 1998, and Kauppinen et al., 1999. Economic evaluation is excluded from evidence tables</li> <li>Mean age 43, female 69%, smokers 24% and FEV<sub>1</sub> 86%PV for intervention grp; mean age 44, female 57%, smokers 20% and FEV<sub>1</sub> 83 %PV in control grp</li> <li>Of 162 patients randomised, 80 and 82 per group, 134 assessed at 60 months. Withdrawal rate of 17% (accounted for), intervention grp 20%, control grp 15%</li> <li>Randomisation method described as using "computerized list with consecutive numbers". Unclear if adequate concealment and blinding for outcome assessment</li> <li>Withdrawals not included in analysis, 17% drop out rate after 5 years, study power only marginally maintained. Withdrawals accounted for</li> </ul>

Table 2: Asthma education with patient self-management (self-monitoring & regular review) compared with usual care (*continued*)

Study source, design and evidence grading	Intervention Comparison/ Educator/setting and duration	Criteria for Inclusion/ Exclusion	N	Results/outcomes				Comments
(Levy, Robb et al. 2000)  RCT  Grade 1+  Country: UK	Education Intervention: Patient education using guided self-management plans (One 1 hour (initial) and 2 x 30 minute (6-weekly intervals with face-to-face or telephone interview) consultations with nurses. (asthma control and self-management using PEFR monitoring or, general asthma information, symptom & medication self-management, assessment) V Control Group: Usual care from GP  <u>Educator</u> Qualified nurse educator  <u>Setting</u> Two ED clinics  Outcome assessment at 6 months	<u>Inclusion:</u> Age 18+ years  Patients attending ED or admitted to hospital for uncontrolled asthma  <u>Exclusion</u> Patients with COPD	237	<u>SGRO (St George) QoL Questionnaire</u>  Total score* mean (se) Baseline 6 months  * all components had no significant difference between groups  <u>Diary entry data</u> Mean PEFR (Educ - cntrl grp) Baseline 6 months  <u>GP audit data (n)</u> Routine GP consultations Before educ- median (range) After - median (range)  Routine nurse consultations Before educ- median (range) After - median (range)  Emergency GP consultations Before educ- median (range) After - median (range)  Hospital consultations Before educ- median (range) After - median (range)	<u>Education Intervention Group</u>  36 (18) 30 (18)  -14 +20  1 (0-15) 1 (1-6)  0 (0-9) 0 (1-5)  0 (0-9) 0 (1-7)  0 (0-3) 0 (1-3)	<u>Control Group</u>  38 (18) 29 (18)  1 (0-32) 1 (1-23)  0 (0-5) 0 (1-8)  0 (0-9) 0 (1-7)  0 (0-6) 0 (1-6)	<u>P value</u>  n.s.  n.s. P<.05  n.s. P<.05  n.s. P<.03  n.s. n.s.  n.s. n.s.	<ul style="list-style-type: none"> <li>• Mean age 43, female 67%, PEFR 49 %PV for education grp; mean age 40, female 57%, PEFR 45 %PV in control grp; mean age 37, female 52% for those who declined patient grp</li> <li>• Of 237 randomised patients, 26 (11%) outside the study protocol inadvertently recruited, leaving 211 (103 intervention and 108 controls) to participate in study. Withdrawals during study were 20/103 (19%) and 12/108 (11%) per group. Overall withdrawal rate of 24% from original 237. ITT analysis, data for all 211 patients included in analysis</li> <li>• Adequate randomisation method (described). Concealment at randomisation but nurses aware for making follow-up appointments of intervention group. Questionnaire interviewer blinded to allocation for outcome assessment</li> </ul>

Table 2: Asthma education with patient self-management (self-monitoring & regular review) compared with usual care (*continued*)

Study source, design and evidence grading	Intervention Comparison/ Educator/setting and duration	Criteria for Inclusion/ Exclusion	N	Results/outcomes			Comments	
(Abdulwadud, Abramson et al. 1999)  RCT  Grade 1-  Country: Australia	Education Intervention: Three education (90 min) group sessions over 3 successive weeks (Asthma knowledge, self-management skills, PEFr monitoring, inhalation and device technique, written materials) V Control group: Usual care  <u>Educator</u> Qualified nurse educators  <u>Setting</u> Hospital outpatient clinic  Evaluation of outcomes at 6 months	<u>Inclusion:</u> Age > 16 years  Dx of asthma (BTS criteria) and asthma primary health problem	125	<u>Questionnaire evaluation</u> (difference in mean change in score c.f. control grp at 6 months & 95% CI)  Asthma knowledge Asthma QoL  <u>Self management skill scores</u> (difference in median change in score c.f. control grp at 6 months)  Slow onset of asthma Rapid onset of asthma	<u>Education Intervention Group</u>  0.6 (-1.05, 2.25) -0.26 (-1.30, 0.77)  0 0	<u>Control Group</u>  n.s. n.s.  n.s. n.s.	<u>P value</u>  n.s. n.s.  n.s. n.s.	<ul style="list-style-type: none"> <li>• Mean age 48, female 61%, secondary-plus education 77% for intervention grp; mean age 43, female 59% and secondary-plus education 94% in control grp</li> <li>• Of 125 patients participating, 77 completed study. Very high withdrawal rate of 38%, with intervention grp. 53% and control grp. 23%. Withdrawals not included in analysis</li> <li>• Power (90%) of original study design not attained, 80% power attained</li> <li>• Randomisation method described as using "random number table". Unclear if adequate concealment</li> <li>• Immediate post-intervention outcome assessment for intervention group only. Comparable outcomes assessment of groups only done at baseline and 6 months</li> <li>• Outcome assessment not blinded to allocation</li> </ul>

Table 2: Asthma education with patient self-management (self-monitoring & regular review) compared with usual care (*continued*)

Study source, design and evidence grading	Intervention Comparison/ Educator/setting and duration	Criteria for Inclusion/ Exclusion	N	Results/outcomes				Comments
(de Oliveira, Faresin et al. 1999) RCT Grade 1- Country: Brazil	Education Intervention: Initial visit with individual education programme on general asthma information, symptoms, exacerbation's, medication use, MDI training  Monthly small group visits including 2 x 1 hour sessions on asthma self-management, treatment plan, symptom awareness with video and written materials V Control group: Usual care  <u>Educator</u> Physician educators  <u>Setting</u> Hospital outpatient clinic  Outcome assessment at 6 months	<u>Inclusion:</u> History of asthma and airflow obstruction according to International Consensus Report on Diagnosis and Management of Asthma (ICRDMA) criteria (Global initiative for asthma, National Heart, Lung, and Blood Institute. Bethesda, USA)	53	<u>Self-reported severity</u>  Hospital admissions n (sd) ED admissions n (sd) Night symptoms n/day (sd) Freq of symptoms score (sd)  <u>Self-reported QoL</u> total score* at 6 months Mean (sd) * all components were statistically significant (P<.01) between groups  <u>Observed MDI use</u> Adequate use of MDI Scale score (sd)  <u>Measured lung function</u> PEFR pre-bronchodilator L min <sup>-1</sup> (sd) PEFR post-bronchodilator L min <sup>-1</sup> (sd)	<u>Education Intervention Group</u>  0 0.7 (1.0) 0.3 (0.5) 1.3 (1)  28 (17)  8 (3)  367 (137) 401 (114)	<u>Control Group</u>  0.5 (0.8) 2 (2) 0.7 (1) 2 (1)  50 (15)  4 (4)  323 (100) 401 (119)	<u>P value</u>  n.s. P=.03 P=.04 P=.04  P=.0005  P=.001  n.s. n.s.	<ul style="list-style-type: none"> <li>• Mean age 41, female 91%, FEV<sub>1</sub> 70 %PV, monthly family income US\$ 486 and &lt; 5 years educ 73% for intervention grp; mean age 38, female 85%, FEV<sub>1</sub> 80 %PV, monthly family income US\$ 413 and &lt; 5 years educ 60% in control grp</li> <li>• Possible selection bias and limited generalisability of study as high proportion of females and low SES patients included</li> <li>• Of 53 randomised patients, 26 and 27 per group, 42 were assessed at 6 months. Withdrawal rate of 21%, where intervention grp 19%, control grp 22%. Withdrawals not included in analysis, potential for low study power</li> <li>• Randomisation method described as "sealed envelope technique". Adequate concealment. Blinding for outcome assessment unlikely as both groups attended by same physicians</li> </ul>

Table 3: Asthma education with patient self-management (optimal self-management) compared with usual care

Study source, design and evidence grading	Intervention Comparison/ Educator/setting and duration	Criteria for Inclusion/ Exclusion	N	Results/outcomes	Comments																									
(Gallefoss, Bakke et al. 1999) RCT Grade 1+ Country: Norway	Education Intervention: Two educational (2 hour) group (5-8 patients) sessions, 1-2 (40 minute) individual sessions  (Asthma knowledge, medication and symptom awareness, PEFr monitoring, compliance, self-management action plan developed, written materials) V Control group: Usual care  <u>Educator</u> Qualified nurse, physiotherapist educators  <u>Setting</u> Hospital outpatient clinic  GP follow-up, evaluation of outcomes at 12 months	<u>Inclusion:</u> Age 18-70 years  Stable bronchial asthma  FEV <sub>1</sub> ≥ 80 %PV  FEV <sub>1</sub> PC <sub>20</sub> and reversibility with 400 µg salbutamol  <u>Exclusion</u> Patients with serious disease	78 *see comments	<u>St George respiratory Questionnaire (SGRO)</u> <u>Self-reported QoL at 12 months</u>  Δ in FEV <sub>1</sub> ml (%)  Mean score (sd) Total QoL score Symptoms Activity Impact	<table border="1"> <thead> <tr> <th></th> <th>Education Intervention Group</th> <th>Control Group</th> <th>P value</th> </tr> </thead> <tbody> <tr> <td></td> <td>+112 (3.4%)</td> <td>-83 (-2.7%)</td> <td>P&lt;.05</td> </tr> <tr> <td>Total QoL score</td> <td>20.2 (15)</td> <td>36.5 (18)</td> <td>P=.0002</td> </tr> <tr> <td>Symptoms</td> <td>31.1 (20)</td> <td>42.5 (20)</td> <td>P=.018</td> </tr> <tr> <td>Activity</td> <td>29.7 (22)</td> <td>44.3 (20)</td> <td>P=.007</td> </tr> <tr> <td>Impact</td> <td>13.8 (14)</td> <td>32.4 (21)</td> <td>P=.0001</td> </tr> </tbody> </table>		Education Intervention Group	Control Group	P value		+112 (3.4%)	-83 (-2.7%)	P<.05	Total QoL score	20.2 (15)	36.5 (18)	P=.0002	Symptoms	31.1 (20)	42.5 (20)	P=.018	Activity	29.7 (22)	44.3 (20)	P=.007	Impact	13.8 (14)	32.4 (21)	P=.0001	<ul style="list-style-type: none"> <li>• QoL outcomes reported in this paper. Same trial Gallefoss, Bakke et al., 2000, reports morbidity outcomes</li> <li>• Mean age 41, female 61%, PEFr meter use 41% and smoker 23% for intervention grp; mean age 44, female 79%, PEFr meter use 31% and smoker 33% in control grp</li> <li>• *The study randomised a total of 140 patients, 78 of whom were asthmatic and 62 with COPD. Study demographics and results are presented separately</li> <li>• Of 78 asthma patient's randomised, 39 per group, 71 completed study. Withdrawal rate of 9% (accounted for), intervention grp 18%, control grp nil</li> <li>• Randomisation/concealment method not described.</li> <li>• 94% of intervention group received standard treatment plans using PEFr monitoring</li> <li>• Unknown if outcome assessment blinded to allocation, withdrawals not included in analysis but are accounted for</li> </ul>
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Table 3: Asthma education with patient self-management (optimal self-management) compared with usual care (*continued*)

Study source, design and evidence grading	Intervention Comparison/ Educator/setting and duration	Criteria for Inclusion/ Exclusion	N	Results/outcomes	Comments																																				
(George, O'Dowd et al. 1999) RCT Grade 1+ Country: USA	<p>Asthma Education: Inpatient Education Programme (IEP) with individual asthma education (general information, symptom &amp; medication, self-management action plan), bedside spirometry, follow-up phonecall (24 hours) and 1 week follow-up (spirometry, examination and education reinforcement) V</p> <p>Control group: (Usual care and routine follow-up)</p> <p><u>Educator</u> Qualified nurse educator</p> <p><u>Setting</u> Hospital ED and outpatient clinic</p> <p>Outcome assessment at 6 months pre and post-intervention</p>	<p><u>Inclusion:</u> Age 18-45 years</p> <p>ED admission with primary acute asthma</p> <p><u>Exclusion</u> Comorbidity or patient admitted to intensive care</p>	77	<p><u>Outcomes</u></p> <table border="1"> <thead> <tr> <th></th> <th><u>Education Intervention Group</u></th> <th><u>Control Group</u></th> <th><u>P value</u></th> </tr> </thead> <tbody> <tr> <td>Mean Hospital LOS (days)</td> <td>2.1</td> <td>2.7</td> <td>n.s.</td> </tr> <tr> <td>Adherence to follow-up appointments n (%)</td> <td>26 (60%)</td> <td>9 (27%)</td> <td>P=.01</td> </tr> <tr> <td>ED visits* n</td> <td></td> <td></td> <td></td> </tr> <tr> <td>(6 months pre-intervention)</td> <td>27</td> <td>17</td> <td></td> </tr> <tr> <td>(6 months post-intervention)</td> <td>3</td> <td>15</td> <td>P=.04</td> </tr> <tr> <td>Hospitalisations* n</td> <td></td> <td></td> <td></td> </tr> <tr> <td>(6 months pre-intervention)</td> <td>26</td> <td>14</td> <td></td> </tr> <tr> <td>(6 months post-intervention)</td> <td>3</td> <td>12</td> <td>P=.04</td> </tr> </tbody> </table> <p>* data include only Medicaid MCO enrolled patients.</p>		<u>Education Intervention Group</u>	<u>Control Group</u>	<u>P value</u>	Mean Hospital LOS (days)	2.1	2.7	n.s.	Adherence to follow-up appointments n (%)	26 (60%)	9 (27%)	P=.01	ED visits* n				(6 months pre-intervention)	27	17		(6 months post-intervention)	3	15	P=.04	Hospitalisations* n				(6 months pre-intervention)	26	14		(6 months post-intervention)	3	12	P=.04	<ul style="list-style-type: none"> <li>• Mean age 29, female 84%, and Medicaid patients 52% for intervention grp, mean age 29, female 73% and Medicaid patients 62% in control grp</li> <li>• Demographic information on existing disease severity, medication use, SES and ethnicity not presented. Authors state no significant differences between groups</li> <li>• Limited generalisability of study given inner city, low SES, minority, Medicaid MCO enrolled patients, and predominantly female study population</li> <li>• Of 77 randomised patients, 44 and 33 per group, there were no withdrawals. Only ED visits and hospitalisation pre and post intervention for Medicaid MCO enrolled patients (n=30 &amp; n=20) evaluated</li> <li>• Randomisation method "by random number generator". Discharge criteria and decisions made by attending physicians not study investigator. Unclear if adequate concealment or blinding for outcome assessment</li> </ul>
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Study source, design and evidence grading	Intervention Comparison/ Educator/setting and duration	Criteria for Inclusion/ Exclusion	N	Results/outcomes				Comments
(Ghosh, Ravindran et al. 1998) RCT Grade 1+ Country: India	<p>Education Intervention: Patient education with self-management training (Four individual 2 hour sessions during first month on asthma control and self-management using PEFR monitoring, general asthma information, symptom &amp; medication self-management) plus usual care</p> <p>V Control Group: Usual care from GP</p> <p><u>Educator</u> Social scientist with GP guidance</p> <p><u>Setting</u> Hospital outpatient clinic</p> <p>Outcome assessment over 12 months</p>	<p><u>Inclusion:</u> Age 10-45 years</p> <p>Patients with FEV<sub>1</sub> &gt;15 %PV or diurnal variation in PEFR &gt; 20%</p> <p>At least one hospital or ED visit in year prior to study</p> <p>On drug therapy for &gt;50% of days in a month</p> <p><u>Exclusion</u> Patients with chronic respiratory infection, other complicating illness, chronic smoker</p>	303	<p><u>Outcome average per patient over 12 months after baseline</u></p> <p>Mean PEFR L/min</p> <p>Productive days lost (sd)</p> <p>Hospital days (all patients)</p> <p>Percent hospitalized</p> <p>ER visits (all patients) (sd)</p> <p>Patients with ER visits</p>	<p><u>Education Intervention Group</u></p> <p>332</p> <p>17.6 (24.2)</p> <p>5.8 (10.7)</p> <p>27.1%</p> <p>11.6 (16.2)</p> <p>42.9%</p>	<p><u>Control Group</u></p> <p>290</p> <p>34.1 (38.8)</p> <p>12.5 (19.8)</p> <p>36.8%</p> <p>21.8 (25)</p> <p>50%</p>	<p><u>P value</u></p> <p>P&lt;.001</p> <p>P=.003</p> <p>P=.016</p> <p>P=.043</p> <p>P=.002</p> <p>n.s.</p>	<ul style="list-style-type: none"> <li>• Mean age N/A, female 57%, PEFR 274 L/min for education grp; mean age N/A, female 61%, PEFR 281 L/min in control grp</li> <li>• Of 303 randomised patients, 276 completed study. Withdrawals during study were 13/153 (8%) and 14/150 (9%) per group. Drop-outs not included in analysis, data for 276 patients included in analysis</li> <li>• Randomisation method not described. Adequate concealment at randomisation. GP's blinded to allocation for outcome assessment</li> </ul>

Table 3: Asthma education with patient self-management (optimal self-management) compared with usual care (continued)

Study Source, design and evidence grading	Intervention Comparison/ Educator/setting and duration	Criteria for Inclusion/ Exclusion	N	Results/outcomes	Comments																																																																																																																								
(Moudgil, Marshall et al. 2000) RCT Grade 1- Country: UK	Education Intervention: Asthma education programme (individual) with 1 x 40 minute session and 2 reinforcement sessions at 4 and 8 months (appropriate prescribing, optimal treatment, drug delivery, compliance, knowledge of symptoms and medications, PEFR monitoring, provision of diary, individualised written self-management plan, written material on asthma, triggers, management) V Control group: Usual care, baseline and end of study interviews  <u>Educator</u> Public health researcher  <u>Setting</u> General practices (12)  Evaluation of outcomes over 12 months	<u>Inclusion:</u> Age 10-45 years  Dx of asthma and registered with participating practices  <u>Exclusion:</u> Other minorities	689	<p><u>Clinical data</u></p> <table border="1"> <thead> <tr> <th><u>Number of patients (events)</u></th> <th><u>Education Intervention Group</u> Number/events</th> <th><u>Control Group</u> Number/events</th> <th><u>Pvalue</u> Number/events</th> </tr> </thead> <tbody> <tr> <td colspan="4"><u>All Patients</u></td> </tr> <tr> <td>Admissions</td> <td>10 (10)</td> <td>18 (30)</td> <td>n.s. 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(P=.02)	ED visits	8 (11)	12 (14)	n.s. (n.s.)	DDS/GP (home visits)	5 (8)	12 (19)	n.s. (n.s.)	GP consultations	127 (341)	167 (476)	P<.01 (P<.01)	Steroids	54 (92)	69 (177)	n.s. (P<.01)	Antibiotics	106 (220)	148 (340)	P<.01 (P<.01)	<u>European Patients</u>				Admissions	2 (2)	9 (19)	n.s. (P=.03)	ED visits	2 (2)	10 (12)	P=.03 (P=.01)	DDS/GP (home visits)	1 (3)	8 (14)	P=.04 (n.s.)	GP consultations	51 (123)	87 (264)	P<.01 (P<.01)	Steroids	24 (34)	40 (105)	P=.02 (P<.01)	Antibiotics	35 (57)	71 (177)	P<.01 (P<.01)	<u>Indian Subcontinent Patients</u>				Admissions	8 (8)	9 (11)	n.s. (P=.06)	ED visits	6 (9)	2 (2)	n.s. (P=.03)	DDS/GP (home visits)	4 (5)	4 (5)	n.s. (P=.04)	GP consultations	76 (218)	80 (212)	n.s. (P<.01)	Steroids	30 (58)	29 (72)	n.s. (P=.02)	Antibiotics	71 (163)	77 (163)	n.s. 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Open study, outcome assessment not blinded to allocation</li> <li>• Study aim to investigate intervention effect on separate ethnic groups. Randomisation of study patients to education and control groups. Age, sex, smokers and mean FEV<sub>1</sub> all show significant differences between ethnic groups. No demographic analysis comparing ethnic groups within education and control groups. Sub-group analysis not done according to original group allocation, reduced power of study results</li> </ul>
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Table 4: Asthma education with patient self-management compared with usual care

Study Source, design and evidence grading	Intervention Comparison/ Educator/setting and duration	Criteria for Inclusion/ Exclusion	N	Results/outcomes				Comments
(Premaratne, Sterne et al. 1999) CRCT Grade 1+ Country: UK	Education intervention practices group: Six sessions on core elements (BTS criteria) of asthma care & management of patients and assistance to practice nurses V Control practices group: Usual care  <u>Educator</u> Qualified nurse educators  <u>Setting</u> General practices (41) and community  Evaluation of outcomes at 12 months	<u>Inclusion:</u> Age 15-50 years  Registered patients of randomised general practices  Respondents to cross-sectional surveys reporting being woken with shortness of breath, or asthma attack, or treatment for asthma over previous 12 months	*see comments	<u>QoL and asthma care among respondents identified as asthmatic during baseline and post-intervention surveys</u>	<u>Education Intervention Practices Group</u>	<u>Control Practices Group</u>	<u>P value</u>	<ul style="list-style-type: none"> <li>• Mean age N/A and female % N/A in both groups. Demographic information not provided</li> <li>• *Of 24,400 patients randomly surveyed in 1993, 12,238 (50%) replied, 1,621 were asthmatic, 1,291 of whom were sent repeat survey in 1996. Of the 24,400 patients newly surveyed in 1996, 10,783 (44%) replied and 1,616 were asthmatic</li> <li>• Cluster RCT design (described) with appropriate statistical tests and adjustments to results for clustering effect. Sufficient power and validation of QoL questionnaire cited but power/sample size analysis not presented in paper</li> </ul>
				QoL Score mean sq root (95% CI)	1.46 (1.38, 1.54)	1.47 (1.41, 1.52)	n.s.	
				Difference (Educ – cntrl) in QoL (95% CI)				
				Adj for clustering by practice	-0.003 (-0.121, 0.115)		n.s.	
				Controlling for baseline QoL, age, sex, single GP practices	-0.066 (-0.14, 0.009)		n.s.	
				Restricted to individuals in same practices at baseline and post-intervention	-0.06 (-0.141, 0.015)		n.s.	
				Restricted to individuals taking asthma drugs post-intervention	-0.084 (-0.172, 0.003)		n.s.	
				<u>Explanation of appropriate action if asthma symptoms worsen</u> N/ N of patients (%)			<u>Odds Ratio</u>	
				All patients	129/293 (44)	170/445 (38)	1.25 (0.92, 1.7)	
				Patients taking asthma medication	120/189 (64)	146/277 (53)	1.41 (0.85, 2.3)	



Table 5: Asthma education with patient self-management with peak-flow monitoring compared to symptom monitoring

Study source, design and evidence grading	Intervention Comparison/ Educator/setting and duration	Criteria for Inclusion/ Exclusion	N	Results/outcomes				Comments
(Lopez-Vina and del Castillo-Arevalo 2000)  RCT  Grade 1-  Country: Spain	Peak Flow Monitoring (PFM) group: (individual asthma education with general information, symptom & medication self-management, adherence-enhancing strategies), pamphlets, PEFR diary cards, individualised action plan on card V  Symptom self-management group: (individual asthma education with general information, symptom & medication self-management, adherence-enhancing strategies), individualised action plan based on symptoms only  <u>Educator</u> Qualified nurse educators  <u>Setting</u> ED clinic  Outcome assessment at 12 months	<u>Inclusion:</u> Age 17-65 years  Dx of asthma (ATS criteria) with episodic wheezing, cough, shortness of breath  Reversibility of FEV <sub>1</sub> > 20% after (0.2mg) salbutamol or FEV <sub>1</sub> PC <sub>20</sub>  <u>Exclusion</u> Concurrent chronic disease (COPD etc.)	150	<u>Outcomes % of patients</u>	<u>Peak-flow monitoring group</u>	<u>Symptom monitoring Group</u>	<u>Pvalue</u>	<ul style="list-style-type: none"> <li>• Mean age N/A, female 46% for PFM grp; mean age N/A, female 57% in symptom grp</li> <li>• Of 150 randomised patients, 50/150 (33%) not evaluated due to non-completion of follow-up period. All demographics, analysis and results presented only for n=100, with 56 patients in PFM group and 44 in symptom group. No ITT analysis and low study power. Likely selection bias</li> <li>• Authors state no significant demographic differences between intervention groups in patients who completed 12 month follow-up and those who did not</li> <li>• Randomisation method not described. Unclear if adequate concealment or blinding for outcome assessment</li> </ul>
				Mean FEV <sub>1</sub> %PV Baseline 12 months	75.1 80.9	79.5 80.8	n.s.	
				Asthma attacks (%) Baseline 12 months	94.6 21.4	84 11.3	n.s.	
				Mean FVC %PV Baseline 12 months	93 99.5	92 94.3	P=.03	
				Days with symptoms (%) Baseline 12 months	73.2 12.5	70.4 13.6	n.s.	
				ED visits (%) Baseline 12 months	89.2 5.3	79.5 0	n.s.	
				Absenteeism work/school (%) Baseline 12 months	33.9 3.5	40.9 0	n.s.	
				Adherence to treatment Baseline 12 months	44.6 83.4	29.6 52.2	P=.05	

Table 6: Asthma education with patient self-management (self-monitoring only) compared with usual care

Study Source, design and evidence grading	Intervention Comparison/ Educator/setting and duration	Criteria for Inclusion/ Exclusion	N	Results/outcomes	Comments																																								
(Opat, Cohen et al. 2000) RCT Grade 1+ Country: Australia	<p>Education intervention: A 67 minute video "Buteyko Breathing Method" (Buteyko Pty Ltd, Brisbane, Australia) with explanation of theory &amp; method, manual provided. View 20 minute self-directed session on method twice per day for 1 month V</p> <p>Control (placebo) group: A 60 minute video "Nature's Landscapes" (ABC Video, Melbourne, Australia) with natural images/music. View 20 minute portion twice per day for 1 month</p> <p><u>Educator</u> Video presenter and public health researchers</p> <p><u>Setting</u> Hospital outpatient clinic</p> <p>Evaluation of outcomes at 1 month</p>	<p><u>Inclusion:</u> Age 18-50 years</p> <p>Dx of asthma</p> <p><u>Exclusion:</u> Subjects using OCS &gt;1600 µg/d</p> <p>Less than 3 doses from bronchodilator per week</p> <p>Severe asthma exacerbation within 6 weeks of study run-in</p>	36	<p><u>QoL Questionnaire</u> <u>Mean QoL score (95% CI)</u></p> <table border="1"> <thead> <tr> <th></th> <th><u>Education Intervention Group</u></th> <th><u>Control Group</u></th> <th><u>P value</u></th> </tr> </thead> <tbody> <tr> <td><u>Between group difference (Educ - cntrl) before and after treatment</u></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Overall</td> <td>-1.29 (-2.53, -0.05)</td> <td></td> <td>P=.04</td> </tr> <tr> <td>Breathlessness</td> <td>-1.53 (-3.06, 0.00)</td> <td></td> <td>P=.05</td> </tr> <tr> <td>Mood disturbance</td> <td>-1.59 (-3.04, -0.15)</td> <td></td> <td>P=.03</td> </tr> <tr> <td>Social disruption</td> <td>-1.16 (-2.54, 0.22)</td> <td></td> <td>P=.01</td> </tr> <tr> <td>Concern for health</td> <td>-0.87 (-2.18, 0.44)</td> <td></td> <td>n.s.</td> </tr> </tbody> </table> <p><u>Clinical data</u> <u>Between group diff (Educ - Cntrl) before and after treatment</u></p> <table border="1"> <thead> <tr> <th></th> <th><u>Education Intervention Group</u></th> <th><u>Control Group</u></th> <th><u>P value</u></th> </tr> </thead> <tbody> <tr> <td>PEFR (L/min)</td> <td>16.7</td> <td></td> <td>n.s.</td> </tr> <tr> <td>Inhaled steroid intake (µg/d)</td> <td>84</td> <td></td> <td>n.s.</td> </tr> </tbody> </table>		<u>Education Intervention Group</u>	<u>Control Group</u>	<u>P value</u>	<u>Between group difference (Educ - cntrl) before and after treatment</u>				Overall	-1.29 (-2.53, -0.05)		P=.04	Breathlessness	-1.53 (-3.06, 0.00)		P=.05	Mood disturbance	-1.59 (-3.04, -0.15)		P=.03	Social disruption	-1.16 (-2.54, 0.22)		P=.01	Concern for health	-0.87 (-2.18, 0.44)		n.s.		<u>Education Intervention Group</u>	<u>Control Group</u>	<u>P value</u>	PEFR (L/min)	16.7		n.s.	Inhaled steroid intake (µg/d)	84		n.s.	<ul style="list-style-type: none"> <li>• Mean age 32, female 50%, PEFR (L/min) 406 in education grp; mean age 33, female 67%, PEFR (L/min) 390 in control grp</li> <li>• Study recruitment through media advertisements, possible selection bias</li> <li>• Of 36 randomised patients, clinical data and analysis available for 28 (78%) patients and QoL data and analysis for 32 (89%) patients. Study power issue addressed. Drop-outs not included in analysis. Losses accounted for</li> <li>• Randomisation method described as using computer generated list. Unclear if concealment adequate. Single blinded study, where patients blinded and investigators not blinded to allocation for outcome assessment</li> </ul>
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# Appendix 1

## SEARCH STRATEGIES FOR ASTHMA EDUCATION AND PATIENT SELF-MANAGEMENT

---

- 1 exp asthma/ (55096)
- 2 self-care/ (7934)
- 3 patient education/ (29979)
- 4 (self manage: or self care).mp. (10281)
- 5 (action plan or action plans).mp. (515)
- 6 or/2-5 (38391)
- 7 1 and 6 (1438)
- 8 limit 7 to adult (522)
- 9 limit 8 to yr=1998-2001 (167)
- 10 from 9 keep (SELECTED REFERENCES)(82)
- 11 from 10 keep 1-82 (82)
- 12 from 11 keep 1-82 (82)
- 13 randomized controlled trials/ or controlled clinical trials/ (19676)
- 14 (randomized controlled trial or controlled clinical trial).pt. (200808)
- 15 meta-analysis.pt. or meta-analysis/ (8319)
- 16 practice guidelines/ (12066)
- 17 guideline.pt. (8582)
- 18 ((systematic: adj3 review:) or (systematic: adj3 overview)).mp. (2735)
- 19 or/13-18 (244114)
- 20 7 and 19 (253)
- 21 limit 20 to yr=1998-2001 (107)
- 22 (child: or pediatr: or paediatr:).ti. (316038)
- 23 adult:.ti. (89240)
- 24 22 not 23 (309869)
- 25 21 not 24 (85)
- 26 from 25 keep 1-85 (85)
- 27 12 not 26 (48)
- 28 from 27 keep 1-48 (48)
- 29 self monitor:.mp. (1400)
- 30 1 and 29 (41)
- 31 28 or 26 (133)
- 32 30 not 31 (36)
- 33 limit 32 to yr=1998-2001 (9)

### ***Embase***

- 1 exp ASTHMA/ (36940)
  - 2 Self Care/ (1861)
  - 3 Patient Education/ (9633)
  - 4 health education/ (9662)
  - 5 self management.mp. (833)
  - 6 (self care or self manage:).mp. (2207)
  - 7 (action plan: or action plans).mp. (502)
  - 8 or/2-7 (21868)
  - 9 1 and 8 (1201)
-

10 limit 9 to yr=1998-2001 (510)  
11 (child: or pediatr: or paediatr:).ti. (125250)  
12 (child: or pediatr: or paediatr:).jw. (125046)  
13 11 or 12 (210389)  
14 10 not 13 (420)  
15 randomized controlled trial/ (53790)  
16 exp Clinical Trial/ (203397)  
17 randomization/ (2899)  
18 Meta Analysis/ (11512)  
19 practice guideline/ (24149)  
20 ((systematic adj3 review:) or (systematic: adj3 overview)).mp. (2164)  
21 or/15-20 (230390)  
22 14 and 21 (115)  
23 from 22 keep 1-115 (115)  
24 (child: or pediatr: or paediatr:).ti. (125250)  
25 adult:.ti. (45154)  
26 24 not 25 (121853)  
27 14 not 26 (420)  
28 27 not 22 (305)  
29 letter/ (208897)  
30 28 not 29 (298)  
31 from 30 keep (SELECTED REFERENCES)(92)  
32 selfmonitor:.mp. (11)  
33 self monitor:.mp. (910)  
34 1 and 33 (36)  
35 limit 34 to yr=1998-2001 (14)  
36 from 35 keep 4-5,13 (3)  
37 31 or 36 (93)  
38 37 not 23 (92)  
39 (cluster: or random:).mp. (198069)  
40 10 and 39 (61)  
41 37 or 23 (207)  
42 40 not 41 (18)  
43 37 (93)

### ***Current Contents***

1 asthma.mp. (23736)  
2 (self care or self manage: or self monitor:).mp. (3138)  
3 1 and 2 (386)  
4 limit 3 to yr=1998-2001 (201)  
5 (child: or pediatr: or paediatr:).ti. (100596)  
6 adult:.mp. (178783)  
7 5 not 6 (88943)  
8 4 not 7 (165)  
9 from 8 keep (SELECTED REFERENCES)(60)  
10 from 8 keep 153,155,158-159,162,164 (6)  
11 9 or 10 (60)  
12 (action plan: or action plans:).mp. (831)  
13 1 and 12 (59)  
14 13 not 8 (47)  
15 limit 14 to yr=1998-2001 (14)  
16 from 15 keep 5,9 (2)  
17 education.mp. (66580)

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- 18 1 and 17 (854)
- 19 limit 18 to yr=1998-2001 (470)
- 20 19 not 5 (354)
- 21 20 not 8 (251)
- 22 letter.pt. (338172)
- 23 21 not 22 (246)
- 24 from 23 keep (SELECTED REFERENCES)(8)
- 25 11 or 16 or 24 (69)

### ***Cinahl***

- 1 exp ASTHMA/ (3870)
- 2 self care/ or self administration/ or self medication/ (4227)
- 3 (self manage: or self monitor: or action plan: or action plans:).mp. (948)
- 4 2 or 3 (4847)
- 5 1 and 4 (288)
- 6 limit 5 to yr=1998-2001 (94)
- 7 (child: or pediatr: or paediatr:).ti. (27627)
- 8 adult.mp. (70606)
- 9 7 not 8 (24771)
- 10 6 not 9 (74)
- 11 from 10 keep (SELECTED REFERENCES)(11)

### ***Premedline***

- 1 asthma.mp. (800)
- 2 educat:.mp. (2511)
- 3 (self care or self manage: or self monitor:).mp. (125)
- 4 2 or 3 (2605)
- 5 1 and 4 (38)
- 6 from 5 keep (SELECTED REFERENCES)

### ***Psychinfo***

- 1 exp ASTHMA/ (1368)
  - 2 self care/ or self administration/ or self medication/ (1947)
  - 3 (self manage: or self monitor: or action plan: or action plans:).mp. (5906)
  - 4 2 or 3 (7781)
  - 5 1 and 4 (152)
  - 6 limit 5 to yr=1998-2001 (48)
  - 7 (child: or pediatr: or paediatr:).ti. (116845)
  - 8 adult.mp. (74235)
  - 9 7 not 8 (109003)
  - 10 6 not 9 (37)
  - 11 exp Self Management/ or exp Self Care Skills/ (3532)
  - 12 1 and 11 (104)
  - 13 limit 12 to yr=1998-2001 (33)
  - 14 13 not 9 (25)
  - 15 10 or 14 (37)
  - 16 from 15 keep (SELECTED REFERENCES)
-

### ***Other databases***

Other databases and sources for which indexing was not available were searched using combinations of keywords from the above strategies, particularly

Asthma AND self monitor\* OR self care OR educat\* OR self manage\* OR action plan(s)

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# Appendix 2

## EVIDENCE GRADING FORMATS

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### ***Intervention***

- Education type, frequency and duration of sessions, description of programme, educator, setting and length of time to outcome assessment

### ***Control***

- In most cases this is usual care with follow-up by medical practitioner

### ***Criteria for inclusion and exclusion***

#### Inclusion

- Age range
- FEV<sub>1</sub> as a % of predictive value if available or change in FEV<sub>1</sub> as a percent change due to exercise challenge or ICS or other medication challenge where FEV<sub>1</sub> %PV not available.
- Description of asthma parameters provided in study if lung function data not available

#### Exclusion

- Prior recent emergency care
- Other relevant and important morbidity

### ***Results/outcomes***

- Generally these will relate to patient morbidity and quality of life
- The education intervention category in the left column is compared to control group column. *P*-values relate to between group difference, the probability that the observed difference could have been obtained by chance alone given random variation

### ***Comments***

- Specifics regarding population demographics e.g. mean age, sex distribution, and ethnicity, mean FEV<sub>1</sub> %PV
  - Study population participation, generalisability, description and comment on randomisation method, concealment, blinding to outcome assessment
  - Other important methodological issues which might undermine study validity
-

# Appendix 3

## **METHODOLOGY CHECKLIST 1: RANDOMISED CONTROLLED TRIALS**

Study identification <i>Include author, title, reference, year of publication</i>		
Checklist completed by:		
<b>SECTION 1: INTERNAL VALIDITY</b>		
<i>Evaluation criterion</i>		<i>How well is this criterion addressed?</i>
1.1	Does the study address an appropriate and clearly focused question?	
1.2	Was the assignment of subjects to treatment groups randomised?	
1.3	Were the treatment and control groups similar at the start of the trial?	
1.4	Was an adequate concealment method used?	
1.5	Were subjects and investigators kept 'blind' about treatment allocation?	
1.6	Are all relevant outcomes measured in a standard, valid and reliable way?	
1.7	Apart from the treatment under investigation, were the groups treated equally?	
1.8	What percentage of the individuals or clusters recruited into the study are included in the analysis? Statistical power adequacy	
1.9	Were all the subjects analysed in the groups to which they were randomly allocated?	

<b>SECTION 2: OVERALL ASSESSMENT OF THE STUDY</b>		
2.1	How well was the study done to minimise bias? <i>Code ++, +, or -</i>	
2.2	If coded as +, or – what is the likely direction in which bias might affect the study results?	
<i>If the study reports an evaluation or comparison of diagnostic tests, please complete a diagnostic studies checklist before completing the next section.</i>		
<b>SECTION 3: DESCRIPTION OF THE STUDY</b>		
3.1	How many patients participated in the study? <i>Overall number, and in each arm of the study.</i>	
3.2	What was the scale and direction of the measured effect?	
3.3	What are the characteristics of the study population? <i>e.g. age, sex, disease characteristics of the population, disease prevalence.</i>	
3.4	Are there any specific issues raised by this study? Make any general comments on the study results and their implications	