Supplementary Material C

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Year and author: Powell and Gibson (2009) **Country:** Australia **Study type:** Systematic review **Evidence level:** I	**Aims:** To evaluate comparative effectiveness of different components of asthma self-management education interventions **Participants:** Predominantly adults over 16 years of age with asthma according to doctors dx or American Thoracic Society guidelines Studies recruited from various settings – approximately half in hospital settings and half outpatient settings **Search period:** Review first published 2002. Included studies published 1990-2001. **Search method:** Cochrane Airways Group Trial Register Reference lists of	**Inclusion:** Randomised trials of asthma interventions which compared two or more interventions of asthma self-management and education **Exclusion:** Non-RCT or CCT Paediatric age range Doctor education	**Exposure:** - Asthma optimised by inhaled cortiocosteroid use by regular medical review compared with individualised action plans - written SM plans based on peak expiratory flow self-monitoring compared with symptom self-monitoring - compared different options for delivery of SME **Comparison:** For all trials optimal self-management that included information, self-monitoring, regular medical review and a written action plan were compared to variations of optimal self-management **Outcome measures:** Hospital admissions ER visits, unscheduled doctor visits Days lost from work/school Lung Function (FEV1) Peak expiratory flow (PEF) Use of rescue beta-agonists Courses of oral corticosteroids Symptom scores	**Results:** N=15 included trials (n=19 publications) N= 2460 participants Drop out 0-60.3% Optimal self-management of medication using written action plan versus adjustment of medication by regular review (N=6 studies) Hospital admissions – no difference Emergency Room visits, unscheduled doctor visits - no significant differences Days lost from work/school – two studies no sig difference; one study in favour of Lung Function (FEV1) Meta-analysis favoured self-management although not significant (SMD 0.10, 95% CI 0.05 – 0.25) Peak expiratory flow (PEF) meta-analysis in favour of self-management (SMD 0.16, 95% CI 0.01- 0.31) Symptom scores – no sig	**Author's conclusions:** Adjustment of medication by either self-management using a written action plan or adjustment by a doctor are equally effective. Adults with asthma can be offered regular medical review or a self-management programme. Self-management using PEF self-monitoring or symptom self-monitoring are equally effective and either can be used. There was no difference between verbal and written action plans. The inclusion of regular review improved outcomes and reduced intensity of education seemed to dilute the effect. Each of these findings comes from single studies and requires further investigation. **Reviewer's conclusions:** Variability in age, setting and types of interventions used between studies made it difficult for reviewers to compare effectiveness. High degree of heterogeneity between studies where meta-analysis was possible. Heterogeneity prevented completion of meta-analysis for most outcomes.

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	articles **Selection of studies:** Two independent reviewers selected and assessed quality of included studies Jadad scores used to assess quality: range 3-5 allocation concealment unclear to adequate No studies double-blind		QoL scores **Follow-up time:** Duration of initial intervention not stated in some studies. Follow-up was not stated for many of the included studies but where stated ranged from 6 months – 5 years.	differences Self-monitoring based on peak expiratory flow v symptom self-monitoring (N=6 studies) Hospital admissions – no significant difference Emergency Room visits – no difference (4 studies); significant reduction using PEF self-management (1 study) Unscheduled doctor visits – no significant difference (5 studies) Courses of oral corticosteriods – sig reduction in number of patients requiring them in 1 study Optimal self-management versus modified optimal self-management (N=3 studies) Optimal self-management versus control group: Higher number of health centre visits and sickness days for control group. Significant improvement in mean percent predicted FEV1 for group receiving regular review. No difference in mean percent predicted PEF or QoL Intensity of asthma education: Reduced intensity led to	Small number of studies for each comparison. Drop out rates high for some studies (up to 60%) with large variability (0.5 – 60.3) **Source of funding:** Cochrane Editorial Unit, UK Cooperative Research Centre for Asthma, Australia **Additional comments:**

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				significantly increased proportion of people making unscheduled doctor visits No difference in QoL scores Better symptom scores for higher intensity education Verbal versus written action plan: No difference in asthma admissions, Emergency Room visits, home visits or PEF variability	
Internal validity:	? Searches except for search dates reported, assessment of study quality performed, no assessment of publication bias.				
Study results – precision:	X Wide heterogeneity in interventions, settings and short-comings in quality of included studies precluded meaningful analysis for many outcomes. Meta-analysis not possible for most outcomes				
Applicability (external validity):	+ Lack of reporting for some study outcomes and follow-up time.				
Overall score:	? Wide heterogeneity in interventions and settings restricted the analyses and conclusions of this review. Included studies were of relatively low quality overall with deficits in methodological reporting, recruitment and dropout rates.				

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Year and author: Shaw, 2006 **Country:** Australia **Study type:** Systematic review **Evidence level:** I	**Aims:** Examine the effectiveness of chronic disease self management for people with asthma, diabetes and coronary heart disease. **Participants:** Adults > 18 years with diabetes, asthma, coronary heart disease and then generic intervention **Search period:** 1994 - 2006 **Search method:** Limited to English language AustHealth Medline, PsycINFO, CINAHL, EMBASE, CENTRAL, Cochrane library, Expert centres, reference lists Search string provided	**Inclusion:** Type of study not specified but included adults, published after 1994, With a control group, in English language, meeting pre-determined quality criteria **Exclusion:** Not relevant to question Not a primary study Univariate analysis only Insufficient data reported to asses quality Quality was weak in four or more pre-determined criteria Absence of specified outcomes	**Exposure:** Intervention had to contain a minimum of two of the following: Problem solving Behavioural support Managing emotions Self monitoring/treatment action plans **Comparison:** Usual care or limited education **Outcome measures:** Quality of life Self efficacy Health service use Physical activity Clinical measures Cost effectiveness **Follow-up time:** 2 weeks to 2 years	**Results:** 21 studies, 8 studies were group, 13 were individual (of which 5 contained ≥ 1 group session). Recruited from clinics, emergency departments, or primary care, apart from 2 which were self selected through advertising. Mean age 44 years, 62% female and one trial included COPD patients. Physical activity – no studies assessed participation. One trial included exercise sessions as a component of the intervention. The intervention programmes made a clinically significant improvement (>50m) in the 6 minute walk test at 6 months and further improvement at 12 months. There were no differences in the control group and between group differences were not presented. Quality of Life – 8/17 studies demonstrated an improvement in QoL with 5/8 showing sustained benefit at ≥ 12 months. Four studies reported a clinically significant improvement, one of which was	**Author's conclusions:** Self management programmes were at least as effective as usual care or minimal education. Those with an action plan were more likely to show benefit than those without. Those with individual sessions were more likely to show benefit than group-only sessions **Reviewer's conclusions:** Well conducted SR which lacked MA due to heterogeneity which makes applicability questionable. There was high attrition in 6/21 studies **Source of funding:** International diabetes institute **Additional comments:**

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				in the control group. Self efficacy – 3/21 reported on this. Self efficacy improved in both groups in two of the studies and one showed improvement in the intervention group. Health service utilisation – This was measured through scheduled and unscheduled visits, emergency department and hospital attendance and hospitalisation. Reported in 15/21 trials. 7/15 showed a benefit of decreased health service utilisation for self management interventions Clinical outcomes – Self reported symptoms, frequency of attacks and lung function. Reported in 20/21 studies. 9/20 showed a benefit (clinical) for intervention. Treatment action plans – 14/21 trials used a treatment action plan. More studies with an action plan showed benefit for QoL, health service use and lung function. There was no difference for treatment compliance. For lung function	

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				studies with a treatment action plan participants were four times more likely to show a benefit compared with studies with no action plan.	
Internal validity:	+				
Study results – precision:	NA				
Applicability (external validity):	?				
Overall score:	?				

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Year and author: Smith et al (2007) **Country:** United Kingdom **Study type:** Systematic review **Evidence level:** I	**Aims:** To examine whether psycho-educational interventions improve outcomes for adults with severe or difficult asthma To identify options for best practice **Participants:** **Search period:** To Dec 2005 **Search method:** Databases and research registers including grey lit and non-English language databases Reference lists Conference abstracts Past issues of key journals	**Inclusion:** RCTs or CCTs Evaluated an educational, self-management, psychological/psychosocial or multi-faceted programme deemed to be psycho-educational Targetted a subgroup of patients with one or more indicators of severe or difficult asthma Included a control group receiving usual care or a placebo (didactic only) intervention Over 50% of the sample were adults Published in English **Exclusion:** Excluded studies where high risk patients were defined solely on the basis of geographical location or attendance at ED on a single occasion because these were assumed only to include a minority of relevant patients	**Exposure:** Educational, self-management, psychological/psychosocial or multi-faceted programme deemed to be psycho-educational **Comparison:** Usual care or a placebo programme which involved didactic exchange of information only **Outcome measures:** Health care utilisation – hospital admissions, ED attendance Health status/QoL Symptom status Psychological morbidity Self-management behaviours Medication Knowledge Scheduled health care attendances Respiratory function Time lost from work **Follow-up time:** Range 3 months to 3 years Median 12 months	**Results:** N=17 included studies N=13 RCTs N=3 educational, n= 4 self-management, n=3 psychosocial and n=7 multifaceted intervention programmes Admission/Readmission N=10 RCTs and n=2 COSs Conflicting findings RR = 0.79 (95% CI 0.55 to 1.14, p=0.21) OR = 0.70 (95% CI 0.49 to 0.99, p=0.04) ED attendance N= 9 studies with conflicting findings. Pooled estimate from 4 studies RR=1.03 (95% CI 0.82 to 1.29, p=0.8) Health status/Quality of Life N=6 studies showing mainly non-significant effects. Pooled estimate from 4 studies reporting asthma-specific QoL SMD=0.45 (-0.07 – 0.98, p=0.09) Psychological morbidity	**Author's conclusions:** Overall no consistent clear evidence of the effectiveness of psycho-educational programmes on a range of outcomes for adults with severe or difficult asthma. For adults with severe asthma or a single risk factor associated with difficult asthma, there is some evidence that psycho-educational programmes may improve self-management behaviours, hospital admissions and some health outcomes in the short term. These findings do not extend to the most at-risk patients with multiple risk factors or complications. **Reviewer's conclusions:** Range of participants who agreed to take part ranged from 41- 100%. Small sample size in many studies and a mixture of RCTs and controlled trials, although RCT findings were reported separately. RCTs were of mixed quality with a lack of reporting in some aspects of study design making it difficult for the authors to accurately assess quality. Wide confidence intervals for some analyses. High quality review with information regarding the theoretical framework

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				N=6 studies with mainly non-significant effects Pooled estimate from 5 studies not significant <u>Medication use</u> n=3 studies, mainly positive effects	and structure of the intervention provided. **Source of funding:** UK Department of Health, Health Technology Assessment Programme **Additional comments:** Psycho-educational approach which was defined as the following: (a) involved *interaction* (i.e., more than just didactic transfer of information) between a *patient* and intervention provider; and (b) involved taking an *educational, cognitive, behavioural, and/or social approach* to improving outcomes in asthma; and/or (c) addressed *educational*, *cognitive*, *behavioural*, *or social issues affecting asthma* or its management; and/or (d) addressed *educational*, *cognitive*, *behavioral or social issues resulting from the consequences of asthma*.
Internal validity:	+ Good descriptions of included patients groups, interventions and measures. Able to assess included studies for quality				
Study results – precision:	? Wide CIs because of small sample sizes in some studies, small numbers of studies for some analyses and heterogeneity in intervention types made it difficult for the authors to come to many firm conclusions. Most effects limited to short to medium term.				
Applicability (external validity):	+ The authors attempted to restrict programmes to those with a psychoeducational, interactive framework and patients to those with severe or difficult asthma				
Overall score:	+ Overall the review aimed high and made a good case for including only patients with severe or difficult asthma, described the characteristics of included studies very well and limited studies to those using psychoeducation interventions, but was let down by the variable quality of included studies, the small sample sizes and the heterogeneity of interventions.				

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Year and author: Tapp, Lasserson and Rowe (2010) **Country:** Canada **Study type:** Systematic review **Evidence level:** I	**Aims:** To assess the effectiveness of educational interventions following an acute exacerbation of asthma leading to presentation in emergency dept. To assess which components of educational interventions are effective **Participants:** Adults > 17 years who presented at emergency department with acute asthma exacerbation defined by doctor or objective criteria **Search period:** Up to Nov 2009 **Search method:** Cochrane Airways Group Trials Register Reference lists Primary authors contacted Studies selected and	**Inclusion:** RCTs Participants >17 years recruited following ED attendance and received an asthma education intervention Studies with some participants <17 years were included and sensitivity analyses were performed Translations attempted for articles in languages other than English **Exclusion:** Not an RCT Participants not >17 years Not recruited following ED attendance Intervention is not asthma education	**Exposure:** Any individual or group educational intervention targeted adults delivered to the patient within 1 week of ED presentation. Intervention may include information, counselling, a change in therapy, the use of home peak flow or sx monitoring or written action plan. Intervention could be delivered by nurse, pharmacist, educator, health or medical practitioner. **Comparison:** Usual care **Outcome measures:** Hospital admissions Re-presentation at ED Doctor visits Lung Function: FEV1; PEF rate Use of rescue medications QoL, functional health status Study withdrawal Days home sick Economic costs **Follow-up time:** 6-18 months Mean = 7.4 months	**Results:** N=13 studies N=2157 participants, majority of participants were female Interventions: Each programme contained some combination of interventions which were classified into the following groups: - written self-management plans - education on symptoms and control - information booklet or card - teaching of use of medication and inhalers (including peak flow meters) - emphasizing importance of follow-up Most sessions conducted by ED nurses (n=11 studies). Education versus Usual Care Hospital admission/readmission RR = 0.5 (95% CI 0.27 – 0.91) NNT = 9 (95% CI 6 – 27)	**Author's conclusions:** Educational interventions given at the time of or after an Emergency Department (ED) presentation to adults with acute asthma can decrease the risk of hospital admissions, improve scheduled appointment attendance and reduce costs. There was no effect on decreasing the number of ED visits, improving PEF control, reduction of days of work, increasing quality of life or decreasing number of participants experiencing symptoms. **Reviewer's conclusions:** Lack of information about the theoretical background to interventions. Wide range of type of interventions with most studies involving a combination of different types of intervention. Authors unable to ascertain which components were effective. Moderate to high heterogeneity for some outcomes. Small number of studies for some analyses – only 1-2 studies for many secondary analyses. Baseline variables – prior asthma knowledge/education, SES etc not reported in many of the studies. Limited follow up for some studies so

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	assessed by two independent reviewers			Presentation at ED: RR = 0.66 (95% CI 0.41 – 1.07) Lung Function – no sig difference Quality of life – no sig difference Days lost from work/school – no sig difference Cost – two studies showed significantly lower ED costs for patients who received education interventions	difficult to be certain of long term effects of education interventions. **Source of funding:** Cochrane Editorial Unit, UK One author's research was supported by a 21st Century Canada Research Chair (Govt of Canada) **Additional comments:**
Internal validity:	+				
Study results – precision:	?				
Applicability (external validity):	?				
Overall score:	? Lack of information about the theoretical background to interventions. Wide range of type of interventions with most studies involving a combination of different types of intervention. Authors unable to ascertain which components were effective.				

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Abdelhamid (2008) **Country:** Sudan **Study type:** RCT **Evidence level:** II	**Aims:** To evaluate the effectiveness of a pharmacy-based asthma self-management intervention in adults with asthma.	**Study setting:** Hospital-based pharmacy service **Participant characteristics:** N=100 adults recruited from ED or hospital clinic **Inclusion:** Previous diagnosis of asthma confirmed by the physicians in attendance at recruitment stage Residence in Khartoum state Age 20-60 years **Exclusion:** Pregnant patients Other respiratory conditions e.g. COPD; emphysema Tuberculosis Mental disturbances Listening or speaking problems	**Exposure: n=60** Pharmacist-led education every 2 weeks for 22 weeks. Included information on non-drug therapy measures; pharmacotherapy, self-management and inhalation technique. Education was individually tailored according to the problems identified for each person in the intervention group and delivered with the help of attending physicians. Drug therapy adjusted according to British Thoracic Society guidelines **Comparison: n=40** Traditional medical consultation and dispensing services **Outcome measures:** Frequency of acute attacks/week Frequency of nocturnal sx/week Frequency of using short acting inhaled beta2-agonist/week Days of sickness/week Rate of hospitalisation Inhaler technique (rated out of 10) Patient knowledge **Follow-up time:** Follow-up every 2 weeks for 22 weeks.	**Results:** Intervention n=60 N=12 drop outs/withdrawals Control n=40 N=10 drop outs/withdrawals Significant reduction in the intervention group of: Frequency of acute attacks/week Intervention Control Baseline 2.1 (SD 1.7) 1.4 (SD 1.2) Week 22 -1.9 (0.18) -1.0 (SD 0.14) Frequency of using inhaled beta2-agonist/week from 6th week on Intervention Control Baseline 26.8 (2.4) 19.1 (2.1) Week 22 -19.9 (2.1) -3.3 (0.3) Decreased rate of hospitalisation (actual rates for each group not reported) No significant difference in PEF rate Significant increase in the	**Author's conclusions:** Lack of adherence to guidelines. The rate of implementation of the pharmacists recommendations by physicians was high. Supports the benefit of collaboration between physician, pharmacist and patient to optimise drug therapy and enhance counselling and monitoring of patients to improve outcomes. **Reviewer's conclusions:** Small sample with ~20% of the sample not completing the intervention. No mention of ITT analyses. Prognostic characteristics of dropouts vs non-dropouts was not reported but 50% of control vs 76% of intervention patients had a dx of asthma for more than 10 years. Some improvements in the control group as well, the authors recognised that simply attending an evaluation every fortnight may be a type of education intervention. No longer term follow up findings. Self-report used for many measures. Allocation method used for randomisation unclear ('simple random sampling'), blinding or allocation concealment not reported.

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				intervention group of: Asthma knowledge Asthma drug therapy knowledge from 10th to 22nd weeks Inhaler technique Intervention Control Baseline 4.6 (0.4) 6.2 (0.5) Week 22 +4.9 (0.5) +1.06 (0.18)	**Source of funding:** Deutscher Akademischer Autausch Dienst (DAAD) No conflict of interest declared **Additional comments:** Problem-solving approach

Bias	Judgement	Support for judgement
Random sequence generation	Unclear risk	No details
Allocation concealment	Unclear risk	No details
Blinding	Unclear risk	No details
Incomplete outcome data	Unclear risk	ITT analysis not reported
Selective reporting	Unclear risk	Unclear from tables whether all data was reported for some measures

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Clark 2007; Clark 2010 **Country:** USA **Study type:** RCT **Evidence level:** II	**Aims:** To determine whether there were longer-term effects on the asthma status and quality of life (QoL) of the participants of a disease management programme.	**Study setting:** Single centre **Participant characteristics:** N=808 Mean age 48.45, primarily white, 30.4% had a high school education or less. **Inclusion:** ≥18 yrs, clinical diagnosis of active asthma symptoms in previous 12 months, enrolled as a patient in a participating clinic, no extenuating medical or mental conditions, not pregnant and access to a telephone **Exclusion:** -	**Exposure: n= 424 Intervention management programme** 'Women Breathe Free' delivered by nurse health educator through telephone counseling using a problem solving approach for self regulation. Each woman selected a problem solving focus on the clinical recommendations of the physician and an educational kit was sent to her home. **Comparison: n=384 usual care** Treatment based on National Asthma Education and Prevention Program (NAEPP) guidelines for diagnosis and treatment of asthma plus telephone follow-up for monitoring and general asthma education **Outcome measures:** Symptoms, medication adherence, health service utilisation, sex and gender related items, Mini Asthma Quality of Life Questionnaire, self regulation through peak flow monitoring, demographic data **Follow-up time:** 24 months	**Results:** There was a significant difference in scheduled office visits in favour of the intervention group There were no differences in other health care utilisation between groups There were no differences in day time symptoms between groups. The only differences in night time symptoms were in the autumn with greater reductions in the intervention group (P≤ 0.05) Intervention group had significantly improved quality of life at follow-up (estimated regression coefficient -0.17, P =0.02), self regulation (0.32, P = 0.01) and self confidence to manage asthma (0.35, P = 0.01) Women in the intervention group reported significantly greater increase in peak flow meter use to monitor the most recent asthma attack than controls (estimated regression coefficient 0.44, P = 0.03) In the long term follow up at 24 months there was evidence of a	**Author's conclusions:** An asthma management programme with a female focus may result in improved QoL and health status for women with asthma **Reviewer's conclusions:** Only included women. Attrition rate 28 % from baseline. Major methodological flaws in design. Long term follow-up found persisting benefits for these women **Source of funding:** NIH **Additional comments:** Problem solving approach

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				significant reduction in the use of short acting bronchodilators compared with controls (rescue medication) estimated regression coefficient -0.59, P ≤ 0.05	

Bias	Judgement	Support for judgement
Random sequence generation	High risk	Groups of 4 participants ID numbers used where first or last IDs were directly assigned to intervention or control and remaining two assigned by coin toss.
Allocation concealment	Low risk	Assigned by data analyst to intervention or control, based on ID number
Blinding	Low risk	Physicians measuring clinical outcomes blind to group assignment. Telephone interviewers also unaware of group assignment. Not specified whether participants were blind to group assignment.
Incomplete outcome data	Low risk	28% attrition from baseline. ITT analyses, modelling used to account for 'missing at random' data
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Janson 2009 **Country:** USA **Study type:** RCT **Evidence level:** II	**Aims:** Evaluate self management education on corticosteroid use in asthma control	**Study setting:** Community clinics in San Fransisco Bay area **Participant characteristics:** Mean age 38.25±9.35 years, 53% female, 64.5% White, average 16 years education. **Inclusion:** N= 280 recruited 95 randomised (11 withdrew during run in phase) Adults 18-55 years with moderate to sever persistent asthma, non-smokers with 5 or less pack-years of smoking history, spirometric evidence of reversible airflow obstruction or bronchial reactivity to inhaled methacholine. **Exclusion:** Receiving systemic steroids within a month of enrollment, URTI within 6 weeks of enrollment, pregnancy, cardiac or GI, psychiatric, or other lung disease, prior participation	4 week run in **Exposure: n= 45** 4 week intervention with bi-weekly visits to clinic Administered in 3 identical 30 minute visits **Comparison: n= 39** Usual care **Outcome measures:** morning peak flow, daily symptoms, night time wakenings, medication useage, quality of life, perceived control of asthma, personal evaluation, spirometry **Follow-up time:** 6 months	**Results:** Medication adherence: No difference in mean adherence between groups (86% in intervention and 76% in control at end of study) There were not differences between groups for being symptom free at the end of the study. Night time awakenings due to asthma related symptoms were significantly reduced in the intervention group. (P=0.03) The use of rescue β agonist decreased significantly in the intervention group during the 'intervention period' (RR 0.56, P < 0.001) but the the effect was not sustained at the end of the follow-up. There were no significant differences between groups for FEV1 or peak flow measures. Perceived control of asthma was significantly increased in the intervention group (P=0.006).	**Author's conclusions:** Little effect on pulmonary function between groups. But improved perceived control and behavioural changes. **Reviewer's conclusions:** Self selected participants may not be representative. Mainly White, well educated. Observed effectiveness in rescue treatment was not sustained over time. Little effect on pulmonary function **Source of funding:** NIH and GlaxoSmithkline **Additional comments:** Duration 4 weeks Based on Banduras Self efficacy theory 3 identical 30 minute visits delivered by certified asthma educator and then respiratory therapist. Content: asthma facts and medication, verbal and graphic interpretation of spirometry, peak flow trends, metered dose errors, results of allergy testing, control of personal environmental exposures.

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		in a formal asthma education programme		Although there was a trend to a significant increase in quality of life in the intervention group compared with the control group this did not reach significance. Intervention group reported significantly more changes in self management behaviour compared with controls (mean 1.82 vs 0.87, P < 0.0005). The intervention group reported improving inhaler technique (P=0.03), reducing outdoor allergen exposure (P=0.02) and reducing indoor dust exposure (P<0.0005) compared with controls.	Written action plan associated with daily clinical readings.

Bias	Judgement	Support for judgement
Random sequence generation	Unclear risk	No details
Allocation concealment	Unclear risk	No details
Blinding	Unclear risk	No details
Incomplete outcome data	Unclear risk	No details
Selective reporting	Unclear risk	No details

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Kuijer (2007) **Country:** Netherlands **Study type:** RCT **Evidence level:** II	**Aims:** To examine the effectiveness of a self-management intervention based on self-regulation and proactive coping theories on quality of life, self-care, self-efficacy and proactive coping. To examine which patients benefit most from the intervention.	**Study setting:** Recruited from hospital outpatients – various hospitals **Participant characteristics:** N= 70 asthma patients (N=55 diabetes patients also recruited to the study but results are reported for asthma patients only in this table) Mean age = 44 years 69% females Moderate to severe asthma: 18% experimental 26% controls **Inclusion:** Medical diagnosis of asthma that was poorly controlled Minimum disease duration of 1 year Age 18-65 years Recently experienced failure in self-management (exacerbation in sx and/or difficulties in following regimens that resulted in repeated non-scheduled	**Exposure: n= 41** See Schreurs et al for details Five sessions with 6-8 people in each group Facilitated by nurse specialist Bi-weekly except last session which was 4 weeks after 4th session. Covered various topics but included a written action plan for goal attainment, discussion, behaviour rehearsal. Practice and homework in 2 weeks between sessions then review, modify action plans, address barriers in the next session. **Comparison: n= 29** Standard care – typically consisted of one scheduled visit to lung specialist every 6 months and referral to an asthma nurse when needed. **Outcome measures:** Quality of life (QOL) – SF-12 and Cantril's ladder Retrospective QoL (then-test measure) measured estimated QoL at start of programme once pts had completed programme Self-efficacy – Lorig et al Proactive coping – Proactive Coping Inventory PC subscale	**Results:** Dropouts and refusals: Initial refusals not reported Of those recruited Intervention 16/41 = 39% did not complete Control 8/29 = 28% did not complete ITT analyses – missing data replaced with baseline scores No significant differences between baseline, post-test and follow-up measures for intervention and control groups. Then-test analyses – participants asked at post-test and follow-up to retrospectively rate their QoL at baseline to mitigate intervention-induced internal bias due to response shift. Intervention patients reported improved quality of life at post-test compared with pre-test (then-test) ($F t (29) = 3.42$, $p<0.001$ and improved physical health QoL but not mental health QoL. No differences between follow-up and pre-test.	**Author's conclusions:** No intervention effects of a self-management intervention on self-efficacy, self-care activities, proactive coping or quality of life. Intervention improved global quality of life and physical health QoL when the then-test analysis was used. Patients in both groups scored relatively high on baseline self-efficacy – may not have been room for improvement. Lack of motivation to change may have been one reason the dropouts were high and the intervention had no effect. **Reviewer's conclusions:** Patients selected for the study from various hospitals by their physician or nurse practitioner. Patients with severe persistent asthma excluded – possible selection bias. Dropouts 39% of intervention group and 28% of controls did not complete all stages. Drop outs were younger, more often male and higher in self-efficacy than those who completed. ITT analyses showed no effect of intervention. Some variance in what standard care meant in the control group . practitioner/specialist. Random allocation resulted in

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		hospital visits **Exclusion:** Severe persistent asthma that was poorly controlled according to a specialist – intervention was deemed unsuitable to meet their needs Patients with psychiatric problems also exluded	Dispositional optimism – Life Orientation Test **Follow-up time:** Self-complete questionnaires: Baseline measures Intervention 12 weeks long Post-test 2 weeks after intervention completed Follow-up 6 months after intervention completed	No significant effects of age, gender, level of education or disease duration. Patients who scored high in optimism benefited more from the intervention than those low in optimism.	uneven group sizes. No details regarding method of randomisation provided. Self-complete questionnaires used, possible source of response bias. Study inadequately powered to detect differences between groups. Then-test retrospective measure of pre-test QoL may be susceptible to recall bias. **Source of funding:** Netherlands Organisation for Scientific Research and Dutch Asthma Foundation **Additional comments:** Self-regulation theory and proactive coping theory

Bias	Judgement	Support for judgement
Random sequence generation	Unclear risk	Random allocation resulted in uneven group sizes. No details regarding method of randomisation provided.
Allocation concealment	Unclear risk	No details
Blinding	High risk	Relied on self-complete questionnaires and patients knew their group assignment
Incomplete outcome data	Low risk	Dropouts 39% of intervention group and 28% of controls did not complete all stages. Patients who dropped out were younger, more often male and higher in self-efficacy than those who completed. Flow chart detailing dropouts and withdrawals provided. ITT analyses completed.
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Magar (2005) **Country:** France **Study type:** RCT - multicentre **Evidence level:** II	**Aims:** To investigate the effectiveness of a self-management programme for patients with asthma on compliance with treatment, quality of life, physical health, psychological health and economic costs.	**Study setting:** 1999-2001 Multiple centres in France – 2 in the south and 2 in the north 26 pneumologists recruited patients Programme delivered by physicians, nurses or physiotherapists trained in delivering programmes (7 day course over 4-6 months) **Participant characteristics:** N=238 18-60 years Each pneumologist asked to recruit first 8 patients who came for consultation and met criteria below **Inclusion:** GINA criteria used to diagnose asthma Ongoing treatment for their asthma (inhaled corticosteroids and/or long-acting beta2-agonists) One daytime or one night time asthma attack per	All participants received printed information about asthma at enrolment **Exposure: n=127** Daily diary – time course of sympoms and healthcare use Self-administered questionnaires Telephone interviews once every 2 months Plus intervention programme consisting of: Initial individual interview, 1 hour Two group sessions, 2.5 hours long, 2 weeks apart Follow-up individual interviews at 3, 6 and 12 months, 1 hour each **Comparison: n=111** Daily diary – time course of sx and healthcare use Self-administered questionnaires Telephone interviews once every 2 months Patients in control group were invited to complete the education programme at the end of the study **Outcome measures:** Primary measures: Compliance with treatment Health-related QoL	**Results:** 80-82% retention rate for intervention and controls Symptom-free days significantly increased (+3.5 per month at 6- and 12-month evaluations) for intervention group ($p<0.03$) but not control (-.22 and -0.26 at 6 and 12 months). Number of night time awakenings decreased significantly for intervention but not control ($p<0.04$). Courses of oral corticosteroids decreased significantly for intervention but not control ($p<0.03$). Days per 6 months on oral corticosteroids: 6 months (SD) 12 months (SD) Interv -8.8 (24.0) -11.2 (22.8) Control -1.8 (19.3) -3.8 (16.9) Fast-acting beta2-agonist consumption decreased significantly for the intervention group between 6 and 12 months with no change for the control group ($p<0.01$).	**Author's conclusions:** Clinical and therapeutic benefits for patients who attended the educational programme. Many results were seen after the 6 month period and were maintained at 12 months. Control patients also improved in some aspects because they were getting better than usual follow-up care from a pneumologist. The programme though had additional benefits for those in the intervention group. **Reviewer's conclusions:** Unclear whether interviewers were blind to group assignment when completing phone interviews. No mention of ITT analyses – 20% of participants dropped out. Some results not reported – treatment compliance and economic cost-benefit. Very large standard deviation for some measures, wide variance in patient response – beta2 agonist consumption and sx free days especially. May have overstated the clinical significance of some results e.g there was only a slight increase in quality of life and locus of control and it is unclear whether this would have

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
		week on average over the past month or once-weekly use of bronchodilator. **Exclusion:** Difficulty speaking or understanding French Refusal to complete telephone interviews Participation in another trial	Economic cost-benefits Secondary measures: Clinical parameters: Number of symptom -free days, night time awakenings, medication use Psychological parameters: anxiety, locus of control Behavioural parameters: smoking, environmental adaptation **Follow-up time:** One year	Inhalations per month: 0-6 months 6-12 months Interv +10.6 (93.0) +1.3 (84.7) Control +7.2 (50.48) +7.2 (66.8) Quality of Life increased slightly for both groups between baseline and 12 months but the difference was statistically significant only for the intervention group ($p<0.01$). Locus of control showed very little change.	therapeutic impact. Anxiety scales not completed properly and were invalidated. **Source of funding:** Laboratoire GlaxoSmithKline **Additional comments:** Problem-solving model (decision simulation) Self-management programme developed according to WHO quality criteria for patient education. Entitled "Un soufflé nouveau". Materials developed by Edusante and designed to facilitate patient interaction, questioning and thought. Used by 150 hospital and non-hospital based teams in France in 2005. *Content* Initial interview: identify education needs, materials, set up times for group work Session 1: Identification of signs of attack, medications, taking medications correctly – practical hands on activities for all topics Session 2: Identifying and avoiding triggers, monitoring asthma by PEF (green, yellow, and red zone goals), plan for controlling asthma based on 1)

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
					avoiding triggers 2) early warning signs and response 3) adapting treatment based on PEF and sx monitoring

Bias	Judgement	Support for judgement
Random sequence generation	High risk	26 pneumologists asked to recruit first 8 patients who met inclusion criteria. Odd/even number generation to assign groups. Recruiting doctors provided with random numbers.
Allocation concealment	Unclear risk	Physicians aware of group allocation, patient awareness of allocation not reported.
Blinding	Unclear risk	Unclear whether interviewers were blind to group assignment when completing phone interviews.
Incomplete outcome data	High risk	No mention of ITT analyses- 20% attrition rate.
Selective reporting	High risk	Some results not reported - treatment compliance and economic costs

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Mancuso (2010) **Country:** USA **Study type:** RCT **Evidence level:** II	**Aims:** To assess the effectiveness of an asthma education intervention to improve asthma knowledge and self-efficacy	**Study setting:** Primary care practice, New York CIty **Participant characteristics:** N=180 (allowing for 10% loss-to-follow-up) N=1016 screened (based on daily appointment visits at the practice). 349 eligible, 180 enrolled Mean age = 43 years 84% female 31.5% white ethnicity 47% college graduate Mean asthma duration = 23 years Mean FEV1 82% of predicted 26% cited depression as a comorbidity **Inclusion:** English-speaking Moderate persistent asthma cacording to national criteria **Exclusion:** Pulmonary or other severe comorbidty, including	Initial face-to-face interview for all patients measuring baseline characteristics, adherence to medications, quality of life, self-efficacy, physical and mental health, social support and spirometry. **Exposure: n=90** Workbook 'Take control of your asthma', based on national education programmes, vignettes, case studies, behaviour contracts Face-to-face session to introduce the workbook Weekly contact by telephone or mail to support workbook use for 12 weeks 3-monthly telephone assessments **Comparison: n=90** Brochures about asthma facts, modifying triggers, peak flow meter use Telephone contact every 3 months Periodic interviews 3-monthly up to 24 months **Outcome measures:** Asthma-related quality of life – AQLQ Health status – SF36 ED visits	**Results:** N=2 lost-to-follow-up for main outcomes ITT analyses No sig differences in length or number of follow-up assessments between intervention and control. Asthma quality of life: 5 month follow-up showed greater improvement for interventions (1.2) than controls (0.3, $p<0.05$) Overall 2 year follow-up showed improvement of 5.1 in QoL scores for both groups (p=0.98). Younger age, more education, better initial ALQL scores, more asthma self-efficacy, more asthma knowledge and fewer depressive symptoms associated with improvement. Health status: No significant differences in SF-36 scores at 2 year follow-up. Fewer depressive symptoms, better initial scores and less comorbidity were associated with better improvement.	**Author's conclusions:** Patients in the intervention group had initial improvements in the first few months but these were not sustained. Both intervention and control participants had improvements in quality of life, health status and similar rates of hospitalisation. Younger age, more education, more asthma self-efficacy, more asthma knowledge and fewer depressive symptoms were associated with greater QoL improvement, less ED use and fewer hospitalisations. Control group was provided with more than usual care and this may have been a form of social support. **Reviewer's conclusions:** Suggests factors such as social support, education, depressive symptoms and self-efficacy influence how well people benefit from the intervention. Authors acknowledged that patients in this study had moderate asthma and it may not be generalisable to those with severe asthma. Hospitalisation and ED data was self-reported and not verified. Patients blind to randomisation. Interviewers/assessors not blinded because they also reinforced

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
		psychiatric	Hospitalisations **Follow-up time:** 2 years Mean time in the study = 27 months	Hospitalisations and ED visits: 30% of controls and 32% of intervention patients had an ED visit over the follow-up period (p=0.84) 7% of controls and 11% of intervention patients had a hospitalisation for asthma (p=0.30) When associations between depressive sx and outcomes were examined separately for intervention and control patients, it appeared that the intervention was beneficial for patients with more depressive symptoms (QoL and hospitalisations).	intervention components. Final follow-up assessors blind to group assignment. Quality control checks during intervention period N=169 of 349 potential participants screened and eligible but overlooked during enrolment or did not attend. May be a self-selected, motivated sample. Some variability in the way the intervention was implemented with participants receiving 0-7+reinforcements. **Source of funding:** National Heart, Lung and Blood Institute **Additional comments:** Social learning theory – emphasizing learning through experience and the example of others

Bias	Judgement	Support for judgement
Random sequence generation	Low risk	Permuted blocks
Allocation concealment	Unclear risk	No details
Blinding	Low risk	Patients blinded, intervention facilitators not blinded, final follow-up data collectors blinded

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Incomplete outcome data	Low risk			ITT - carried forward enrolment scores for patients with missing data	
Selective reporting	Low risk			A priori outcomes reported	

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Milenkovic (2007) **Country:** Serbia **Study type:** RCT **Evidence level:** II	**Aims:** To compare the effectiveness of a one-year peak-flow based self-management programme with conventional treatment on short and long-term outcomes	**Study setting:** Outpatients department of two clinics **Participant characteristics:** N= 80 clinically stable adult patients with persistent, controlled asthma, 18-60 years, mean age 47 yrs, 53% female, mean asthma duration ~10.5 years, 27.5% ex smokers, ~50% mild, 35% moderate, 15% severe persistent asthma **Inclusion:** 18-60 years Continued use of inhaled steroids for at least the last year Stable phase of disease during the last 3 months Confirmed diagnosis according to national and international guidelines **Exclusion:** Smoking history of 15 or more pack years Other diseases that could	**Exposure: n=40** Peak-flow based self-management: <u>Session 1</u> Patients asked to measure PEF 3 times/day and measure personal best Individualized written action plan based on personal-best peak-flow measurements with recommended action for each cut-off zone Specific instruction on how to implement their action plan Patients asked to monitor: Daily symptoms Use of supplement beta2-agonist Self-management behaviour Two visits to outpatients at 6- and 12 months **Comparison: n=40** Conventional treatment: No peak-flow meter Advised to take reliever medication if symptoms worsened and to seek advice from primary care physician re controller medication 6 monthly outpatient visits – 6 months and 12 months **Outcome measures:** Lung function	**Results:** Dropouts: 37 patients in each group completed 1 year programme N= 7 patients from intervention group did not present diaries at visit 3. Visit 3 – one year after intervention began Lung Function: No significant differences between SME group and control group at 1 year follow-up. Asthma exacerbations: Significantly fewer exacerbations in SME group at 1 year follow-up (mean SME=1.7, mean control=2.4, $p<0.05$). Significant decrease in exacerbations for SME (pre-test 2.4, post-test 1.7) but not control group (pre-test 2.2, post-test 2.4). Hospital care: Significantly fewer ED visits, GP and specialist visits for SME group compared with control at 1 year follow-up. Significant decrease for SME group but not control. No difference in hospitalisations	**Author's conclusions:** No improvement in lung function in either group – not expected because participants in the study had stable, well-controlled asthma. Asthma morbidity was mostly reduced in those patients who were instructed to use a self-management plan compared with those who had conventional treatment. Asthma exacerbations were dealt with in a timely fashion in this group and additional interventions were less frequent. **Reviewer's conclusions:** Possible selection bias – no details of method of selection and recruitment Possible education in control group via primary care physician Analyses were not ITT – comparisons made within and between groups No comparison with control group at 6-year follow-up Relied on patient reports of asthma-related difficulties – measures not well-described but the authors discussed the limitation of not checking patient self-reports against medical records. No indication as to whether participants were aware of

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
		influence bronchial sx or lung function	Asthma exacerbations Hospital admissions Unscheduled visits to ER, GP or specialist Treatment requirements during exacerbations Days off work Asthma symptoms **Follow-up time:** One year intervention and followed up five years later. Control group was only followed up to 1 year (end of intervention).	between groups. Medications: Significant increase in beclomethasome and decrease in oral prednisolone for SME group. No change for control group. Days off work: Mean SME = 0.7 +/- 1.1 Mean control = 6.9 +/- 3.3 P<0.0001 69% of patients still using the PEF-based programme at 6 years follow-up	their group allocation. Participants were those with persistent, stable, 'well-controlled' asthma – may have been different from the general popn in terms of motivation and adherence to treatments. **Source of funding:** Not stated **Additional comments:** Theoretical model not specified.

Bias	Judgement	Support for judgement
Random sequence generation	Unclear risk	No details
Allocation concealment	Unclear risk	No details
Blinding	Unclear risk	No details
Incomplete outcome data	High risk	Analyses were not ITT- comparisons made within and between groups. No comparison with control group at 6-year follow-up. 40 people originally recruited for each group but 37 analysed. 7 participants in intervention group did not submit diaries at 1 year follow-up.
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Shackelford and Bachman (2009) **Country:** USA **Study type:** **RCT** **Evidence level:** **II**	**Aims:** To compare the effectiveness of an individually-tailored asthma self-management programme with a standardised SM programme	**Study setting:** Allergy and Respiratory Clinic **Participant characteristics:** N=88 Aged 18 years and older 75-80% female 81.8% white 49% had previous asthma education 35-40% in highest income bracket **Inclusion:** Diagnosis of asthma and no other chronic respiratory conditions (aside from allergies and sinusitis) Able to read and speak English **Exclusion:** -	**Exposure: n=44** Individualised SM programme Informal, semi-structured, 1-6 patients per session Applied andragogical principles Researcher facilitated and managed educational activities Participants shared their experiences with asthma and learning goals, role of learner was participatory **Comparison: n=44** Standardised SM programme Group-based, 2-8 patients per session Content driven and formally scripted, lecture-style Researcher-directed, role of learner active listening and questioning **Outcome measures:** Asthma Control Test (ACT): Asthma sx Limited activity days Shortness of breath Perceived asthma control Frequency of rescue inhaler use PEF **Follow-up time:** 4 weeks	**Results:** 75-80% married, female, Caucasian participants. Higher proportion married in intervention group. Higher proportion of lowest income group in standardised SM programme. These were reported as being not significant differences. ACT scores: No significant difference in ACT scores between intervention and control groups. Both groups ACT scores improved significantly from pre- to post-test ($p<0.05$). PEF readings: No significant difference between intervention and control groups pre- and post-test readings ($p=0.15$)	**Author's conclusions:** Both approaches to conducting sessions were effective and this study provides support for the application of andragogical principles of learning in asthma education programmes **Reviewer's conclusions:** No description of randomisation, blinding or allocation concealment Short follow-up – 4 weeks Unclear as to whether different people facilitated each of the groups but may have been the same researcher About 50% of patients had previously had asthma education Self-report measures utilised which may have been prone to bias Content of the courses not well described **Source of funding:** Not stated **Additional comments:** Andragogical principles include self-directed learning, problem-centred learning and application, and individual goal-setting. Adult-appropriate learning practices Individual differences incorporated in learning, self-directed learning principles applied, 90 minute sessions.

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Bias	**Judgement**			**Support for judgement**	
Random sequence generation	Unclear risk			No details	
Allocation concealment	Unclear risk			No details	
Blinding	Unclear risk			No details	
Incomplete outcome data	Unclear risk			No details	
Selective reporting	Low risk			A priori outcomes reported	

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Sun (2010) **Country:** China **Study type:** RCT **Evidence level:** II	**Aims:** To compare the effectiveness of educational and psychological counselling on QoL and psychological status of patients with asthma	**Study setting:** Weifang Asthma Hospital clinic **Participant characteristics:** N=374 Mean age = 42.9 years intervention, 37.5 years control (sig difference) 45% female 22% university education 76% married 10% years of asthma not specified 41% <5 years of asthma **Inclusion:** Established diagnosis of asthma 18-70 years old **Exclusion:** Serious psychiatric illness Somatic comorbidities Did not give consent Unable to adhere to follow-up schedule	**Exposure: n=228** Two week intervention involving group-based education and psychological counselling. Education = group-based (n=20). 4xone hour sessions with a nurse educator covering symptoms, medication, lifestyle and living environment changes and individualised asthma action plan. Counselling = group based (n=20). 6x one hour sessions with a clinical psychologist covering psychosocial factors in asthma, coping strategies, individualised relaxation and exercise regimen, group psychological counselling for distress. **Comparison: n=146** No education or counselling All patients received guideline-based pharmacologic and non-pharmacologic care e.g. physiotherapy in addition to that specified by their group assignment **Outcome measures:** Quality of life Psychological distress (Profile of Mood States questionnaire) Knowledge of asthma	**Results:** N=400 screened N=374 recruited ITT analyses No dropouts Quality of life: Overall QoL significantly higher in the intervention group following the two-week programme and at three months follow-up. This was also true for all subscales (physical activity, asthma symptom control, psychological wellbeing, self health-caring). Overall QoL score Interv Control p-value 2 wks 130.2 111.6 <0.001 3 mths 144.4 121.5 <0.001 Profile of mood states: Total POMS for negative emotionality was significantly higher in the control group following the intervention and at 3 months follow-up. This was true for all subscales (tension, depression, anger, fatigue, confusion) Overall POMS score	**Author's conclusions:** Education combined with psychological counselling improved quality of life, psychological state and knowledge of asthma and this was sustained 3 months after the intervention. Whether this would translate to better asthma control requires further investigation. **Reviewer's conclusions:** No clinical data - changes in QoL or emotional state may not translate into better management of asthma symptoms. Use of self-complete questionnaires – no indication as to whether patients were blind to their group assignment Severity of asthma of included patients not described. Relatively short follow-up so unable to gauge long-term effects Little actual difference between intervention and control groups for some of the POMS and QoL subscales as well as asthma knowledge, even though these were statistically significant – large sample size may have detected differences which are not clinically significant. Differing numbers of patients in the intervention and control groups because of ethics board

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
			Follow-up time: 3 months	Interv Control p-value 2 wks 12.0 23.0 <0.001 3 mths 10.2 22.8 <0.001 Asthma Knowledge: Asthma knowledge score significantly higher in intervention group following the intervention (9.0 v 7.5) and 3 months post-intervention (9.4 v 7.5).	requirements. **Source of funding:** Partly funded by Ministry of Education (Peoples Republic of China) grant **Additional comments:** Psychosocial counselling

Bias	Judgement	Support for judgement
Random sequence generation	Low risk	Random number generator; 1.6:1 intervention:control ratio due to ethics requirements
Allocation concealment	Unclear risk	Unclear whether those allocating treatment group were unaware of which group would receive the intervention
Blinding	High risk	Investigators who evaluated education and counselling sessions were blind to group allocation. Clinicians who conducted sessions were not. No indication as to whether patients were blind to their group assignment and all measures were based on self-complete questionnaires by the patients
Incomplete outcome data	Low risk	No dropouts. 400 screened of whom 374 were considered eligible according to inclusion/exclusion criteria
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: van der Meer 2009; van der Meer 2010 **Country:** **Netherlands** **Study type:** RCT **Evidence level:** II	**Aims:** Evaluate the effectiveness of internet based asthma self management	**Study setting:** 37 general practices and 1 academic outpatient department in the Netherlands **Participant characteristics:** 30.5% male, mean age 36.5 years range 18 – 50; mean duration of asthma 16.5 years, 51% had high level of education **Inclusion:** Physician diagnosis of asthma, aged 18-50 years, prescription of inhaled corticosteroids for at least 3 months in previous year, no serious comorbid condition affecting asthma treatment, internet access at home, mastery of Dutch language. **Exclusion:** Maintenance oral glucocorticosteroids	In a two week baseline …All participants received basic education on asthma, action of medications, inhaler technique, how to measure FEV1 with hand held spirometer and to report these values on the Web as well as daytime and night time symptoms and complete the Asthma Control Questionnaire **Exposure: n=101 Internet based self management programme** Weekly asthma control monitoring and treatment advice, online and group education remote Web communications with a specialised asthma nurse for 12 months Based on weekly asthma control questionnaire results treatment could be adjusted following a plan or to contact the asthma nurse Web based content: asthma information, news, FAQ, interactive communication with asthma nurse. 2 x Group based sessions: 45-60 minutes within 6 weeks of randomisation. Exploration of interests and knowledge (negotiating an agenda and patient centred education), personalised feedback, empowerment of self management (self efficacy and	**Results:** There was no between group differences in increased asthma knowledge (P=0.70) although both groups improved. No between group differences in inhalation technique (P=0.14) although both groups improved. No between group differences in medication adherence The internet group had slightly fewer physician visits but this did not reach statistical significance. Asthma QoL Questionnaire improved more in the internet group (adj 0.38; 95%CI 0.20 – 0.56, P < 0.001) The internet group showed greater improvement in asthma control (adj -0.47; 95%CI -0.64 - -0.30; P <0.001) Not significantly different between 3 and 12 months. After 12 months the proportion of symptom free days in the previous 2 weeks increased by an absolute of 18% in the internet group and 7.3% in the	**Author's conclusions:** Internet self management improves quality of life, asthma control, lung function and increases symptom free days compared with usual care. The effectiveness was particularly highlighted for those with partly or uncontrolled asthma at baseline **Reviewer's conclusions:** Well designed RCT. Sustained improvements seen in clinical and psychological measures. Adherence to the internet programme was 67%. Effectiveness appeared to be increased for those with partly or poorly controlled disease at baseline, probably through the individual tailoring of medication **Source of funding:** Netherlands Organization for Health Research and Development, Netherlands Asthma Foundation **Additional comments:** Individualised and group sessions Web based. Not theory stated but focused on empowerment and self efficacy

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
			implementing plan for change). Pathophysiology of asthma inhalational technique, web based action plan, mechanism and side effects of medication and trigger avoidance. **Comparison: n=99 Usual care** Care based on Dutch general practice guidelines, medication review and treatment adjusted every 2-4 weeks in unstable asthma and medical review 1-2 times annually in stable asthma. **Outcome measures:** Asthma Control Questionnaire Consumer Asthma Knowledge Questionnaire Dutch Asthma Foundation checklist to evaluate inhalation technique Health care provider contacts Medication use Asthma Quality of Life Questionnaire FEV1 Exacerbations **Follow-up time:** 12 months	usual care group (P=0.039). Daily inhaled corticosteroid dose did not differ overall between groups at 12 months No difference in number of exacerbations during follow-up. FEV1 increased in the internet group compared with usual care Mean difference 0.25; 95%CI 0.03 – 0.46; P = 0.025	
Bias	**Judgement**			**Support for judgement**	

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Random sequence generation	Unclear risk			No details	
Allocation concealment	Unclear risk			No details	
Blinding	Unclear risk			No details	
Incomplete outcome data	Unclear risk			No details	
Selective reporting	Unclear risk			No details	

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Wilson (2010) **Country:** USA **Study type:** RCT **Evidence level:** II	**Aims:** To compare the effectiveness of SME using shared decision-making with SME using clinician decision-making or usual care on controller medication adherence and clinical outcomes in patients with poorly controlled asthma. Target population = those with poorly controlled asthma, inadequate adherence to asthma regimen, 18-70 years	**Study setting:** Better Outcomes of Asthma Treatment (BOAT) – a three-arm, multisite RCT. Study care managers were Kaiser Permanente nurses, respiratory therapists, pharmacists, nurse practitioners and physician assistants, most of whom served as asthma care managers already. **Participant characteristics:** N=612 patients with poorly controlled asthma 83.9% poorly or very poorly-controlled asthma (GINA guidelines + symptoms + meds use) Mean age ~45 years 57% female 62% white 38.4% university education 16% current smoker **Inclusion:** Evidence of poorly controlled asthma Overuse of rescue	**Exposure: n= 408** Asthma education via two in-person and three telephone sessions. Self-management education was delivered using a shared decision making (SDM) approach or clinician decision-making (CDM) approach. **Shared decision-making (SDM) = 204** patient and clinician negotiate treatment regimen together encompassing patient goals and preferences **Clinician decision-making (CDM)=204** treatment regimen devised by clinician without inclusion of patient preferences/goals and regimen is communicated to patient. SDM and CDM interventions were otherwise identical in format, content and materials. **Comparison: n= 204** Control group = usual care **Outcome measures:** Primary: Adherence to controller medications (dispensing records) Asthma-related quality of life (Juniper mini asthma QoL	**Results:** Dropouts: N=5414 possible participants N=2534 contactable and screened N=1170 eligible for inclusion N=453 (38.7%) refused, 100 ineligible N=612 finally recruited of whom 551 (90%) completed 1 year follow-up clinic visit Estimated costs: SDM = US$174 per patient CDM = US$142 per patient Controller medication: At 1 year follow-up, SDM patients significantly more likely to adhere to ICS and other controller therapy and to LABA medications than CDM or usual care patients. Asthma-related QoL: Both SDM (mean=5.5) and CDM (mean=5.4) had significantly higher mean sx subscale scores than usual care (mean = 5.1, p<0.0001) Healthcare utilisation: SDM (mean 1.0/year) and CDM (mean 1.1/year) had	**Author's conclusions:** A shared decision-making approach in the context of asthma care management improves both medication adherence and clinical outcomes. **Reviewer's conclusions:** Session one 30 mins longer on average for the SDM v CDM groups Medical records complete due to recruitment only of KP members Asthma diaries used, self-report for QoL measures and may have been subject to bias. Lung function measured by participating primary care physicians, unclear whether they were blind to group assignment. Some asthma care management (patient education in adherence, self-management issues) available at some sites and may have been taken up by controls or intervention patients. Was an exclusion criterion for original enrolment but may have been taken up after that. QoL did not differ in a therapeutically meaningful way. Not powered to detect differences in ED visits or hospitalisations. Missing data not imputed – analyses based

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
		medications identified through hospital records or a recent asthma-related ED visit or hospitalisation Kaiser Permanente members **Exclusion:** Intermittent asthma (brief exacerbations or sx less than once/week) COPD or emphysema Insufficient pulmonary function reversibility Regular use of oral corticosteroids Current asthma care management	questionnaire) Healthcare utilisation for acute sx Secondary: Short-acting beta-agonist use (dispensing records) Lung function Asthma control **Follow-up time:** Session 1 and 2 about 1 month apart. Sessions 3, 4 and 5 by telephone 3, 6 and 9 months after session 1. 1 year follow-up clinic visit 2 years post-randomisation measures	significantly fewer asthma-related hospital visits than the usual care group (mean 1.4/year, p <0.05). SABA use: SDM (mean 6.5) and CDM (mean 7.1) acquired significantly fewer albuterol canister equivalents than usual care (mean 8.1). Lung Function: SDM significantly better than usual care but not CDM group. Asthma control: SDM and CDM had greater odds of reporting no sx than usual care SDM odds ratio = 1.9 (95% CI 1.3 – 2.9, p <0.01) CDM odds ratio = 1.6 (95% CI 1.1 – 2.4, p<0.05) ATAQ scores at one year follow-up decreased in all 3 groups	on complete data only. Few differences between SDM and CDM groups. **Source of funding:** **Additional comments:** Shared decision-making (SDM) process (Charles et al 1997; 1999) and motivational interviewing techniques. SDM involves active participation by the patient and includes the following 4 features of clinician/patient interaction: 1) sharing of relevant information 2) expression of treatment preferences 3) deliberation of options 4) agreement on treatment Intervention protocol: Session 1: face-to-face SDM and CDM approaches similar except in SDM session, the facilitator identifies patient goals and preferences and negotiates the treatment regimen with the patient to develop a written action plan. Session 2: face-to-face Approx 1 month after session one Patient progress assessed and medications adjusted using SDM or

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
					CDM approach. Sessions 3, 4, 5: telephone-based Patient progress assessed and medications adjusted using SDM or CDM approach. Standardised intervention scripts and materials. Study care managers received standardised training. Audiotapes of both sessions for 10% of patients were quality control checked.

Bias	Judgement	Support for judgement
Random sequence generation	Low risk	Computer-based adaptive randomisation algorithm, balanced across the 3 groups for age, sex, ethnicity, hospitalisation in the prior 2 years, and frequency of asthma controller use in the past week.d
Allocation concealment	Low risk	Concealment from randomisation staff ensured
Blinding	Unclear risk	Not stated. Pharmacy data based on medical records, quality of life data based on patient self-report and may have been subject to bias. Lung function measured by participating primary care physicians, unclear whether they were blind to group assignment.
Incomplete outcome data	High risk	N=5414 possible participants, N=2534 contactable and screened, N=1170 eligible for inclusion, N=453 (38.7%) refused, 100 ineligible, N=612 finally recruited of whom 551 (90%) completed 1 year follow-up clinic visit. Missing data not imputed - baseline and follow-up analyses based on complete data sets.
Selective reporting	Low risk	A priori outcomes reported

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Rowett et al (2005) **Country:** Australia **Study type:** RCT – cluster-randomised **Evidence level:** II	**Aims:** To compare the effectiveness of a Flinders Sharing Health Care self-management programme with usual care - described as a demonstration project	**Study setting:** Four GP practices (2 intervention, 2 control) **Participant characteristics:** Recruited March 2002 – June 2003 N=33 Mean age = 71 yrs, 53% female, 94% pensioners, 38% had a carer, 46% also had CVD Carers of enrolled patients were also invited to participate **Inclusion:** 50 years or older Moderate to severe airflow limitation; severe chronic asthma; pulmonary fibrosis or bronchiectasis and at least one concurrent condition (inc mood, CVD, osteoporosis, diabetes, or arthritis) **Exclusion:** Chronic medical conditions likely to impose severe exercise restriction unrelated to respiratory	**Exposure: n=19** Flinders Sharing Health Care self-management programme: Flinders Partners in Health scale Cue and Response interview Problems and goals to negotiate and develop a care plan Also received the Pulmonary Rehabilitation programme – intensive education and exercise sessions tailored to each individual **Comparison: n=14** Usual care from GP **Outcome measures:** Health status for chronic airflow limitation, QoL - St Georges Respiratory Questionnaire (self-complete) Psychiatric morbidity – GHQ-28 COPD self-efficacy scale Carer's questionnaire Beliefs about medicines scale Satisfaction with information about medicines scale 6-minute walk **Follow-up time:** Some measures up to 6 months,	**Results:** 16 GP practices (n=114 GPs) approached, 4 practices (n=6 GPs) agreed to take part 42 patients recruited, 33 agreed to participate 1 intervention patient and 3 controls withdrew by 12 months 15 care plans using Flinders model developed in the intervention group (79%) ITT analyses completed Quality of life: No sig differences. Scores on SGRQ improved for both groups in first 6 months of trial 6-minute walk test Significant improvement in intervention but not control group. Note though that the intervention group appeared to perform much worse on this test at baseline (50m less achieved) . Distance in metres – 6 min walk Baseline 6 mths 12 mths Interv 361.5 419.5 435.9 Control 410.7 432.1 446.1	**Author's conclusions:** Study demonstrated significant and sustained advantages in favour of self-management for people with severe chronic lung diseases. **Reviewer's conclusions:** Underpowered? Sample size small and aimed for 6 GP practices originally, target sample size 68, achieved 33. Differences between practices recruitment methods – some identified every eligible patient and contacted, some recruited opportunistically during appointments Differences in the way each practice/GP implemented the intervention model. GPs also reported improvement in the use of intervention tools as they worked with patients so the intervention was not standardised. Very low recruitment rate of GP practices and participating GPs (5%) Intervention and control patients were not matched at baseline – psychiatric morbidity higher for intervention, 6 minute walk higher for controls, FEV1 lower for intervention Potential contamination between groups - GPs in control group implemented care plans as part of

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		disease or shorten survival Presence of known cancer likely to be fatal within 12 months Severe cognitive deficit	some to 12 months Staggered entry to the study so follow-up was completed over 26 months	Psychiatric Morbidity – GHQ No sig differences at baseline, 6 mths or 12 mths. 42% of intervention and 30% of controls met criteria for significant psychiatric distress at baseline. Self-efficacy: No significant differences at 6 and 12 months Lung Function: No significant differences between intervention and control	their usual practice **Source of funding:** **Additional comments:** Flinders Model – used Flinders Chronic Condition Self-Management (CCSM) tools – Partners in Health and Cue and Response interviews Aimed to develop partnership between patients and GPs to improve self-management outcomes. Flinders unit provided training for GPs and other health professionals in how to use the tools and teach sessions

Bias	Judgement	Support for judgement
Random sequence generation	Unclear risk	No details
Allocation concealment	Unclear risk	No details
Blinding	High risk	No blinding
Incomplete outcome data	Unclear risk	No details
Selective reporting	Low risk	A priori outcomes reported