Supplementary Material B

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Year and author: Adams 2007 **Country:** USA **Study type:** Systematic review **Evidence level:** I	**Aims:** To assess the efficacy of chronic care model (CCM) components in COPD management **Participants:** Mean age ranged from 42 to 76 years. % male ranged from 23 to 100%. No other participant details **Search period:** Inception to August 2005 **Search method:** MEDLINE, CINAHL, the Cochrane Library, reference lists from retrieved articles, hand searching abstracts from national conferences and communication with experts	**Inclusion:** Adults with COPD, interventions with CCM components, inclusion of comparison group or measures at 2 points, relevant outcomes (see next column). **Exclusion:** Studies evaluating therapeutic measures	**Exposure:** One or more components of CCM; these include self-management support, delivery system design, decision support and clinical information systems. Duration: 1-15 hours **Comparison:** Not specified **Outcome measures:** Knowledge, dyspnea, QOL, lung function, performance-based test, health care use, clinical endpoints (mortality or number of acute exacerbations of COPD, cost. **Follow-up time:** Mostly greater than 6 months	**Results:** - Dyspnoea: 3 RCTs: MD -0.63 (-1.09 to -0.18). 4 other studies found no difference. - Quality of life: 1 CCM component: 2/10 studies found improvements in QOL in intervention group 2+ CCM components: no evidence of statistical difference - Lung function: No evidence of statistical difference in 5 studies with 1 CCM component, one other study with 4 CCM components found a mean change in FEV1 of 7.50% predicted. - Performance-based measures: 5/5 studies found no significant difference between groups - Health care use: ED/unscheduled visits: 3 studies with multiple CCM components: RR 0.58 (0.42 to 0.79) plus 4 other studies showed benefits for intervention	**Author's conclusions:** Patients with COPD who received interventions with 2 or more CCM components had lower rates of hospitalisations and emergency/unscheduled visits and a shorter length of stay when compared to control. **Reviewer's conclusions:** Due to heterogeneity in the included studies, the authors could not determine the optimal combination, specific types and duration of the interventions. **Source of funding:** Not stated **Additional comments:** Useful categorisation of CCM according to number of components

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				group 1 study with 1 CCM component showed no difference between groups. Hospitalisations: 4 studies with multiple CCM components: RR 0.79 (0.66 to 0.94) 0.79 (0.66 to 0.94) plus 5/6 other studies showed benefits for the intervention group 2/5 studies with 1 CCM component found a benefit for the intervention group Mean hospital length of stay: 2 studies with multiple CCM components: WMD -2.51 days (-3.40 to -1.61) plus 4 other studies found benefits for the intervention group 4 studies with 1 CCM component found no evidence of a difference between groups.	
Internal validity:	+				
Study results – precision:	+				
Applicability (external validity):	+ Subgroup analyses useful for determining which aspects of the intervention are effective				
Overall score:	+				

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Year and author: Coventry 2007 **Country:** UK **Study type:** Systematic review **Evidence level:** I	**Aims:** To estimate the clinical effect of pulmonary rehabilitation (with or without education) on anxiety and depression in patients with COPD **Participants:** Clinically stable adult patients with moderate to severe COPD (defined), mean age 61-68 years, male 42-100% **Search period:** Inception to August 2006 **Search method:** MEDLINE, EMBASE, PsycINFO, CINAHL, British Nursing Index, the Cochrane Library, reference lists of retrieved studies, Current Controlled Trials register and the National Research Register	**Inclusion:** RCTs of clinically stable adult patients with moderate to severe COPD, comprehensive outpatient pulmonary rehabilitation (PR) programs, standard care or education in control groups, outcomes (see next column) **Exclusion:** Other chronic obstructive airways diseases, other chronic diseases, severe psychiatric disease, home based or inpatient PR programs, conference abstracts and posters	**Exposure:** Comprehensive outpatient PR programs of ≥ 4 weeks that included at least 2 weekly sessions of low intensity and/or incremental high-intensity supervised exercise training sessions **Comparison:** Standard care in outpatient or primary care settings or education about disease management **Outcome measures:** Primary: anxiety and/or depression scores Secondary: Generic or disease-specific health-related QOL **Follow-up time:** 6-12 weeks or 12 months	**Results:** - Pulmonary Rehabilitation (PR) versus standard care: Anxiety: SMD -0.33 (-0.57 to -0.09), p=0.008, 3 studies Depression: SMD -0.58 (-0.93 to -0.23), p=0.001, 3 studies - PR versus education alone: No evidence of significant differences between groups - Exercise alone versus standard care: No evidence of significant differences between groups - Health-related QOL: Mixed results for the secondary outcome: health-related QOL	**Author's conclusions:** PR programs that include up to 3 sessions a week of incremental and supervised exercise, along with education and psychosocial support, significantly reduce anxiety and depression more than standard care in patients with COPD. **Reviewer's conclusions:** Participants selected according to pulmonary status rather than psychological status making it difficult to draw conclusions about patients with varying levels of symptoms. Gains achieved in the short term but not sustained at 12 months **Source of funding:** Medical Research Council Special Training Fellowship in Health Services Research **Additional comments:** Uncertain applicability as summary effect measurements as standardised mean differences. Unknown clinical significance.
Internal validity:	+				

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Study results – precision:	? publication and language bias cannot be excluded but impact discussed				
Applicability (external validity):	X results expressed as standardised mean differences. Not possible to determine whether the statistically different changes in scales are clinically important				
Overall score:	? Uncertain applicability but valid design				

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Year and author: Effing 2007 **Country:** Netherlands **Study type:** Systematic review **Evidence level:** I	**Aims:** To evaluate whether self management education programs in COPD lead to improved health outcomes and a reduction of health care utilisation **Participants:** Mean age ranged from 57 to 71 years, mean FEV1 ranged from 36 to 59% predicted, proportion of males ranged from 33 to 100% **Search period:** 1985 to January 2006 (prior to 1985, COPD care was considered different) **Search method:** MEDLINE, Cochrane Airways Group Trial Register and abstracts of medical conferences	**Inclusion:** RCTs and controlled clinical trials assessing the efficacy of self management education compared to usual care in COPD patients **Exclusion:** Studies published prior to 1985, focusing mainly on pulmonary rehabilitation, primary diagnosis of asthma	**Exposure:** COPD education and/or self treatment guidelines (ie. Action plan) with the goal of improving the knowledge and understanding of COPD **Comparison:** Usual care **Outcome measures:** Health-related QOL, symptom scores, number and severity of exacerbations, courses of oral steroids or antibiotics, use of rescue medication, hospital admissions, emergency room visits, use of other health care facilities, days lost from work, lung function, exercise capacity **Follow-up time:** Ranged from 2 to 24 months, majority at 12 months	**Results:** Self management education versus usual care: - At least one hospital admission: OR 0.64 (0.47 to 0.89), NNT ranged from 10 (6 to 35) for patients with a 51% risk of exacerbation to NNT 24 (16 to 80) for patients with a 13% risk of exacerbation - Disease-specific QOL (SGRQ): Total score: WMD -2.58 (-5.14 to -0.02), Impact domain: WMD -2.83 (-5.65 to -0.02) but these did not reach the clinically important difference of 4 points No evidence of group differences in number of exacerbations, ED visits, lung function, exercise capacity, days lost from work. Inconclusive results for doctor and nurse visits, symptoms other than dyspnoea, use of courses of oral corticosteroids and antibiotics and rescue	**Author's conclusions:** Because of the heterogeneity in interventions, study populations, follow up time and outcome measures, it is not possible to formulate clear recommendations regarding the form and content of self management education programs in COPD. However, it is likely that self management education is associated with a reduction in hospital admissions and improvement in quality of life with no indications for detrimental effects in other outcome measures. **Reviewer's conclusions:** The significant improvement in quality of life was too small to be clinically relevant. The authors' cautious conclusions reflect the heterogeneous studies. **Source of funding:** Netherlands Asthma Foundation **Additional comments:** Wide variation in outcome measures, follow up, participants (severity of disease) and intervention

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				medication	
Internal validity:	+				
Study results – precision:	+				
Applicability (external validity):	+				
Overall score:	+ Suitably cautious conclusions based on heterogeneous evidence base				

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Year and author: Blackstock 2007 **Country:** Australia **Study type:** Systematic review **Evidence level:** I	**Aims:** To determine the benefits of disease-specific health education for people with COPD **Participants:** Primary diagnosis of COPD, mean age ranged from 57 to 70 years, % male 41-100%, FEV1 predicted ranged from 36 to 59% **Search period:** Inception to June 2005 **Search method:** MEDLINE, CINAHL, EMBASE, PsycINFO, Physiotherapy Evidence Database Library, Cochrane Library, reference lists of retrieved papers. Studies published in languages other than English and abstracts excluded.	**Inclusion:** RCTs or clinical controlled trials assessing the impact of education on quality of life and health care utilisation in the COPD population, and at least one of the outcomes described in next column. **Exclusion:** Participants who didn't have a primary diagnosis of COPD, where other chronic diseases were included in the sample, where education was not disease specific to the COPD population, where exercise was also included as an intervention or where the control group did not receive usual medical care.	**Exposure:** Patient education (defined as formal delivery of education on COPD topics with the aim to improve the knowledge and understanding of COPD. Further divided into self management education (education focusing on changing health behaviours through knowledge, goal setting and development of action plans) and didactic education (where participants received education in a passive lecture format with no focus on health behaviour change) Duration: 1-26 hours **Comparison:** Usual medical care (no further details provided) **Outcome measures:** QOL or self efficacy, functional status or health care utilisation (including physician consultation frequency, pharmaceutical usage, hospitalisation, emergency visit or length of stay) **Follow-up time:** Mostly 12 months (4/13 studies had follow up < 6 months).	**Results:** - GP visits (2 studies): MD 0.53 visits (-0.7 to 1.75) NS - Total hospital bed days (2 studies): MD 3.0 (-0.49 to 6.5) NS - Admission to hospital (3 studies): RR 2.3 (1.5 to 3.5) P value not reported - Health-related quality of life (8 studies): 1/8 studies found improvement for some aspects in the education group - Exercise tolerance (4 studies): 4/4 studies found no evidence of a difference - Pulmonary function (2 studies): 1/2 studies found a smaller decline in the education group - Self efficacy (1 study): No evidence of a significant difference	**Author's conclusions:** Didactic educational intervention for the COPD population appeared to have minimal effect on health outcomes, including QOL, health care utilisation, exercise capacity or lung function and is therefore not the education delivery method recommended. Education focusing on self management showed encouraging results with a tendency for improvements in QOL and health care utilisation, but the results did not reach statistical significance and no confident recommendations can be made. **Reviewer's conclusions:** Not possible to combine results in meta-analyses due to the heterogeneity of studies **Source of funding:** Not stated **Additional comments:** Indirect comparisons between didactic and self management education Potential language and publication bias.
Internal validity:	? Mostly rigorous methodology but publication and language bias cannot be excluded				

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Study results – precision:	na				
Applicability (external validity):	+				
Overall score:	? The extent of benefits with patient education aimed at self management is unclear because the inclusion criteria accepted trials of both self management and didactic education; authors attempted to divide the trials according to type of education but indirect comparisons were made and the trials did not directly compare both types of education.				

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Year and author: Lacasse 2006 **Country:** Canada **Study type:** Systematic review **Evidence level:** I	**Aims:** To assess the impact of pulmonary rehabilitation on health-related QOL and exercise capacity in patients with COPD **Participants:** Not reported **Search period:** Inception to July 2004 **Search method:** Cochrane Airways Group Specialised Register of Trials	**Inclusion:** RCTs comparing rehabilitation of at least 4 weeks to conventional community care in patients where at least 90% had COPD **Exclusion:** Trials where the control group had education	**Exposure:** Inpatient, outpatient or home-based rehabilitation program that included exercise therapy with or without any form of education and/or psychological support **Comparison:** Conventional community care **Outcome measures:** Health-related QOL and/or maximal or functional exercise capacity (peak capacity measured in the exercise laboratory using an incremental exercise test and results of timed walk tests) **Follow-up time:** 1 month to 12 months	**Results:** Statistically significant improvements for all outcomes: Chronic Respiratory Questionnaire: for each domain – dyspnoea, fatigue, emotional function and mastery – the effect size exceeded the minimal clinically important difference SGRQ: for each domain – total, symptoms, impact and activity – the effect size exceeded the minimal clinically important difference Maximal exercise capacity: MD 8.4 watts (3.4 to 13.4) Functional exercise capacity: MD 48 m (32 to 65)	**Author's conclusions:** PR relieves dyspnoea and fatigue, improves emotional function and enhances patients' sense of control over their condition. These improvements are moderately large and clinically significant. PR forms an important component of the management of COPD **Reviewer's conclusions:** Difficult to assess the contribution that education and psychological support had to the exercise training in PR **Source of funding:** Merck Frosst Canada, Nederlands Astma Fonds **Additional comments:** 12 of the 31 studies had psych support and/or education in addition to exercise training
Internal validity:	+				
Study results – precision:	+				
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: Peytremann-Bridevaux 2008 **Country:** Switzerland, Canada **Study type:** Systematic review **Evidence level:** I	**Aims:** To assess the effectiveness of COPD disease-management programs **Participants:** Mean age ranged from 62 to 75 years, FEV1 ranged from 31 to 58%, 43-100% male **Search period:** Inception to Dec 2006 **Search method:** MEDLINE, EMBASE, CINAHL, PsycINFO, the Cochrane Library, CENTRAL, and hand searching of reference lists of retrieved articles and reviews	**Inclusion:** Adult patients with COPD, structured interventions of disease management (strictly defined), and not including only inpatients **Exclusion:** Programs offered only in hospital or targeting patients receiving palliative care or with end-stage COPD	**Exposure:** Disease management program (defined as including 2 or more different components (physical exercise, self management, structured follow up), 2 or more health professionals actively involved in patient care, patient education considered and at least 1 component lasting a minimum of 12 months). **Comparison:** Usual care but no other details provided. **Outcome measures:** All cause mortality, lung function, exercise capacity, health-related QOL, respiratory symptoms, acute exacerbations and health care use. **Follow-up time:** Primarily 12 months, but some outcomes reported at 18 and 24 months.	**Results:** - Lung function tests: 1/7 studies found a statistically significant, but not clinically significant, change in FEV1 (<12% improvement) - Exercise capacity: In 5/7 studies measuring this outcome, WMD 32.2 m (4.1 to 60.3) favouring disease management (p=0.02) - Health-related QOL: 9/13 studies found positive effects in some aspects of QOL for the intervention group - Symptoms: 2/7 studies found improvements in symptoms for the intervention group - Exacerbations: 1/3 studies found fewer exacerbations in the intervention group - Health care use: 7/10 studies found lower hospitalisation rates and outpatient visits in the intervention group	**Author's conclusions:** Disease management programs for patients with COPD slightly improve exercise capacity and quality of life and reduce hospitalisation. **Reviewer's conclusions:** Unclear which aspects of the program contributed to the benefits **Source of funding:** Grant from the Bourse de la commission pour la promotion academique des femmes, faculte de biologie et medicine de l'universite de Lausanne **Additional comments:** Long term (12 months or more) Mixture of both qualitative synthesis (narrative) and MA (only for exercise capacity and mortality) Heterogeneous population and intervention.
Internal validity:	+				

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Study results – precision:	+ Summary effect measures could only be generated for 2 outcomes				
Applicability (external validity):	? Heterogeneous population and interventions mean it is unclear how to apply results without further stratification according to individual features of programs				
Overall score:	+ Uncertain applicability but well designed good quality RCT				

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Year and author: Puhan 2010 **Country:** USA **Study type:** Systematic review - Cochrane **Evidence level:** I	**Aims:** To assess the effects of pulmonary rehabilitation (PR) after COPD exacerbations on future hospital admissions and other patient-important outcomes (mortality, health-related QOL and exercise capacity) **Participants:** Mean age 62-70 years, mean FEV1 predicted 36-52%, 41-90% male **Search period:** Inception to March 2010 **Search method:** CENTRAL, MEDLINE, EMBASE, PEDRO, Science Citation Index and the Cochrane Airways Register of Controlled Trials	**Inclusion:** RCTs, COPD patients after in or outpatient care for acute exacerbation, in or outpatient program of PR, including at least physical exercise, outcomes detailed in next column **Exclusion:** Not reported	**Exposure:** Inpatient and/or outpatient PR program, including at least physical exercise, delivered to patients who have received acute care for an exacerbation of COPD. **Comparison:** Usual care – conventional community care **Outcome measures:** Primary: future hospital admissions Secondary: mortality, health-related QOL, exercise capacity **Follow-up time:** Ranged from 11 days to 4 years (mostly >3 month)	**Results:** Hospital admissions: OR 0.22 (0.08 to 0.58), NNT 4 (3 to 8) over 25 weeks Health-related QOL: CRQ: MD for emotional function and mastery domains between 0.81 (fatigue: (0.16 to 1.45)) and 0.97 (dyspnoea: (0.35 to 1.35)) SGRQ total score: MD -9.88 (-14.4 to -5.37); impacts domain: MD -13.94 (-20.37 to -7.51) and activity limitation domain: MD -9.94 (-15.98 to -3.89) No significant difference for the symptoms domain of the SGRQ Exercise capacity: 6 minute walk test: MD 77.7m (12.21 to 143.20); shuttle walk test: MD 64.35 (41.28 to 87.43) (improvement >MID) No adverse events	**Author's conclusions:** PR is a highly effective and safe intervention to reduce hospital admissions and mortality and to improve health-related QOL in COPD patients who have recently had an exacerbation of COPD **Reviewer's conclusions:** Conclusion based on evidence from 9 small studies of moderate methodological quality. Large effects found; positive effects unlikely to be overturned by negative unpublished studies. **Source of funding:** Not stated **Additional comments:** Applicability enhanced by calculation of NNTs and MID
Internal validity:	+				
Study results – precision:	+ large effects				

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Applicability (external validity):	+				
Overall score:	+ rigorous Cochrane review				

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Year and author: Taylor 2005 **Country:** UK **Study type:** Systematic review **Evidence level:** I	**Aims:** To determine the effectiveness of innovations in management of chronic disease involving nurses for patients with COPD **Participants:** Mean age ranged from 63 to 71 years, moderate to severe COPD, FEV1 predicted ranged from 0.78 to 1.8 l or 27% to 50%, 36-85% male **Search period:** January 1980 to January 2005 **Search method:** 16 electronic English language databases and 8 Dutch databases, hand searching conference procedings and writing to authors and researchers for unpublished studies	**Inclusion:** RCTs, evaluating clinical service interventions or packages of care aimed at improving the management of COPD patients in the community, inpatient, outpatient or community based interventions that were either nurse led, nurse coordinated or largely delivered by nurses **Exclusion:** Drug trials, hospital at home or early discharge schemes for patients with acute exacerbations, educational interventions directed solely at other health care providers, studies in which a substantial proportion of participants did not have COPD	**Exposure:** Interventions for chronic disease management led by nurses – variations on a case management approach using home visits but promotion of self care or self management was a major component **Comparison:** Not clearly specified **Outcome measures:** Mortality, use of health care resources, activities of daily life, patients health-related QOL, carers QOL **Follow-up time:** All > 3 months, most were 12 months 2 trials had short term interventions – 1 month duration. All other trials had longer term interventions – approx. 12 months	**Results:** No figures reported but judgments made based on the evidence. Possible benefits for: - ED visits - Patient knowledge 'Equivocal' evidence of effect for: - Hospital readmissions - Days spent in hospital - GP visits No or weak evidence for: - Self management skills - Smoking cessation - Patients and carers satisfaction - Carers QOL - Effect on other community services No difference for: - Patient QOL - Patient psychological well being - Impairment and disability - COPD exacerbations - Pulmonary function	**Author's conclusions:** There is little evidence to date to support the widespread implementation of nurse led management interventions for COPD **Reviewer's conclusions:** Wide variations in the interventions that were eligible; insufficient evidence to make clear recommendations **Source of funding:** NHS research and development service delivery and organisation program **Additional comments:** Insufficient evidence base. Also poor synthesis of included studies.

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
				- Mortality - Out patient visits - Psychological well being - Social support - Unscheduled or respiratory readmission - Symptoms	
Internal validity:	+				
Study results – precision:	X studies not well synthesized – judgments made about reliability of the evidence without full discussion of the findings of individual studies				
Applicability (external validity):	X results either equivocal or based on weak evidence – requires further research				
Overall score:	? evidence base insufficient to reach reliable conclusions other than the need for more research				

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Year and author: Walters 2010 **Country:** Australia **Study type:** Systematic review **Evidence level:** I	**Aims:** To determine whether action plans for the management of exacerbations improve health outcomes in people with COPD **Participants:** Mean age 60-72 years, 34-67% male, mean FEV1 predicted 35-64% **Search period:** Inception to July 2009 **Search method:** Cochrane Airways Group Specialised Register of RCTs, CENTRAL, CINAHL, MEDLINE, National Research Register of Ongoing Trials, reference lists of retrieved studies	**Inclusion:** RCTs, patients with primary COPD diagnosed by clinical criteria such as GOLD, history of smoking, action plans vs usual care. For eligible outcomes, see next column **Exclusion:** Participants with a primary diagnosis of asthma, broader self management support interventions even if they included action plans	**Exposure:** Action plan – defined as the use of guidelines detailing self initiated interventions which are undertaken in response to alterations in the state of patients COPD – educational component permitted if duration was short, up to 1 hour **Comparison:** Usual care **Outcome measures:** Primary: health care utilisation (including hospital admission, treatment in ED, GP visits), use of medications Secondary: Health-related QOL, COPD self management knowledge and actions, acute exacerbations, mortality, psychological morbidity, lung function, functional capacity, symptoms scores, days lost from work **Follow-up time:** 6 – 12 months	**Results:** No evidence of group differences for: - Hospital admission - ED visits - GP visits Significant group differences for: - Use of oral corticosteroids: MD 0.74 (0.14 to 1.35) - Rx with antibiotics (OR 1.65 (1.01 to 2.69) - Recognition of a severe exacerbation: MD 2.50 (1.04 to 3.96) - Self initiating action in a severe exacerbation: MD 1.5 (0.62 to 2.38) No evidence of group differences for: - Health-related QOL - Psychological morbidity - Mortality - Symptom scores - Functional capacity - Lung function - Days lost from work - Satisfaction with care	**Author's conclusions:** Action plans with limited COPD education aid recognition of and response to an exacerbation with initiation of antibiotics and corticosteroids. There is no evidence of reduced health care resources utilisation or improved health-related QOL. The practice of giving patients an action plan and limited self management education for the management of COPD exacerbations, without a multi-faceted self management program or ongoing case management, cannot be recommended as a standard of care in COPD **Reviewer's conclusions:** Because the evidence base is small, the review may be underpowered to adequately assess effects on some outcomes **Source of funding:** University of Tasmania, Commonwealth Department of Health and Aging **Additional comments:** Well designed SR but based on small studies with limited numbers of participants

Reference	Aims, participants and search method	Inclusion and exclusion criteria	Exposure, comparison and outcome measures	Results	Conclusions, quality issues
Internal validity:	+				
Study results – precision:	+				
Applicability (external validity):	+				
Overall score:	+ Suitably cautious conclusions, based on limited evidence				

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Berry 2010 **Country:** USA **Study type:** RCT **Evidence level:** II	**Aims:** To compare the effectiveness of a traditional exercise therapy (TET) program with a behavioural lifestyle activity program (LAP) in promoting physical activity	**Study setting:** Community **Participant characteristics:** Mean age 66 years, mean current smoking rate 26-29%; moderate to very severe disease severity 92-94%; 54% male participants, mean FEV1 predicted 51-53% **Inclusion:** FEV1/FVC < 70%; FEV1 ≥ 20% of predicted; difficulty in performing daily activities because of dyspnea; free of significant ACD or peripheral vascular disease; not undergoing Rx for cancer, free from uncontrolled hypertension or diabetes, not participated in a pulmonary rehabilitation or exercise program for the previous 3 months; willing to accept randomisation into either arm **Exclusion:** Not reported	**Exposure: n=87** (Centre based exercise therapy and bimonthly education classes at a clinic + behavioural goal setting program for independent exercise (LAP)) **Comparison: n=89** (Centre based exercise therapy and bimonthly education classes at a clinic (TET)) Duration=3 months **Outcome measures:** Primary: Weekly energy expenditure from moderate physical activity (measured by Community Health Activities Model Program for Seniors (CHAMPS)) Secondary: • Physical function (walk, climb, balance measured by Short Physical Performance Battery (SPPB) • Self reported disability • Health-related quality of life (measured by CESD, subscales from RAND Health Survey, Chronic Respiratory Disease Questionnaire)	**Results:** Physical activity levels: No significant differences between groups Physical function: No significant differences between groups Self reported disability: No significant differences between groups Quality of life: No significant differences between groups Exercise capacity: No significant differences between groups Safety: No significant differences between groups in serious adverse events	**Author's conclusions:** Although there was no difference between treatment groups, the TET and LAP were both effective at increasing moderate levels of physical activity at 3 months and maintaining moderate physical activity levels 12 months post randomisation **Reviewer's conclusions:** Not clear whether beneficial effects can be maintained longer term > 12 months **Source of funding:** National Institutes of Health grants HL 53755, AG 21332 and M01 RR07122 **Additional comments:** No non exercise control group

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
			• Exercise capacity (peak oxygen consumption) • Pulmonary function (measured by plethysmograph) • Compliance • Safety outcomes (death, adverse event, hospitalisation, significant disability) **Follow-up time:** 3, 6 and 12 months		

Bias	Judgement	Support for judgement
Random sequence generation	Low risk	Web-based randomisation application using blocks of 4 to 6 participants
Allocation concealment	Low risk	Only the statisticians unblinded to the randomisation scheme
Blinding	Low risk	Assessors blinded
Incomplete outcome data	Unclear risk	26/87 analysed in LAP group and 69/89 analysed in TET group; analyses performed of dropouts; similar rates between groups
Selective reporting	Low risk	Protocol not identified but unlikely that other outcomes could have been measured

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Casas 2006 **Country:** Spain and Belgium **Study type:** RCT **Evidence level:** II	**Aims:** To assess whether a simple well defined integrated care intervention with the support of information and communication technologies is effective in the prevention of hospitalisations for exacerbations in COPD patients	**Study setting:** Community (shared care between primary care, hospital and community services) **Participant characteristics:** Moderate to severe COPD, mean age 70-72 years, proportion male 77-88%, mean FEV1 predicted 41-43% **Inclusion:** COPD patients with a previous episode of exacerbation requiring hospitalisation > 48 hours **Exclusion:** Not living in the health care area, severe comorbid conditions and extremely severe neurological or cardiovascular disorders, logistical limitations due to extremely poor social conditions, being admitted to a nursing home	**Exposure: n=65** Integrated care intervention (IC) – included individually tailored care plan upon discharge shared with the primary care team, comprehensive educational program and accessibility to a specialized nurse case manager through a web based call centre. Weekly phone calls **Comparison: n=90** Usual care (UC) – discharged from hospital by physician who decided on the outpatient control regimen following standard protocols. Visits scheduled by physician every 6 months **Outcome measures:** Hospital admissions, mortality **Follow-up time:** 1, 3, 6, 9 and 12 months	**Results:** Rehospitalisation rate, IC versus UC: HR 0.55 (0.34 to 0.87), p=0.01 Mortality, IC versus UC: 19% versus 16%, NS	**Author's conclusions:** A standardised integrated care intervention based on shared care arrangements among different levels of the system with support of information technologies effectively prevents hospitalisations for exacerbations in COPD patients **Reviewer's conclusions:** Although groups not equal at baseline, statistical analyses adjusted for the differences. Strict exclusion criteria limits the applicability of the findings **Source of funding:** CHRONIC project (IST-1999/12158) from the European Union; Marato de TV3, Comissionat per a Universitats I Recerca de la Generalitat de Catalunya (SGR-00386), Red Respira Instituto de Salud Carlos III (ISCIII)-Redes Tematicas de Investigacion Cooperativa (RTIC)-03/11, Red Telemedicina ISCIII-RTIC-03/117 **Additional comments:** Unequal numbers in the groups relates to a different randomisation sequence used in Spain (1:2 ratio). Statistical analysis allowed for adjustment for variables which were different at baseline. Differential care

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
					between the 2 sites

Bias	Judgement	Support for judgement
Random sequence generation	Low risk	Computer generated numbers
Allocation concealment	Low risk	Blindly assigned
Blinding	Unclear risk	Unlikely but not reported
Incomplete outcome data	Low risk	Dropouts due to exclusions or death
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: Coultas 2005 **Country:** USA **Study type:** RCT **Evidence level:** II	**Aims:** To investigate the effectiveness of increasing access to selected components of PR by providing nurse-assisted home care that was composed of patient education, efforts to improve patient self management skills and enhanced follow up	**Study setting:** Primary care clinics **Participant characteristics:** Mean age 69 years, 57% female **Inclusion:** Diagnosis of COPD, 45 years or more, current or former smoker with at least a 20-pack-year smoking history and at least one respiratory symptom during the past 12 months, airflow obstruction (FEV1/FVC < 70% and FEV1 < 80% predicted **Exclusion:** Not stated	**Exposure:** **(1) n=72** Nurse-led medical management – trained according to GOLD guidelines – included education, patient self management, smoking cessation, follow up and action plan for exacerbations **(2) n=72** Nurse-led collaborative management – trained according to GOLD guidelines – included medical management training plus training in collaborative care – patient centred and intended to facilitate the adoption of healthy behaviours, including lifestyle and self management skills. **Comparison: n=73** Usual care – educational booklets and advice to follow recommendations of physician **Outcome measures:** Primary: health-related QOL (SGRQ), generic QOL (SF-36), illness intrusiveness scale and self reported health care utilisation **Follow-up time:** 6 months	**Results:** Illness intrusiveness scale: Difference between collaborative care and usual care: -7.0 (-15 to -0.5), p value not reported. No evidence of significant group differences for any other health-related QOL measures, generic QOL measures or self reported health care utilisation	**Author's conclusions:** Interventions to enhance patient education, self management skills and follow up among patients with COPD do not result in clinically meaningful improvements in health status or self reported health care utilisation **Reviewer's conclusions:** Results possibly underpowered to find differences **Source of funding:** Not stated **Additional comments:**

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Bias	**Judgement**			**Support for judgement**	
Random sequence generation	Low risk			Computer generated numbers	
Allocation concealment	Unclear risk			No details	
Blinding	Unclear risk			No details	
Incomplete outcome data	High risk			22/73 (30.1%) in usual care group, 23/72 (32%) in medical management group and 21/72 (29%) in collaborative management group withdrew (reasons given)	
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: Efraimsson 2008 **Country:** Sweden **Study type:** RCT **Evidence level:** II	**Aims:** To examine the effects of a structured educational intervention program at a nurse-led primary health care clinic on quality of life, knowledge about COPD and smoking cessation in patients with COPD	**Study setting:** Nurse-led primary health care clinic **Participant characteristics:** Mean age 68 years, 50% male, mild to very severe COPD **Inclusion:** Patients diagnosed with mild, moderate, severe or very severe COPD based on spirometry, lung capacity after bronchodilator use, based on GOLD criteria **Exclusion:** Patients diagnosed with severe mental disorders, excluding anxiety and depression	**Exposure: n=26** Standard care + 2 extra visits to a nurse who delivered education with an emphasis on self-care ability and support of patients based on their requirements and abilities to cope with disease and treatment – included motivational dialogue, counseling and individual treatment plan) **Comparison: n=26** Standard care – 2 visits to the COPD clinic) **Outcome measures:** QOL (measured by SGRQ), knowledge of COPD, smoking status **Follow-up time:** At end of treatment which occurred over 3 to 5 month interval	**Results:** Change from baseline values: - SGRQ: perceived symptoms: Average 25.2 units change in intervention group – difference between intervention and control, p=0.00035. - SGRQ: perceived restrictions in daily living because of dyspnoea: Average 5.6 units change in intervention group – difference between intervention and control, p=0.03 - SGRQ: psycho-social health: Average 3.4 units change in intervention group – difference between intervention and control, p=0.02 - SGRQ: QOL: Average 8.2 units change in intervention group – difference between intervention and control, p=0.0003 - Smoking status: 6/16 in intervention group stopped smoking 0/14 in control group stopped smoking, p=0.02 - Knowledge about COPD: 19/26 in intervention group	**Author's conclusions:** A statistically significant increase was found in the intervention group on QOL, the number of patients that stopped smoking and patients' knowledge of COPD on follow up. A structured program with self care education is needed to motivate patients for lifestyle changes. **Reviewer's conclusions:** Benefits found for the self care management program may have been influenced by the Hawthorne effect where participants in the self care group were in a dependent relationship with one of the researchers. Some of the participants in the control group were disappointed that they were not assigned to the intervention group. **Source of funding:** County Council of Dalarna, Sweden **Additional comments:** Possible confounding from one of the researchers performing the intervention – Hawthorne effect Not all patient population were smokers.

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
				reported good knowledge 5/26 in control group reported good knowledge, p<0.001	

Bias	Judgement	Support for judgement
Random sequence generation	Low risk	Drew lots for randomisation
Allocation concealment	Low risk	Independent person performed allocation
Blinding	High risk	No blinding
Incomplete outcome data	Low risk	Analyses appear to be ITT but 10/52 participants dropped out - not clear what their group allocation was
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: Gadoury 2005 **Country:** Canada **Study type:** RCT **Evidence level:** II	**Aims:** To assess the long term impact on hospitalisation of a self management program for COPD patients	**Study setting:** Study visits in hospital but home management **Participant characteristics:** Mean age 69 years, mean FEV1 ranged from 0.98 to 1.0 L, moderate to severe COPD, 52-59% male **Inclusion:** Aged 50 years or more, current or former smokers, FEV1 < 70% predicted, hospitalised once or more for COPD exacerbation in the preceding year **Exclusion:** Asthma as primary diagnosis, major comorbidities such as documented left ventricular failure and any terminal disease, dementia or uncontrolled psychiatric illness	**Exposure: n=96** Self management – a multi component program 'Living Well with COPD' consisting of 1 hour each week of skill oriented teaching for 7 to 8 weeks – included patient workbook, action plan for exacerbations and simple home exercise program **Comparison: n=95** Standard care – managed by usual physicians **Outcome measures:** Primary: all cause hospital admissions Secondary: all cause emergency visits **Follow-up time:** 1 and 2 years	**Results:** 2 year follow up Hospitalisations per patient-year: 1.21 in self management group, 1.65 in control group, MD -0.44 (-0.68 to -0.21), p value not reported ED visits per patient year: 2.5 in self management group, 3.2 in control group, MD -0.7 (-0.58 to -0.82), p value not reported	**Author's conclusions:** Patients with COPD who received educational intervention with supervision and support based on disease-specific self management maintained a significant reduction in hospitalisations after a 2 year period **Reviewer's conclusions:** The effects on reduction in health care resources were less at 2 years follow up than at one year follow up but still significantly different. This could be partially explained by imperfect implementation of the program in the second year of the study. Any contamination of the intervention during later follow up would lead to an under estimation of the results, but the findings were still significant. **Source of funding:** Fond de la recherché en santé de Quebec and an unrestricted grant from Boehringer Ingelheim Canada **Additional comments:** Later f up of RCT (Bourbeau 2003) which found that self management reduced the utilisation of health services and improved health status in the short term (1 year)
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	High risk			No blinding	
Incomplete outcome data	Low risk			11/95 withdrew by 2 years in intervention group (2 data not available, 9 deaths); 5/96 withdrew by 2 years in control group (all deaths)	
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: Garcia-Aymerich 2007 **Country:** Spain **Study type:** RCT **Evidence level:** II	**Aims:** To assess the effectiveness of an integrated care intervention compared to usual care in COPD patients with recent exacerbations of COPD	**Study setting:** Patients recruited consecutively from the hospital setting and administered after discharge **Participant characteristics:** Mean age 72 to 74 years, 86% male, FEV1 predicted 1.0 to 1.2 l **Inclusion:** COPD patients admitted to hospital because of an episode of exacerbation requiring hospitalisation for > 48 hours. **Exclusion:** Not living in the health care area or living in a nursing home; lung cancer or other advanced malignancy; logistic limitations; extremely severe neurological or cardiovascular comorbidities.	**Exposure: n=44** Usual care and integrated care, including: comprehensive assessment of patient at discharge, educational session of 2 hours on self management of the disease, individually tailored care plan, following international guidelines, access to health professionals through a web based call centre **Comparison: n=69** Usual care: included pharmacological prescriptions at discharge and in hospital treatment following standard protocols **Outcome measures:** Clinical status (including dyspnoea score FEV1 etc), health-related QOL (measured by SGRQ), generic health-related QOL (measured by Euroqol), life style factors (smoking and physical activity status etc), knowledge about COPD, adherence, correct techniques, long term oxygen therapy, vaccination status, use of medications, satisfaction with health care **Follow-up time:** 6 and 12 months	**Results:** - BMI: Llinear regression coefficient 1.34kg (0.31 to 2.37), p=0.012 (increase in intervention group) - COPD knowledge: Name of disease, 81% vs 44%, p=0.005 Identification of COPD exacerbation, 85% versus 22%, p<0.001 Early Rx of COPD exacerbation, 90% vs 60%, p=0.036 (chi square analyses, figures not reported) - Adherence to inhaled treatment 71 versus 37%, p=0.009 (chi square, figures not reported) - Correct inhaler manoeuvre 86 vs 24%, p<0.001 (chi square, figures not reported) There were no significant differences between groups for any of the other outcomes measured, including QOL, clinical status, lifestyle factors, medication use or satisfaction	**Author's conclusions:** Integrated care improved disease knowledge and treatment adherence after one year of intervention, suggesting that these factors may play a role in the prevention of severe COPD exacerbations triggering hospital admissions **Reviewer's conclusions:** Due to large attrition and small sample, the conclusions of the authors should be considered tentative. **Source of funding:** Linkcare eTEN C517435 (European Union), Marato de TV3, Comissionat per a Universitats i Recerca de la Generalitat de Catalunya (SGR-00386) and Red Respira-ISCIII-RTIC-03/11 and Red Telemedicina ISCIII-RTIC-03/117 **Additional comments:** Large attrition could have biased findings. Interventions delivered over 12 months but small sample. Insufficient detail provided on analyses performed. This study is a later analysis of participants in a single centre in a two centre RCT (Casas 2006),

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

Bias	Judgement	Support for judgement
Random sequence generation	Low risk	Computer generated numbers
Allocation concealment	Low risk	Assignment blinded
Blinding	Unclear risk	Unclear if participants blinded
Incomplete outcome data	High risk	At 12 months follow up, 23/44 (53%) had withdrawn or dropped out in interv group and 28/69 (41%) had withdrawn or dropped out in the control group
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: Hospes 2009 **Country:** Netherlands **Study type:** RCT **Evidence level:** II	**Aims:** To assess whether a 12 week pedometer-based exercise counselling strategy is feasible and effectively enhances daily physical activity in outclinic COPD patients who do not participate in a PR program	**Study setting:** Outpatient clinic **Participant characteristics:** Mean age ranged from 61 to 63 years, mostly stage II COPD, mean FEV1 predicted ranged from 62 to 67%, 56-65% male **Inclusion:** Diagnosis of stable COPD and aged between 45 and 75 years **Exclusion:** Significant comorbidity interfering with physical activity	**Exposure: n=20** Exercise counseling designed to enhance physical activity – included principles of goal setting, implementation of goals, motivational interviewing technique – 5 sessions over 12 weeks **Comparison: n=19** Usual care All patients wore a pedometer **Outcome measures:** Primary: daily physical activity (pedometer) Secondary: pulmonary function (spirometer), physical fitness, health-related QOL (Clinical COPD Questionnaire, SGRQ, SF-36), fatigue (Dutch Exertion Fatigue Scale), depression (BDI), self efficacy (LIVAS), motivation (Exercise Self Regulation Questionnaire) **Follow-up time:** 12 weeks	**Results:** Physical activity (mean steps per day): 7872 (3962) in intervention group, 6172 (3194) in control group, p=0.01 (increase of 11% versus decrease of 18%) Leg strength: 13.3 (2.4) in intervention group, 10.9 (2.8) in control group, p=0.01 Arm strength: 18.9 (4.9) in intervention group, 15.1 (4.4) in control group, p=0.03 SGRQ total score: 34.2 (13.5) in intervention group, 38.3 (16.8) in control group, p=0.05 Intrinsic motivation score in the Exercise Self Regulation Questionnaire: 5.5 (1.5) in intervention group, 5.0 (1.4) in control group, p=0.01 No significant differences for other physical fitness scores, Clinical COPD Questionnaire scores, SF-36 scores, fatigue, depression, self efficacy and other motivation scores.	**Author's conclusions:** A 12 week pedometer-based exercise counselling strategy is feasible and effectively enhances daily physical activity, physical fitness, health-related QOL and intrinsic motivation in outclinic COPD patients who do not participate in a rehabilitation program **Reviewer's conclusions:** Study significantly underpowered – authors conclusions may be overstated as only some physical fitness measures and one health-related QOL measure were significantly different between groups **Source of funding:** Research grant from Boehringer Ingelheim BV **Additional comments:** Very short term study
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	High risk			No blinding	
Incomplete outcome data	Low risk			2/20 (10%) in intervention group and 2/19 (11%) dropped out (reasons given)	
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: Karapolat 2007 **Country:** Turkey **Study type:** RCT **Evidence level:** II	**Aims:** To evaluate the short term benefits of a PR program in COPD patients	**Study setting:** Outpatient clinic **Participant characteristics:** Mild and moderate COPD, mean age ranged from 65 to 67 years, mean FEV1 predicted was 55%, 81-94% male **Inclusion:** FEV1 30 to 80% predicted, clinical condition stable, no infections or COPD exacerbations in preceding 4 weeks **Exclusion:** Other severe medical problems such as heart failure, recent MI, CVD, orthopaedic problems and severe liver or kidney problems	**Exposure: n=27** Rehabilitation program – 8 week outpatient program with education and an exercise training component – included advice and coping strategies **Comparison: n=22** No rehabilitation program – no other details given **Outcome measures:** Lung function, arterial oxygenation, dyspnea, walking distance, health-related QOL **Follow-up time:** At end of intervention (8 weeks) and 12 weeks	**Results:** 8 week data: Dyspnoea (VAS): 3.1 (1.6) in intervention group, 5.8 (1.8) in control group, p<0.05 Walking distance (m): 383.2 (50.4) in intervention group, 241.9 (57.4) in the control group, p<0.05 SGRQ Total Score: 28.3 (15.2) in intervention group, 47.0 (17.3) in control group, p<0.05 12 week data: Dyspnoea (VAS): 4.1 (2.1) in intervention group, 6.1 (2.0) in control group, p<0.05 Walking distance (m): 308.6 (58.2) in intervention group, 215.7 (64.1) in control group, p<0.05 SGRQ Total score: 35.6 (16.2) in intervention group, 46.5 (17.5) in control group, p<0.05 There was no evidence of group differences for any of the measures of lung function or arterial oxygenation	**Author's conclusions:** Rehabilitation resulted in improvements in exercise capacity, health status and dyspnea, which deteriorated in the first month after rehabilitation finished. **Reviewer's conclusions:** The findings showed a deterioration in the effects of rehabilitation by 12 weeks which suggests that rehabilitation may not have long term effects, unless additional programs of encouragement etc are put in place **Source of funding:** Not stated **Additional comments:** Very short term study

Bias	Judgement	Support for judgement
Random sequence generation	Low risk	Sealed envelopes

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Allocation concealment	Low risk			Sealed envelopes	
Blinding	Unclear risk			Unlikely to be blinded	
Incomplete outcome data	High risk			1/27 (4%) in intervention group and 8/27 (30%) did not complete the study; reasons given	
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: Khdour 2009 **Country:** UK **Study type:** RCT **Evidence level:** II	**Aims:** To investigate the impact of a disease and medicine management program, focusing on self management in patients with COPD	**Study setting:** Recruited from hospital outpatient clinic and delivered by pharmacist in consultation with a consultant. Patients reviewed at outpatient clinic **Participant characteristics:** Most patients were elderly (mean age 66-67 years), not highly educated and and had moderate to severe COPD (FEV1 about 50% predicted), 44% male **Inclusion:** Confirmed diagnosis of COPD for at least 1 year, FEV1 30 to 80% predicted and >45 years old. **Exclusion:** Congestive heart failure, moderate to severe learning difficulties, attended PR program in last 6 months, severe mobility problems or terminal illness	**Exposure: n=86** Disease and medicine management program: education on COPD, prescribed medication, importance of adherence, inhaler technique, and management of symptoms. Emphasized the importance of exercise and correct technique. Also included motivational interviewing, customised action plan and attempts to increase self efficacy **Comparison: n=87** Usual hospital outpatient care from medical and nursing staff **Outcome measures:** Health resources utilisation, health-related disease-specific QOL (measured by SGRQ), FEV1, body mass index, adherence to prescribed medication, knowledge of medication and disease management **Follow-up time:** 6 and 12 months	**Results:** Health resource utilisation at 1 year: ED visits:40 versus 80, p=0.02 Hospital admission: 26 versus 64, p=0.01 Health-related QOL at 1 year: Symptoms: difference -7.5 (-14.1 to 0.1), p=0.04 Impact: difference -7.4 (-14 to 0.6), p=0.03 No differences between groups for activity domain or total score No significant differences between groups for FEV1 predicted or BMI at 1 year. Adherence to medication at 1 year: 77.8% versus 60%, p=0.019 Knowledge of medication and disease management at 1 year: Median 75.0 versus 59.3, p=0.001	**Author's conclusions:** The clinical pharmacy-led management program can improve adherence, reduce the need for hospital care in patients with COPD and improve aspects of their health-related QOL **Reviewer's conclusions:** Findings suggested a drop off in benefits of the intervention over time. Not clear how health-related QOL benefited, as intervention impacted on only some domains **Source of funding:** Chest Heart and Stroke (Northern Ireland) **Additional comments:** Some analyses may be underpowered as recruitment did not reach required sample size.
Bias	**Judgement**		**Support for judgement**		

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Random sequence generation	Low risk			Minimisation technique	
Allocation concealment	Unclear risk			No details	
Blinding	Unclear risk			Unlikely to be blinding	
Incomplete outcome data	Low risk			Similar reasons for drop outs. 17% in each group	
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: Kunik 2008 **Country:** USA **Study type:** RCT **Evidence level:** II	**Aims:** To compare cognitive behavioural therapy (CBT) treatment for anxiety and depression with COPD education for COPD patients with moderate to severe anxiety and/or depressive symptoms	**Study setting:** Medical centre **Participant characteristics:** Veterans, mostly male, mean FEV1 predicted 57.2% **Inclusion:** Diagnosis of COPD confirmed with spirometry, moderate anxiety and/or moderate depression (measured by BAI, BDI and DSM-IV), treatment by a primary care provider or pulmonologist **Exclusion:** Cognitive disorder (score of 23 or less on MMSE), psychotic disorder, current non-nicotine substance abuse or dependence	**Exposure: n=118** CBT: 8 1 hour sessions integrating interventions for anxiety and depression – included education and awareness training, relaxation training, increasing pleasurable activity and decreasing anxiety-related avoidance, cognitive therapy, problem-solving techniques, sleep management skills, skills review and planning for maintenance of gains **Comparison: n=120** 8 1 hour sessions of COPD education – included breathing strategies and airway management, pathophysiology of lung disease, medications, use of oxygen, avoidance of environmental irritants, nutrition, exercise, smoking cessation and end of life planning Trained therapists administered both treatments **Outcome measures:** Primary: Disease-specific and generic QOL (measured by Chronic Respiratory Questionnaire (CRQ) and Medical Outcomes Survey Short Form-36 (SF-36)) Secondary: anxiety (BAI), depressive symptoms (BDI), 6	**Results:** There were no significant differences between groups in the rate of change from baseline to follow up for any of the QOL measures, anxiety symptoms, depressive symptoms, 6 minute walk distance and use of health services. For both groups, the difference between baseline scores and end of treatment scores was significantly different for all domains of the CRQ, BDI, BAI, mental health and emotional composite from the SF-36, and 6 minute walk distance.	**Author's conclusions:** CBT group treatment and COPD education can achieve sustainable improvements in QOL for COPD patients experiencing moderate to severe symptoms of depression or anxiety **Reviewer's conclusions:** Potential for large confounding – opportunity for intervention group to have substantial interaction and support in comparison to the control group. Limited generalizability. About 40% of participants did not have a clinical diagnosis of depression **Source of funding:** Grant No. IIR 00-097 from the Department of Veterans Affairs **Additional comments:** Significant dropout could have caused bias

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
			minute walk distance and use of health services **Follow-up time:** 4, 8 and 12 months		

Bias	Judgement	Support for judgement
Random sequence generation	Low risk	Computer generated block randomisation
Allocation concealment	Low risk	Statistician in charge of allocation concealment
Blinding	Unclear risk	Not reported
Incomplete outcome data	High risk	Outcomes assessed at 1 year follow up; 64/120 analysed in control group, 56/118 analysed in intervention group. Analyses of dropouts undertaken to compare group
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: Lamers 2010 **Country:** Netherlands **Study type:** RCT **Evidence level:** II	**Aims:** To evaluate the effectiveness of a nurse-led Minimal Psychological Intervention (MPI) in reducing depression and anxiety and improving disease-specific QOL in elderly COPD patients	**Study setting:** Primary care **Participant characteristics:** Mean age 71 to 72 years, 58-61% male **Inclusion:** Patients aged 60 years or older with a diagnosis of COPD with minor depression, mild major depression, moderate major depression or dysthmia **Exclusion:** Patients with severe major depression and patients with suicidal risk, bedridden patients, those on a waiting list for a nursing home, those using antidepressants, major psychiatric conditions, receiving psychosocial/psychiatric treatment, serious cognitive problems, recently lost spouse, not fluent in Dutch	**Exposure: n=96** MPI: nurse administered minimal psychological intervention which included elements of CBT and self-management, tailored to individual patients, 2 to 10 visits over 3 months (adherence to protocol checked) **Comparison: n=91** Usual care according to Dutch clinical guidelines for the treatment of COPD **Outcome measures:** Depressive symptoms (measured by BDI), anxiety (measured by the anxiety subscale of the Symptom Checklist-90 (SCL), disease-specific QOL (measured by SGRQ) **Follow-up time:** 1 week, 3 months, 9 months	**Results:** Mean difference between interv and control groups: BDI at 9 months: MD 2.92 (0.17 to 5.68), p=0.04 No differences for other follow up SCL at 9 months: MD 3.69 (1.29 to 6.09), p=0.003 No differences for other follow up SGRQ Activity at 1 week: MD 7.52 (2.39 TO 12.66), P=0.004 SGRQ at 3 months: MD 6.37 (0.87 to 11.87), p=0.02 No differences for 9 month follow up SGRQ Impact at 3 months: MD 6.35 (1.1 to 11.61), p=0.02 SGRQ Impact at 9 months: MD 8.62 (3.04 to 14.21), p=0.003 No differences for 1 week follow up No differences for SGRQ Symptoms subscale SGRQ Total at 1 week: MD 5.14 (0.59 to 9.70), p=0.03 SGRQ Total at 3 months: MD 6.97 (2.14 to 11.80), p=0.005	**Author's conclusions:** Nurse-led MPI reduced symptoms of depression and anxiety and improved disease-specific QOL in elderly COPD patients **Reviewer's conclusions:** Well designed study **Source of funding:** Netherlands Organisation for Health Research and Development, program on Health Care Efficiency Research, grant no. 945-03-047 **Additional comments:** Previous protocol identified, well designed study with minimal risk of bias. High attrition but used LOCF.

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
				SGRQ at 9 months: MD 7.94 (2.67 to 13.32), p=0.004	

Bias	Judgement	Support for judgement
Random sequence generation	Low risk	Computer generated
Allocation concealment	Low risk	Externally controlled
Blinding	High risk	No blinding
Incomplete outcome data	High risk	38/96 had dropped out in intervention group at 9 months follow up; 0/91 dropped out of the control group at 9 months follow up. Details of reasons given.
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: McGeogh 2006 **Country:** New Zealand **Study type:** RCT **Evidence level:** II	**Aims:** To assess whether self management plans in primary care have beneficial effects on quality of life, self-care behaviour and health outcomes in the long term for patients with COPD	**Study setting:** General practices in Christchurch, NZ **Participant characteristics:** Mean age: 70-72 years; mean current smoking rate: 23-31%; mean IHD rate: 24-26%; median FEV1 predicted 54%, 52-67% male. **Inclusion:** COPD (according to American Thoracic Society criteria); FEV1/FVC < 70%; symptoms at least weekly; Hx of one or more exacerbations in the previous 12 months requiring an increase in therapy **Exclusion:** Unable/unwilling to sign consent form; primary diagnosis of asthma; other primary functionally limiting disease; other medical condition likely to affect patient mortality; hospital-level residential care; already using a self management plan; on	**Exposure: n=86** Usual care and education on the use of a self management (action plan) delivered in an individual session of 1 hour from a practice nurse/respiratory educator in association with the GP **Comparison: n=73** Usual care (denied access to the written self management plan) **Outcome measures:** Primary: Change in St Georges Respiratory Questionnaire (SGRQ) (quality of life) Secondary: Frequency of hospital and primary care attendance; frequency of use of courses of antibiotics and oral corticosteroids over 12 months; change in Hospital Anxiety and Depression Scale (HADS); self management knowledge (measured by the COPD Self Management Interview (SMI)) **Follow-up time:** 6 and 12 months	**Results:** Primary: SGRQ: No significant differences for SGRQ symptoms, activity, impacts or total scores. Secondary: 1. HADS: No significant differences for HADS anxiety or HADS depression scores 2. Health care utilisation: no significant differences for ED attendances, hospital admissions, GP visits, antibiotic courses, steroid courses 3. SMI: Well knowledge: exp 23.9, comp 22.8 (p=0.001); well actions: exp 22.5, comp 22.0 (p=0.19); early exacerbation knowledge: exp 20.6, comp 18.8 (p=0.001); early exacerbation actions: exp 19.5, comp 17.2 (p=0.001); severe exacerbation knowledge: exp 17.2, comp 14.7 (p=0.002); severe exacerbation	**Author's conclusions:** Self management was higher in the intervention group but there was no difference in quality of life or health outcomes due to self management plans **Reviewer's conclusions:** Study underpowered to adequately assess some outcomes **Source of funding:** Pegasus Health, an independent practitioner association, the Canterbury Respiratory Research Trust and the Asthma and Respiratory Foundation of NZ. **Additional comments:** Randomisation was by practice rather than participant as the authors considered this would be less likely to result in bias. However, this could cause unit of analysis errors.

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
		domiciliary oxygen therapy; attending a general practice that regularly uses self management plans; exacerbation of COPD requiring increased treatment within 6 weeks or admission to hospital within 3 months; cognitive impairment of < 75% (3MS); alpha-1 antitrysin deficiency		actions: exp 21.9, comp 20.4 (p=0.005) (max score 26)	

Bias	Judgement	Support for judgement
Random sequence generation	Low risk	Random number tables
Allocation concealment	Unclear risk	No details
Blinding	High risk	No blinding
Incomplete outcome data	Low risk	minimal loss to follow up: 2/86 in intervention group; 3/73 in control group (reasons given)
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: Norweg 2005 **Country:** USA **Study type:** RCT **Evidence level:** II	**Aims:** To assess the short and long term effects of combining activity training or lectures to exercise training on QOL, functional status and exercise tolerance	**Study setting:** Outpatient rehab centre **Participant characteristics:** Mean age 74 years, mean FEV1 predicted 55%, 10-50% male **Inclusion:** Medically stable COPD, aged 60 to 92 years, literate and coherent in the English language **Exclusion:** Cognitive deficits (MMSE < 24), dementia, blindness, unstable angina, any other disabling condition that could interfere with participation	**Exposure:** (1) n=18, Exercise training + activity training (structured behavioural intervention that emphasized dyspnoea management strategies) (2) n=10, Exercise training + education (didactic instruction) **Comparison: n=15** Exercise training alone **Outcome measures:** Health-related QOL (CRQ), functional status (PFSDQ-M and CSES), exercise tolerance (6 minute walk test) **Follow-up time:** 6, 12, 18 and 24 weeks from the commencement of rehabilitation	**Results:** Exercise training + education vs exercise training alone at 12 weeks (older participants) (PFSDQ-M): - dyspnoea score, p=0.009 and p=0.003 - fatigue score, p=0.003 and p=0.001 - activity involvement, p=0.02 and p=0.03 - total functional status, p=0.01 and p=0.03 Exercise training + activity vs exercise training + education at 12 weeks (older participants): - dyspnoea score, p=0.04 and p=0.02 - fatigue score: p=0.001 and p=0.01 - activity involvement: p=0.0004 and p<0.0001 - total functional status: p=0.02 and p=0.01 CRQ Total Score: intervention 1 versus intervention 2, p<0.05 CRQ emotional function score: intervention 1 versus intervention 2, p<0.05 CRQ emotional function score: intervention 2 versus usual care, p<0.05	**Author's conclusions:** A behavioural method emphasizing structured controlled breathing and supervised physical activity was statistically significantly more effective than didactic instruction in reducing dysponea and fatigue, and increasing activity involvement and total functional status in the short term and greater total quality of life in the longer term **Reviewer's conclusions:** Treatments not standardised and potential for confounding through greater attention. Underpowered to find differences **Source of funding:** New York State Occupational Therapy Association **Additional comments:** May not have sufficient power for multiple comparisons and stratification by age

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
				No significant group differences for other scores CSES: No significant group differences for any measures Exercise tolerance: No significant differences for any measures	

Bias	Judgement	Support for judgement
Random sequence generation	Low risk	Biased coin design and probability table
Allocation concealment	Unclear risk	No details
Blinding	High risk	No blinding
Incomplete outcome data	High risk	12/18 (67%) in exercise + activity group, 2/10 (20%) in exercise + education group and 8/15 (53%) in usual care group withdrew by 24 weeks follow up
Selective reporting	High risk	One of the outcomes did not find evidence of a significant difference between groups but these results were minimised and not discussed in relation to the positive findings

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Year and author: Rice 2010 **Country:USA** **Study type:** RCT **Evidence level:** II	**Aims:** To determine whether a simplified disease management program reduces hospital admissions and emergency department visits due to COPD.	**Study setting:** Community **Participant characteristics:** Mostly male (97-98%) with severe COPD (mean FEV1 predicted ranged from 36 to 38%), mean age 69-71 years **Inclusion:** COPD and one or more of: hospital admission or ED visit for COPD, chronic home oxygen use or use of systemic corticosteroids for COPD plus ability to consent, spirometry showing FEV1 < 70% predicted and FEV1/FVC < 70 **Exclusion:** Any condition that might preclude effective participation or reduce life expectancy to < 1 year, no access to a telephone	**Exposure: n=372** Disease management program consisting of a single 1 to 1.5 hour education session, an action plan for self treatment of exacerbations and monthly follow up calls from a case manager **Comparison: n=371** Usual care (one page handout plus telephone number for 24 hour nursing helpline) **Outcome measures:** Primary: Combined number of hospital admissions and ED visits for COPD during 12 month follow up Secondary: Hospitalisations and ED visits for other causes, hospital and ICU lengths of stay, respiratory medication use, change in respiratory QOL (measured by SGRQ) and all cause mortality **Follow-up time:** 12 months	**Results:** Hospital admissions and ED visits: At 1 year, mean cumulative frequency of COPD-related hospitalisations and ED visits was 0.82 per patient in usual care and 0.48 per patient in disease management (difference: 0.34 (0.15 to 0.52), p<0.001 Differences also found for hospitalisation for cardiac and other pulmonary conditions, but not for other conditions. Total hospital days: difference 1.1 days (0.2 to 2.0), p=0.03 Respiratory health status: Mean SGRQ status: Difference between groups: 5.1 (2.5 to 7.6), p<0.001 (less decline in exposure group) Prednisone use: Difference 775mg (528 to 1022), p<0.001 Antibiotic use: Difference 2.5 courses (2.0 to 3.0), p<0.001 No differences for other outcomes, including mortality	**Author's conclusions:** A relatively simple disease management program reduced hospitalisations and ED visits for COPD **Reviewer's conclusions:** The COPD disease management program reduced by 41% the composite endpoint of ED visits and hospitalisations in mostly male patients with advanced COPD over a period of one year **Source of funding:** Grant from Veterans Integrated Service Network 23 Primary Care and Research Services and by the Centre for Chronic Disease Outcomes Research, a Veterans Affairs Health Services Research and Development Centre of Excellence **Additional comments:** Well designed and powered study. Insufficient power to assess mortality
Bias	**Judgement**		**Support for judgement**		

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Random sequence generation	Low risk			Permuted block randomisation	
Allocation concealment	Unclear risk			No details	
Blinding	Unclear risk			Assessor blinded, participants unlikely to be blinded	
Incomplete outcome data	Low risk			48/371 (13%) dropped out in the usual care group and 36/372 (10%) dropped out in the intervention group at one year follow up but outcomes measured by intention to treat	
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: Steele 2008 **Country:** USA **Study type:** RCT **Evidence level:** II	**Aims:** To assess the effectiveness of an exercise adherence intervention to maintain daily activity, adherence to exercise and exercise capacity over 1 year after completion of an outpatient PR program	**Study setting:** Home **Participant characteristics:** 85/106 (80%) had COPD; the majority were men ; the majority had severe to very severe COPD (38-43% FEV1 predicted). Mean age 67 years **Inclusion:** Self reported diminished physical functioning related to a pulmonary problem, pulmonary function impairment, ambulatory, able to read and speak English, at least 45 years old **Exclusion:** Inpatient admission within the past 2 months, asthma with episodic abnormality in pulmonary function, pulmonary exacerbation within the past 2 weeks, unstable cardiopulmonary or sensorimotor problems, daily use of a motorised cart, already exercising at least 30 minutes 3 or more	**Exposure: n=54** Exercise adherence – included establishing an exercise program through self monitoring, development of problem solving skills and encouragement to participate in exercise with others via weekly phone calls and home visit; also provided with pedometer for self monitoring and exercise handbook **Comparison: n=57** Continuing care with the referring provider and individual recommendations for continuation of the exercise program **Outcome measures:** Primary: daily activity (accelerometer), exercise adherence (exercise diary) and exercise capacity (six minute walk test) QOL, symptom management and experiences, health status, walking self efficacy **Follow-up time:** At 20 weeks (after intervention) and 1 year	**Results:** Daily activity (at 20 weeks and 1 year): no evidence of group differences 6 minute walk (at 20 weeks)(change in time between Rx and 20 weeks): -10.7mins (63.1) in intervention group, -35.4mins (49.1) in control group, p=0.02 Self reported minutes of activity (at 20 weeks): 3mins (39) in intervention group, -13mins (26) in control group, p=0.01 No evidence of group differences in 6 minute walk test and minutes of activity at 1 year. There was no evidence of group differences in the secondary outcomes.	**Author's conclusions:** The intervention enhanced exercise adherence and exercise capacity in the short term but produced no long term benefit **Reviewer's conclusions:** Although this was a well designed study, it was not possible to control for potential bias from lack of blinding, and low enrolment suggesting lack of power to find differences and unequal groups **Source of funding:** Department of Veterans Affairs, Veterans Health Administration, Health Services Research and Development Service (grant no. NRI 98-194) and the University of Washington School of Nursing (research and intramural funding grant) **Additional comments:** Study controlled for baseline differences in the analyses. Groups not comparable at baseline (control group had a greater proportion of very severe COPD)

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
		days per week, impairment of cognition or communication, active malignancy or rapidly declining clinical course with expected survival < 1 year, suboptimal medical management and/or history of drug or alcohol treatment within the past 6 months			

Bias	Judgement	Support for judgement
Random sequence generation	Low risk	Block randomisation
Allocation concealment	Unclear risk	No details
Blinding	High risk	No blinding
Incomplete outcome data	Unclear risk	10/57 (17%) in intervention group and 12/54 (22%) in control group withdrew by the end of follow up (reasons given)
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: Wood-Baker 2006 **Country:** Australia **Study type:** RCT **Evidence level:** II	**Aims:** To assess the effects of an individualised written self management plan in patients with COPD in a community setting, on health-related QOL, physiological impairment, physical activity and the use of health care resources	**Study setting:** Community **Participant characteristics:** Mean age ranged from 69 to 71 years, mean FEV1 predicted ranged from 44.2 to 46.3%, 49-67% male **Inclusion:** COPD as primary functionally limiting illness, aged > 50 years, tobacco smoking history of > 10 pack-years, FEV1 < 65% predicted, FEV1/FVC <70% **Exclusion:** Nursing home residents	**Exposure: n=67** Education + written self management action plan individualised by GP **Comparison: n=72** Education alone **Outcome measures:** Primary: health-related QOL (measured by SGRQ) Secondary: physical activity (number of steps), use of antibiotics, oral steroids, number of GP consultations, hospitalisations and attendances at ED, lung function **Follow-up time:** 3, 6, 9 and 12 months	**Results:** No evidence of group differences for SGRQ scores, physical activity or lung function. Antibiotic use: 83% intervention group versus 67% control group, X^2 3.9, p=0.05 Oral corticosteroid use: X^2 14.3, p<0.001 No evidence of group differences in consultations, hospitalisations or ED visits	**Author's conclusions:** The use of a written action plan in COPD increased appropriate therapeutic interventions for exacerbations but this effect was not associated with a decrease in the use of health care resources **Reviewer's conclusions:** The study may have been underpowered to determine whether the effects of increased use of medications for exacerbations also influenced health care resources **Source of funding:** Unrestricted educational grant from Boehringer Ingelheim **Additional comments:** Cluster randomisation (GPs) rather than participants, but participants were the unit of analysis.

Bias	Judgement	Support for judgement
Random sequence generation	Low risk	Computer generated
Allocation concealment	Unclear risk	No details
Blinding	High risk	No blinding

Reference	Aims	Participants	Exposure, comparison, outcome measures and follow up	Results	Conclusions, quality issues
Incomplete outcome data	Unclear risk			13/67 and 14/72 withdrew, died or were lost to follow up (reasons supplied)	
Selective reporting	Low risk			A priori outcomes reported	