Preparing Summary of Findings tables for Cochrane Reviews

Introduction Translating and presenting numbers GRADEing the evidence

> Applicability and Recommendations Methods Group (schuneh@mcmaster.ca)

Content

- Introduction to Summary of Findings Tables
- Format of Summary of Findings Tables
- Translating and presenting results from systematic reviews
- GRADEing the evidence from systematic reviews
- GRADEpro software to create Summary of Findings Tables

Self management for patients with chronic obstructive pulmonary disease

Patient or population: patients with chronic obstructive pulmonary disease Settings: primary care, community, outpatient Intervention: self management¹

Comparison: usual care

Outcomes	Outcomes Illustrative comparative risks* (95% CI)		Relative effect	No of Participants	Quality of the	Comments
	Assumed risk usual care	Corresponding risk self management	(95% CI)	(studies)	(GRADE)	
Quality of Life St George's Respiratory Questionnaire. Scale from: 0 to 100. (follow-up: 3 to 12 months)	The mean quality of life ranged across control groups from 38 to 60 points	The mean quality of Life in the intervention groups was 2.58 lower (5.14 to 0.02 lower)		698 (7)	⊕⊕⊖O moderate ²	Lower score indicates better quality of life. A change of less than 4 points is not shown to be important to patients.
Dyspnoea Borg Scale. Scale from: 0 to 10. (follow-up: 3 to 6 months)	The mean dyspncea ranged across control groups from 1.2 to 4.1 points	The mean dysphoea in the intervention groups was 0.53 lower (0.96 to 0.1 lower)		144 (2)	eeoo low ^{3,4}	Lower score indicates improvement
Number and severity of exacerbations ⁶	See comment	See comment	Not estimable ⁶	591 (3)	See comment	Effect is uncertain
Respiratory- related hospital admissions (followare: 3 to 12	Low risk populati	on®	OR 0.64	866	eeeo _	
	10 per 100 7 per 100 (5 to 9)		(0.47 to 0.89)	(8)	moderate'	
months)	High risk population					
	50 per 100	39 per 100 (32 to 47)				
Emergency department visits for lung diseases (follow-up: 6 to 12 months)	The mean emergency department visits for lung diseases ranged across control groups from 0.2 to 0.7 visits per person per year	The mean emergency department visits for lung diseases in the intervention groups was 0.1 higher (0.2 lower to 0.3 higher)		328 (4)	⊕⊕⊖O moderate ⁴	
Doctor and nurse visits (follow-up: 6 to 12 months)	The mean doctor and nurse visits ranged across control groups from 1 to 5 vists per person per year	The mean doctor and nurse visits in the intervention groups was 0.02 higher (1 lower to 1 higher)		629 (8)	⊕⊕⊖O moderate ⁸	

*The basis for the assumed risk (e.g. the median control group risk across studies) is provided in footnotes. The corresponding risk (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).

CI: Confidence interval; OR: Odds ratio;

Summary of Findings Table

 presentation of the results of a review that is easier to understand

a rating of the quality of the evidence (how confident we are in the effect and the size of the effect)

Summary of key information from systematic reviews: PICO

Self-management education for patients with chronic obstructive pulmonary disease (Review)

Effing T, Monninkhof EM, van der Valk PDLPM, van der Palen J, van Herwaarden CLA, Partidge MR, Walters EH, Zielhuis GA

Status: Updated

This record should be cited as:

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ABSTRACT

Background

There is great interest in chronic obstructive pulmonary disease (COPD) and the associated large burden of disease. COPD is characterised by frequent day by day fluctuations, and repetitive clinical exacerbations are typical. Self-management is a term applied to educational programmes aimed at teaching skills needed to carry out medical regimens specific to the disease, guide health behaviour change, and provide emotional support for patients to control their disease and live functional lives. In COPD, the value of self-

Summary of key information from systematic reviews: results

and one study (Howland 1986) scored one point (Jadad 1996).

RESULTS

Health-related quality of life

Instruments for measurement of HRQoL differed widely among the studies. COPD-specific HRQoL was measured by means of the St. George's Respiratory Questionnaire (SGRQ) in seven studies (Watson 1997; Gallefoss 1999a; Bourbeau 2003; Monninkhof 2003; Martin 2004; Boxall 2005; (Coultas 2005a; Coultas 2005b)). The SGRQ-total and -domain scores in the self-management groups were all lower (indicating a better HRQoL) or equal to the scores in the usual care groups. The differences on the SGRQ-total (WMD -2.58; 95% CI (-5.14 to -0.02)) and impact scores (WMD -2.83; 95% CI (-5.65 to -0.02)) reached statistical significance at the 5% level, but did not reach the clinically relevant improvement of 4 points. No significant or clinically relevant difference was found on the SGRQ-symptom score (WMD-1.45; 95% CI (-4.41 to 1.51)). The SGRQ-domain physical activity did not show a statistically significant effect in favour of treatment (WMD -2.88; 95% CI (-5.9 to 0.13)). The level of statistical heterogeneity for this outcome may be related to the outlying effect reported in Watson 1997, since its removal led to a lower I square statistic (65% versus 0%). Exploration of varying study charactereral HRQoL was not significantly different between the self-management and control group. Gourley 1998 showed significantly improved scores for the well-being dimension of the Health Status Questionnaire 2.0 in the intervention group. Coultas 2005b found a statistically significant improvement in the perceived Illness Intrusiveness instrument in one of the intervention groups (nurse assisted collaborative management) compared with usual care. However, the author noted that the clinical relevance of this finding was uncertain.

Symptoms

The effect of self-management education on COPD symptoms was examined in five studies (Gourley 1998; Watson 1997; Bourbeau 2003; Monninkhof 2003; Boxall 2005). In the studies by Gourley 1998 and Boxall 2005, dyspnoea was assessed with the BORG-scale. Meta-analysis showed a small but significant effect at the 5% level in favour of treatment (WMD -0.53; 95% CI (-0.96 to -0.10)). In the study by Gourley 1998, the Global Assessment Scale (measuring symptom severity on a 6-point scale) was also used. It showed a reduction (not statistically significant) in symptom severity in the self-management education group, while in the control group no reduction was observed. In the study by Watson 1997, patients scored their respiratory status in symptom diaries on a four-point scale (usual; mild; moderate; severe). They found no significant between-group differences in the proportion of days rated as mild, moderate or severe. In the study by Monninkhof

Summary of key information from systematic reviews: Forest and Funnel Plots

Analysis 01.01. Comparison 01 Self-management versus control, Outcome 01 HRQOL: SGRQ total

Review: Self-management education for patients with chronic obstructive pulmonary disease

Comparison: 01 Self-management versus control

Outcome: 01 HRQOL: SGRQ total

N Mean(SD) N Mean(SD) 95% CI (%) 95% CI Bourbeau 2003 81 50.60 (17.80) 76 54.20 (17.60) 21.4 -3.60 [-9.14, 1.94] Bourbeau 2005 23 50.70 (11.80) 23 59.60 (13.30) 12.4 -8.90 [-16.17, -1.63] Coultas 2005a 49 58.60 (20.40) 26 58.80 (16.40) 9.1 -0.20 [-8.71, 8.21] Coultas 2005b 51 55.10 (16.40) 25 58.80 (16.40) 10.6 -3.70 [-11.55, 4.15] Gallefors 1999a 26 40.00 (16.00) 27 43.10 (21.00) 65 -3.10 [-13.13, 6.93] Monninkhof 2003 122 37.40 (18.80) 113 3770 (17.00) 31.3 -0.30 [-4.88, 4.28] Watson 1997 29 39.00 (17.00) 27 39.00 (16.00) 8.8 0.00 [-8.64, 8.64] Test for heterogeneity-chi-equare=4.72 d*=6 p=0.58 P = 0.05 -1000 -2.58 [-5.14, -0.02] -1000	Study		Treatment		Control	Weigh	ted Mean	Difference ((Fored)	Weight	Weighted Mean Difference (Fixed)	
Bourbeau 2003 81 50.60 (17.80) 76 54.20 (17.60) 21.4 -3.60 [-9.14, 194] Boxal 2005 23 50.70 (11.80) 23 59.60 (13.30) 12.4 -8.90 [-16.17, -16.3] Coultas 2005a 49 58.60 (20.40) 26 58.80 (16.40) 9.1 -0.20 [-8.71, 8.21] Coultas 2005b 51 55.10 (16.40) 25 58.80 (16.40) 10.6 -3.70 [-11.55, 4.15] Gallefors 1999a 26 40.00 (16.00) 27 43.10 (21.00) 65 -3.10 [-13.13, 6.93] Monninkhof 2003 122 37.40 (18.80) 113 3770 (17.00) 31.3 -0.30 [-4.88, 4.28] Watson 1997 29 39.00 (17.00) 27 39.00 (16.00) 8.8 0.00 [-8.64.864] Total (95% Cl) 381 31.7 100.0 -258 [-5.14, -0.02] -258 [-5.14, -0.02] -1000 -500 500 100.0	100000	N	Mean(SD)	N	Mean(SD)	113942	95	% CI	012036	(%)	95% CI	
Boxall 2005 23 50.70 (11.80) 23 59.60 (13.30) 12.4 -8.90 [-16.17, -1.63] Coultas 2005a 49 58.60 (20.40) 26 58.80 (16.40) 9.1 -0.20 [-8.71, 8.31] Coultas 2005b 51 55.10 (16.40) 25 58.80 (16.40) 10.6 -3.70 [-11.55, 4.15] Gallefors 1999a 26 40.00 (16.00) 27 43.10 (21.00) 6.5 -3.10 [-13.13, 6.93] Monninkhof 2003 122 37.40 (18.80) 113 37.70 (17.00) 31.3 -0.30 [-4.88, 4.28] Watson 1997 29 39.00 (17.00) 27 39.00 (16.00) 8.8 0.00 [-8.64, 8.64] Total (95% Cl) 381 31.7 100.0 -2.58 [-5.14, -0.02] -2.58 [-5.14, -0.02] Test for heterogeneity chi-square=4.72 cf=6 p=0.58 l ³ = 0.0% -100.0 -50.0 50.0 100.0	Bourbeau 2003	81	50.60 (17.80)	76	54.20 (17.60)					21.4	-3.60 [-9.14, 1.94]	
Coultas 2005a 49 58.60 (20.40) 26 58.80 (16.40) 9.1 -0.20 [-8.71, 8.31] Coultas 2005b 51 55.10 (16.40) 25 58.80 (16.40) 10.6 -3.70 [-1.15, 4.15] Gallefoss 1999a 26 40.00 (16.00) 27 43.10 (21.00) 65 -3.10 [-13.13, 6.93] Monninkhof 2003 122 37.40 (18.80) 113 37.70 (17.00) 31.3 -0.30 [-4.88, 4.28] Watson 1997 29 39.00 (17.00) 27 39.00 (16.00) 88 0.00 [-8.64, 8.64] Total (95% Cl) 381 31.7 100.0 -2.58 [-5.14, -0.02] Test for heterogeneity chi-square=4.72 ch ² =6 p=0.58 l ² = 0.0% -100.0 -50.0 50.0 100.0	Boxall 2005	23	50.70 (11.80)	23	59.60 (13.30)		-			12.4	-8.90 [-16.17, -1.63]	
Coultas 2005b 51 55.10 (16.40) 25 58.60 (16.40) 10.6 -3.70 [-11.55, 4.15] Gallefors 1999a 26 40.00 (16.00) 27 43.10 (21.00) 6.5 -3.10 [-1.3.13, 6.93] Monninkhof 2003 122 37.40 (18.60) 113 37.70 (17.00) 31.3 -0.30 [-4.88, 4.28] Watson 1997 29 39.00 (17.00) 27 39.00 (16.00) 8.8 0.00 [-8.64, 8.64] Total (95% Cl) 381 31.7 100.0 -2.58 [-5.14, -0.02] Text for heterogeneity dhi-square=4.72 df=6 p=0.58 P = 0.0% -100.0 -50.0 50.0 100.0	Coultas 2005a	49	58.60 (20.40)	26	58.80 (16.40)		+			9.1	-0.20 [-8.71, 8.31]	
Gallefors: 1999a 26 40.00 (16.00) 27 43.10 (21.00) Monninkhof 2003 122 37.40 (18.60) 113 37.70 (17.00) Watson 1997 29 39.00 (17.00) 27 39.00 (16.00) Total (95% Cl) 381 31.7 Test for heterogeneity chi-square=472 cf=6 p=058 l ² =0.0% 100.0 -2.58 [-5.14, -0.02] -1000 -500	Coultas 2005b	51	55.10 (16.40)	25	58.80 (16.40)					10.6	-3.70 [-1 1.55, 4.15]	
Monninkhof 2003 122 37.40 (18.60) 113 37.70 (17.00) 31.3 -0.30 [-4.88, 4.28] Watson 1997 29 39.00 (17.00) 27 39.00 (16.00) 8.8 0.00 [-8.64, 8.64] Total (95% CI) 381 31.7 100.0 -2.58 [-5.14, -0.02] Test for heterogeneity chi-square=4.72 dF=6 p=0.58 I ² = 0.0% 100.0 -50.0 50.0 100.0	Gallefoss 1999a	26	40.00 (16.00)	27	43.10 (21.00)		+			6.5	-3.10 [+13.13, 6.93]	
Watson 1997 29 39.00 (17.00) 27 39.00 (16.00) 6.8 0.00 [-8.64, 8.64] Total (95% CI) 381 317 100.0 -2.58 [-5.14, -0.02] Test for heterogeneity chi-square=4.72 dF=6 p=0.58 IP =0.0% 100.0 -2.58 [-5.14, -0.02] Test for overall effect z=1.98 p=0.05 -100.0 -50.0 0	Manninkhof 2003	122	37.40 (18.80)	113	37.70 (17.00)					31.3	-0.30 [-4.88, 4.28]	/
Total (95% CI) 381 317 100.0 -2.58 [-5.14, -0.02] Test for heterogeneity chi-square=4.72 df=6 p=0.58 I ² =0.0% Test for overall effect z=1.98 p=0.05 -100.0 -50.0 0 50.0 100.0	Watson 1997	29	39.00 (17.00)	27	39.00 (16.00)		+			8.8	0.00 [-8.64, 8.64]	
Test for overall effect z=1.98 p=0.05 -1000 -500 0 500 1000	Total (95% CI)	381		317			•			100.0	-2.58 [-5.14, -0.02]	į,
Test for overall effect z=1.98 p=0.05 -1000 -500 0 500 100.0	Test for heterogeneity	chi-squar	re=4.72 df=6 p=0	58 l² =0	0%							1
-1000 -500 0 500 1000	Test for overall effect z	=1.98	p=0.05									
-1000 -500 0 500 1000							<u> </u>				1	1
						-100.0 -5	0 0.0	50.0 10	0.00			1
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Summary of key information from systematic reviews: Bias



Risk of Bias Tables

Summary of key information from systematic reviews: Abstract

Background

There is great interest in chronic obstructive pulmonary disease (COPD) and the associated large burden of disease. COPD is characterised by frequent day by day fluctuations, and repetitive clinical exacerbations are typical. Self-management is a term applied to educational programmes aimed at teaching skills needed to carry out medical regimens specific to the disease, guide health behaviour change, and provide emotional support for patients to control their disease and live functional lives. In COPD, the value of selfmanagement education is not yet clear. The first Cochrane review about self-management was published in 2003. It was intended to shed light on the effectiveness of self-management programmes in COPD and the relative efficacy of their constitutive elements. No conclusions about the effectiveness of self-management could be drawn because of the large variation in outcome measures used in the limited number of included studies. This article describes the first update of this review.

Objectives

The objective of this review was to assess the settings, methods and efficacy of COPD self-management education programmes on health outcomes and use of health care services.

Search strategy

We searched the Cochrane Airways Group trial register, MEDLINE (January 1985 to January 2006), reference lists, and abstracts of medical conferences.

Selection criteria

Controlled trials (randomised and non-randomised) of self-management education in patients with COPD. Studies focusing mainly on pulmonary rehabilitation and studies without usual care as a control group were excluded.

Data collection and analysis

Two reviewers independently assessed study quality and extracted data. Investigators were contacted for additional information.

Main results

The reviewers included 15 group comparisons drawn from 14 trials. They assessed a broad-spectrum of interventions and health outcomes with different follow-up times. Meta-analyses could often not appropriately be performed because of heterogeneity among studies. The studies showed a significant reduction in the probability of at least one hospital admission among patients receiving self-management education compared to those receiving usual care (OR 0.64; 95% CI (0.47 to 0.89)). This translates into a one year NNT ranging from 10 (6 to 35) for patients with a 51% risk of exacerbation, to an NNT of 24 (16 to 80) for patients with a 13% risk of exacerbation. On the disease specific SGRQ, differences reached statistical significance at the 5% level on the total score (WMD -2.58; 95% CI (-5.14 to -0.02)) and impact domain (WMD -2.83; 95% CI (-5.65 to -0.02)), but these difference did not reach the clinically relevant improvement of 4 points. A small but significant reduction was detected in dyspnoea measured with the BORG-scale (WMD -0.53; 95% CI (-0.96 to -0.10)). No significant effects were found either in number of exacerbations, emergency department visits, lung function, etercise capacity, and days lost from work. Inconclusive results were observed in doctor and nurse visits, on symptoms other than dyspnoea, the use of courses of oral corticosteroids and antibiotics, and the use of rescue medication.

Authors' conclusions

It is likely that self-management education is associated with a reduction in hospital admissions with no indications for detrimental effects in other outcome parameters. This would in itself already be enough reason for recommending self-management education in COPD. However, because of heterogeneity in interventions, study populations, follow-up time, and outcome measures, data are still insufficient to formulate clear recommendations regarding the form and contents of self-management education programmes in COPD. There is an evident need for more large RCTs with a long-term follow-up, before more conclusions can be drawn.

Summary of Findings Table: A summary of key information from systematic reviews

Settings: primary o Intervention: self r Comparison: usua	care, community, out; management ¹ Il care	patient				
Outcomes	Illustrative comparative risks* (95% CI) Assumed risk Corresponding risk usual care self management			No of Participants (studies)	Quality of the evidence (GRADE)	Comments
Quality of Life St George's Respiratory Questionnaire. Scale from: 0 to 100. (follow-up: 3 to 12 months)	The mean quality of life ranged across control groups from 38 to 60 points	nean quality of The mean quality of nged across Life in the ol groups from intervention groups 60 points was 2.58 lower (5.14 to 0.02 lower)		898 (7)	⊕⊕⊖O moderate ²	Lower score indicate better quality of life. change of less than points is not shown i be important to patients.
Dyspnoea Borg Scale. Scale from: 0 to 10. (follow-up: 3 to 6 months)	The mean dyspncea ranged across control groups from 1.2 to 4.1 points	The mean dyspnoea in the intervention groups was 0.53 lower (0.96 to 0.1 lower)		144 (2)	eeoo low ³⁴	Lower score indicate improvement
Number and severity of exacerbations ⁶	See comment	See comment	Not estimable ⁶	591 (3)	See comment	Effect is uncertain
Respiratory-	Low risk populati	OR 0.64	966	eeeo _		
related hospital admissions (follow-up: 3 to 12	10 per 100	(0.47 to 0.89)	(8)	moderate'		
months)	High risk population					
	50 per 100	39 per 100 (32 to 47)				
Emergency department visits for lung diseases (follow-up: 8 to 12 months)	The mean emergency department visits for lung diseases ranged across control groups from 0.2 to 0.7 visits per person per year	The mean emergency department visits for lung diseases in the intervention groups was 0.1 higher (0.2 lower to 0.3 higher)		328 (4)	⊕⊕⊖O moderate ⁴	
Doctor and nurse visits (follow-up: 6 to 12 months)	The mean doctor and nurse visits ranged across control groups from 1 to 5 vists per person per year	The mean doctor and nurse visits in the intervention groups was 0.02 higher (1 lower to 1 higher)		629 (8)	⊕⊜⊜O moderate ⁸	

relative effect of the intervention (and its 95% CI).

CI: Confidence interval; OR: Odds ratio;

Summary of Findings table

- New to Cochrane reviews & RevMan 5
- User tested, based on a broader system of evaluating and presenting evidence
- SoFs and evidence profiles are starting to be used by a variety of organisations (WHO, NICE, CADTH, guideline developers, etc.) – is a record of the evidence
- increases the usability of reviews and helps people make better informed decisions

EXAMPLE: Should self management programmes be recommended/funded for people with COPD?

- Will people have a better quality of life if they attend? Fewer exacerbations? Fewer visits to see their doctor? Fewer visits to emergency?
- If you tell me that research says it improves my COPD, how much does it improve? Will that make a difference in a person's life?
- How likely is it that scientists are going to change their mind tomorrow and tell me it doesn't improve symptoms?

Summary of Findings Table answers these questions

Format of a Summary of Findings Table

- PICO
- Outcomes
- Results
 - Participants and studies
 - Relative effects
 - Baseline/Assumed Risk and Intervention/Corresponding Risks
- Quality of the Evidence
- Comments
- Footnotes

Participants, interventions, comparisons, outcomes

Self managemen	t for patients with	chronic obstructi	ive pulmo	narv diseas	e .		
Self management for patients with chronic obstructive pulmonary disease							
Patient or populati Settings: primary c Intervention: self m Comparison: usual	ion: patients with chr are, community, outp nanagement ¹ I care	onic obstructive pulm patient	ionary dise	ase			
Outcomes	Illustrative compa (95% CI) Assumed risk usual care	rative risks* Corresponding risk self management	Relative effect (95% Cl)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments	
Quality of Life St George's Respiratory Questionnaire. Scale from: 0 to 100. (follow-up: 3 to 12 months)	The mean quality of life ranged across control groups from 38 to 60 points	The mean quality of Life in the intervention groups was 2.58 lower (5.14 to 0.02 lower)		698 (7)	⊕⊕⊕O moderate ²	Lower score indicates better quality of life. A change of less than 4 points is not shown to be important to patients.	
Dyspnoea Borg Scale. Scale from: 0 to 10. (follow-up: 3 to 6 months)	The mean dyspnoea ranged across control groups from 1.2 to 4.1 points	The mean dyspnoea in the intervention groups was 0.53 lower (0.96 to 0.1 lower)		144 (2)	€€00 low ^{3,4}	Lower score indicates improvement	
Number and severity of exacerbations ⁵	See comment	See comment	Not estimable ⁵	591 (3)	See comment	Effect is uncertain	
Respiratory-	Low risk populati	on ^e	OR 0.64	966	8880		
related hospital admissions	10 per 100	7 per 100 (5 to 9)	(0.47 to 0.89)	(8)	moderate ⁷		
(follow-up: 3 to 12 months)	High risk population	on°					
inentite)	50 per 100	39 per 100 (32 to 47)					
Emergency department visits for lung diseases (follow-up: 6 to 12 months)	The mean emergency department visits for lung diseases ranged across control groups from 0.2 to 0.7 visits per person per year	The mean emergency department visits for lung diseases in the intervention groups was 0.1 higher (0.2 lower to 0.3		328 (4)	⊕⊖⊖O moderate ⁴		

Primary outcomes – up to 7

Self management for patients with chronic obstructive pulmonary disease

Patient or population: patients with chronic obstructive pulmonary disease Settings: primary care, community, outpatient Intervention: self management¹ Comparison: usual care

Outcomes	Illustrative compa (95% CI)	rative risks*	Relative effect (95% CP	No of Participants (studies)	Quality of the evidence	Comments
	usual care	self management	(00 % 01)	(studies)	(GRADE)	
Quality of Life St George's Respiratory Questionnaire. Scale from: 0 to 100. (follow-up: 3 to 12 months)	The mean quality of life ranged across control groups from 38 to 60 points	The mean quality of Life in the intervention groups was 2.58 lower (5.14 to 0.02 lower)		698 (7)	⊕⊕⊕O moderate ²	Lower score indicates better quality of life. A change of less than 4 points is not shown to be important to patients.
Dyspnoea Borg Scale. Scale from: 0 to 10. (follow-up: 3 to 6 months)	The mean dyspnoea ranged across control groups from 1.2 to 4.1 points	The mean dyspnoea in the intervention groups was 0.53 lower (0.96 to 0.1 lower)		144 (2)	⊕⊜00 low ^{3,4}	Lower score indicates improvement
Number and severity of exacerbations ⁶	See comment	See comment	Not estimable ⁶	591 (3)	See comment	Effect is uncertain
Respiratory-	Low risk populati	on ^s	OR 0.64	966	eeeo ,	
related hospital admissions (fallow up: 2 to 12	10 per 100	7 per 100 (5 to 9)	(0.47 to 0.89)	(8)	moderate'	
(follow-up: 3 to 12 months)	High risk population	on°				
ŕ	50 per 100	39 per 100 (32 to 47)				
Emergency department visits for lung diseases (follow-up: 6 to 12 months)	The mean emergency department visits for lung diseases ranged across control groups from 0.2 to 0.7 visits per person per year	The mean emergency department visits for lung diseases in the intervention groups was r0.1 higher (0.2 lower to 0.3 higher)		328 (4)	⊕⊕⊕O moderate ⁴	
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primary outcomes

 patient important outcomes

 outcomes with or without results

 Better description of the outcomes – more meaning

Results – Number of Participants/studies

Self management for patients with chronic obstructive pulmonary disease

Patient or population: patients with chronic obstructive pulmonary disease Settings: primary care, community, outpatient Intervention: self management¹ Comparison: usual care

Outcomes	Illustrative compa (95% CI)	rative risks*	Relativ effect	No of Participant	Quality of s the	Comments
	Assumed risk usual care	Corresponding risk self management	(95% C) (studies)	evidence (GRADE)	
Quality of Life St George's Respiratory Questionnaire. Scale from: 0 to 100. (follow-up: 3 to 12 months)	The mean quality of life ranged across control groups from 38 to 60 points	The mean quality of Life in the intervention groups was 2.58 lower (5.14 to 0.02 lower)		698 (7)	⊕⊖⊖O moderate ²	Lower score indicates better quality of life. A change of less than 4 points is not shown to be important to patients.
Dyspnoea Borg Scale. Scale from: 0 to 10. (follow-up: 3 to 6 months)	The mean dyspnoea ranged across control groups from 1.2 to 4.1 points	The mean dysphoea in the intervention groups was 0.53 lower (0.96 to 0.1 lower)		144 (2)	⊕eoo Iow ^{3,4}	Lower score indicates improvement
Number and severity of exacerbations ⁶	See comment	See comment	Not estimab	591 e ⁵ (3)	See comment	Effect is uncertain
Respiratory-	Low risk populati	on®	OR 0.64	966	eeeo	
related hospital admissions	10 per 100	7 per 100 (5 to 9)	(0.47 to 0.89)	(8)	moderate'	
(follow-up: 3 to 12 months)	High risk populati	on°				
	50 per 100	39 per 100 (32 to 47)				
Emergency department visits for lung diseases (follow-up: 6 to 12 months)	The mean emergency department visits for lung diseases ranged across control groups from 0.2 to 0.7 visits per person per year	The mean emergency department visits for lung diseases in the intervention groups was 0.1 higher (0.2 lower to 0.3 higher)		328 (4)	⊕⊖⊖O moderate ⁴	

Moves away from simply saying "this review found 12 low to moderate quality studies" and these are the results

 More clear that only some studies contributed information about an outcome

Results – Relative effects

Self management for patients with chronic obstructive pulmonary disease

Patient or population: patients with chronic obstructive pulmonary disease Settings: primary care, community, outpatient Intervention: self management¹ Comparison: usual care

Outcomes	Illustrative compa (95% CI)	rative risks*	Relative effect	No of Participants	Quality of the	Comments
	Assumed risk usual care	Corresponding risk self management	(95% CI)	(studies)	evidence (GRADE)	,
Quality of Life St George's Respiratory Questionnaire. Scale from: 0 to 100. (follow-up: 3 to 12 months)	The mean quality of life ranged across control groups from 38 to 60 points	The mean quality of Life in the intervention groups was 2.58 lower (5.14 to 0.02 lower)		898 (7)	⊕⊕⊕O moderate ²	Lower score indicates better quality of life. A change of less than 4 points is not shown to be important to patients.
Dyspnoea Borg Scale. Scale from: 0 to 10. (follow-up: 3 to 6 months)	The mean dyspnoea ranged across control groups from 1.2 to 4.1 points	The mean dyspnoea in the intervention groups was 0.53 lower (0.96 to 0.1 lower)		144 (2)	eeoo low ^{3,4}	Lower score indicates improvement
Number and severity of exacerbations ⁶	See comment	See comment	Not estimable ⁵	591 (3)	See comment	Effect is uncertain
Respiratory-	Low risk populati	on ^s	OR 0.64	966	eeeo	
related hospital admissions	10 per 100	7 per 100 (0.47 t (5 to 9) 0.89)		(8)	moderate'	
(Ionow-up. 3 to 12 months)	High risk population	on°				
,	50 per 100	39 per 100 (32 to 47)				
Emergency department visits for lung diseases (follow-up: 6 to 12 months)	The mean emergency department visits for lung diseases ranged across control groups from 0.2 to 0.7 visits per person per year	The mean emergency department visits for lung diseases in the intervention groups was 0.1 higher (0.2 lower to 0.3 higher)		328 (4)	⊕⊕⊕O moderate ⁴	
Dector and purce	The mean dester	The mean destar		820		

From metaanalysis

Relative Risks, Odds ratios, Hazard ratios, etc.

Results – Baseline risks (Assumed Risk)

Self management	for patients with	chronic obstructi	ive pulmo	nary diseas	e	
Patient or population Settings: primary can Intervention: self m Comparison: usual	on: patients with chr are, community, outp anagement ¹ care	onic obstructive pulm patient	onary dise	ase		
Outcomes	Illustrative compa (95% CI) Assumed risk Isual care	rative risks* Corresponding risk self management	Relative effect (95% Cl)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
Quality of Life St George's Respiratory Questionnaire. Scale from: 0 to 100. (follow-up: 3 to 12 months)	The mean quality of ife ranged across control groups from 8 to 60 points	The mean quality of Life in the intervention groups was 2.58 lower (5.14 to 0.02 lower)		698 (7)	⊕⊕⊕O moderate ²	Lower score indicates better quality of life. A change of less than 4 points is not shown to be important to patients.
Dyspnoea Borg Scale. Scale from: 0 to 10. (follow-up: 3 to 6 months)	The mean tysphoea ranged teross control troups from 12 to 4.1 points	The mean dyspnoea in the intervention groups was 0.53 lower (0.96 to 0.1 lower)		144 (2)	⊕⊜00 low ^{3,4}	Lower score indicates improvement
Number and severity of exacerbations ⁵	See comment	See comment	Not estimable ⁶	591 (3)	See comment	Effect is uncertain
Respiratory-	Low risk population	n ^s	OR 0.64	966	eeeo	
related hospital admissions (fallow up: 2 to 12	0 per 100	7 per 100 (5 to 9)	(0.47 to 0.89)	(8)	moderate'	
(1010W-up. 5 to 12 months)	High risk populatio	n°				
	i0 per 100	39 per 100 (32 to 47)				
Emergency department visits for lung diseases (follow-up: 6 to 12 months)	The mean emergency lepartment visits or lung diseases anged across control groups from 1.2 to 0.7 visits per person per year	The mean emergency department visits for lung diseases in the intervention groups was 0.1 higher (0.2 lower to 0.3 binber)		328 (4)	⊕⊕⊕O moderate ⁴	

 Indication of what happens to people without intervention

 Representative of population at different levels of risk

Results – Risk with intervention (Corresponding Risk)

Self management for patients with chronic obstructive pulmonary disease

Patient or population: patients with chronic obstructive pulmonary disease Settings: primary care, community, outpatient Intervention: self management¹ Comparison: usual care

Outcomes	Illustrative comp (95% CI)	arative risks*	Relative effect	No of Participants	Quality of the	Comments
	Assumed risk usual care	Corresponding risk self management	(95% CI)	(studies)	evidence (GRADE)	1
Quality of Life St George's Respiratory Questionnaire. Scale from: 0 to 100. (follow-up: 3 to 12 months)	The mean quality of life ranged across control groups fror 38 to 60 points	f The mean quality of Life in the intervention groups was 2.58 lower (5.14 to 0.02 lower)		698 (7)	⊕⊕⊕O moderate ²	Lower score indicates better quality of life. A change of less than 4 points is not shown to be important to patients.
Dyspnoea Borg Scale. Scale from: 0 to 10. (follow-up: 3 to 6 months)	The mean dyspnoea ranged across control groups from 1.2 to 4.1 points	The mean dyspnoea in the intervention groups was 0.53 lower (0.96 to 0.1 lower)		144 (2)	⊕⊜00 low ^{3,4}	Lower score indicates improvement
Number and severity of exacerbations ⁶	See comment	See comment	Not estimable ⁶	591 (3)	See comment	Effect is uncertain
Respiratory-	Low risk popula	ion ^s	OR 0.64	966	eeeo ,	
related hospital admissions	10 per 100	7 per 100 (5 to 9)	(0.47 to 0.89)	(8)	moderate'	
(follow-up: 3 to 12 months)	High risk popula	ion°				
,	50 per 100	39 per 100 (32 to 47)				
Emergency department visits for lung diseases (follow-up: 6 to 12 months)	The mean emergency department visits for lung diseases ranged across control groups fror 0.2 to 0.7 visits p person per year	The mean emergency department visits for lung diseases in the intervention groups was er 0.1 higher (0.2 lower to 0.3 higher)		328 (4)	⊕⊕⊕O moderate ⁴	
Dector and purse	The mean doctor	The mean doctor		820	A AAO	

What happens to people with the intervention

Calculated using Relative Effects or Mean Differences

Confidence intervals provided

Quality of the Evidence

Self management for patients with chronic obstructive pulmonary disease

Patient or population: patients with chronic obstructive pulmonary disease Settings: primary care, community, outpatient Intervention: self management¹ Comparison: usual care

Outcomes	Illustrative compa (95% CI)	arative risks*	Relative effect	No of Participan	Quality of (s the	omments
	Assumed risk usual care	Corresponding risk self management	(95% CI)	(studies)	evidence (GRADE)	
Quality of Life St George's Respiratory Questionnaire. Scale from: 0 to 100. (follow-up: 3 to 12 months)	The mean quality of life ranged across control groups from 38 to 60 points	The mean quality of Life in the intervention groups was 2.58 lower (5.14 to 0.02 lower)		698 (7)	⊕⊕⊕O l moderate ² t I	ower score indicates etter quality of life. A hange of less than 4 oints is not shown to e important to atients.
Dyspnoea Borg Scale. Scale from: 0 to 10. (follow-up: 3 to 6 months)	The mean dyspnoea ranged across control groups from 1.2 to 4.1 points	The mean dysphoea in the intervention groups was 0.53 lower (0.96 to 0.1 lower)		144 (2)	eeoo l Iow ^{3,4} i	ower score indicates nprovement
Number and severity of exacerbations ⁵	See comment	See comment	Not estimable ⁶	591 (3)	See E comment	ffect is uncertain
Respiratory-	Low risk populati	on ^s	OR 0.64	966	eeeo ,	
related hospital admissions	10 per 100	7 per 100 (5 to 9)	(0.47 to 0.89)	(8)	moderate'	
(follow-up: 3 to 12 months)	High risk populati	on°				
	50 per 100	39 per 100 (32 to 47)				
Emergency department visits for lung diseases (follow-up: 6 to 12 months)	The mean emergency department visits for lung diseases ranged across control groups from 0.2 to 0.7 visits per person per year	The mean emergency department visits for lung diseases in the intervention groups was r0.1 higher (0.2 lower to 0.3 higher)		328 (4)	⊕⊕⊕O moderate ⁴	

 Evidence for each outcome is graded

 Based on the GRADE approach

> Uses information from the Risk of Bias tables

Comments

Self management for patients with chronic obstructive pulmonary disease

Patient or population: patients with chronic obstructive pulmonary disease Settings: primary care, community, outpatient Intervention: self management¹

Comparison: usual care

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect	No of Participants	Quality of the	Comments
	Assumed risk usual care	Corresponding risk self management	(95% CI)	(studies)	evidence (GRADE)	
Quality of Life St George's Respiratory Questionnaire. Scale from: 0 to 100. (follow-up: 3 to 12 months)	The mean quality of life ranged across control groups from 38 to 60 points	The mean quality of Life in the intervention groups was 2.58 lower (5.14 to 0.02 lower)		698 (7)	⊕⊕⊖O moderate ²	Lower score indicates better quality of life. A change of less than 4 points is not shown to be important to patients.
Dyspnoea Borg Scale. Scale from: 0 to 10. (follow-up: 3 to 6 months)	The mean dyspnoea ranged across control groups from 1.2 to 4.1 points	The mean dysphoea in the intervention groups was 0.53 lower (0.96 to 0.1 lower)		144 (2)	⊕eoo Iow ^{3,4}	Lower score indicates improvement
Number and severity of exacerbations ⁵	See comment	See comment	Not estimable ⁵	591 (3)	See comment	Effect is uncertain
Respiratory-	Low risk populati	on®	OR 0.64	966	eeeo	
related hospital admissions	10 per 100	7 per 100 (5 to 9)	(0.47 to 0.89)	(8)	moderate'	
(follow-up: 3 to 12 months)	High risk population	risk population°				
·	50 per 100	39 per 100 (32 to 47)				
Emergency department visits for lung diseases (follow-up: 6 to 12 months)	The mean emergency department visits for lung diseases ranged across control groups from 0.2 to 0.7 visits per person per year	The mean emergency department visits for lung diseases in the intervention groups was 0.1 higher (0.2 lower to 0.3 higher)		328 (4)	⊕⊕⊕O moderate ⁴	

More description

 EG. relevance of findings, notes when no data, no metaanalysis, or meta-analysis plus studies not in metaanalysis

Footnotes

¹ Self-management is a term applied to any formalized patient education programme aimed at teaching skills needed to carry out medical regimens specific to the disease, guide health behaviour change, and provide emotional support for patients to control their disease and live functional lives. Of the 14 studies, there were four in which the education delivery mode consisted of group education; nine which were individual education and one study which was written education material only. In six studies the use of an action plan for self-treatment of exacerbations was assessed.

² Seven other studies were not pooled and some showed non-significant effects.

³ No allocation concealment in 1 study. Incomplete follow-up.

⁴ Sparse data.

⁵ Different definitions of exacerbations used and studies could not be pooled.

 6 The low and high risk values are the two extreme numbers of admissions in the control groups from two studies (8% was rounded to 10% and 51% to 50%).

⁷ Two studies with very severe COPD patients weighted heavily in meta-analysis. Therefore, there is some uncertainty with the applicability of effect to all risk groups.

⁸ Unexplained heterogeneity.

Clarification

- Judgements
- Transparency

Where do the numbers come from?

Dichotomous and Continuous Outcomes

DICHOTOMOUS OUTCOMES YES/NO



Amantadine to prevent the influenza

Outcome: cases of infection (infection or not)

Results from meta-analysis: Relative Risk, Odds Ratio...

Results presented as: #s per 100/1000

Information from Meta-analysis

	Treatm	nent	Contr	ol		Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% Cl	M-H, Random, 95% Cl
Finklea 1967	1	104	11	133	25.1%	0.12 [0.02, 0.89]	e
Payler 1984	3	267	29	269	74.9%	0.10 [0.03, 0.34]	
Total (95% CI)		371		402	100.0%	0.11 [0.04, 0.30]	
Total events	4		40				
Heterogeneity: Tau² = Test for overall effect:	0.00; Chi Z = 4.30 (i ^z = 0.01 (P < 0.0	1, df = 1 (1001)	P = 0.9	3); I² = 0%	5	0.005 0.1 1 10 200 Favours treatment Favours control

DICHOTOMOUS OUTCOMES YES/NO

Outcomes	Illustrative cor Cl)	nparative risks* (95%	Relative effect	No of Parti (studies)
	Assumed risk	Corresponding risk	(95% Cl)	· · ·
	Control	Amantadine		
Cases of Infection with	Medium risk p	opulation 🦯	RR 0.11	773
prophylaxis (fallow one 14,40 one due)	10 per 100	1 per 100	(0.04 to 0.3)	(2)
(tollow-up: 14-18 weeks)	-	(0 to 3)		

Converting RR to # per 100

<u>RR = 0.11</u>

The risk of infection is less likely in people who take amantadine

or...

The risk of infection in the amantadine group is 0.11 times the risk in the group not taking amantadine

DICHOTOMOUS OUTCOMES YES/NO

Outcomes	IIIustrative con CI) Assumed risk Control	nparative risks* (95% Corresponding risk	Relative effect (95% Cl)	No of Parti (studies)
Cases of Infection with prophylaxis (follow-up: 14-18 weeks)	Control Medium risk p 10 per 100	opulation 1 per 100	RR 0.11 (0.04 to 0.3)	773 (2)

Step 1: Assumed Risk

How many people have an infection without amantadine?

- Based on a median risk in the control groups from the studies
- or, baseline risk from observational studies
- or, different risk groups (low to high) in studies

In this case, there were 2 studies in the meta-analysis, calculation of the median risk was representative

• 10 out of 100 people have the infection if they don't take amantadine

Information from Meta-analysis



DICHOTOMOUS OUTCOMES YES/NO

Outcomes	Illustrative co	mparative risks* (95%	Relative	No of Parti
	CI)		effect	(studies)
	Assumed risk	Corresponding risk	(95% Cl)	
	Control	Amantadine		
Cases of Infection with	Medium risk p	oopulation 🏾 🌔	RR 0.11	773
prophylaxis	10 per 100	1 per 100	-(0.04 to 0.3)	(2)
(tollow-up: 14-18 weeks)		(0 to 3)		

Step 2: Relative effectRR = 0.11

Step 3: Corresponding Risk How many people have an infection with amantadine?

assumed risk X relative risk = corresponding risk $10 \quad X \quad 0.11 = 1$

1 per 100 people have the infection if they take amantadine

Example: Heparin to reduce clots – outcome death

	Heparin		parin Control		Risk Ratio		Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% Cl	M-H, Random, 95% Cl
1.1.1 LMWH vs. Contr	loi						
Karthaus 2006	4	285	1	140	8.1%	1.96 [0.22, 17.42]	
Monreal 1996	1	16	1	13	5.4%	0.81 [0.06, 11.77]	
Verso 2005	13	191	20	194	86.5%	0.66 [0.34, 1.29]	
Subtotal (95% CI)		492		347	100.0%	0.73 [0.39, 1.36]	•
Total events	18		22				
Heterogeneity: Tau² =	0.00; Chi	i ^z = 0.8!	9, df = 2 (P = 0.6	4); I ^z = 09	6	
Test for overall effect:	Z = 0.99 ((P = 0.3)	32)				
Total (95% CI)		492		347	100.0%	0.73 [0.39, 1.36]	•
Total events	18		22				
Heterogeneity: Tau² =	0.00; Chi	i ^z = 0.8!	9, df = 2 (P = 0.6	4); I ^z = 09	6	
Test for overall effect:	Z = 0.99 ((P = 0.3	32)				Favours Heparin Favours Control
Heterogeneity: Tau ² = Test for overall effect:	0.00; Chi Z = 0.99 (i ^z = 0.89 (P = 0.3	9, df = 2 (32)	P = 0.6	4); I² = 09	6	0.01 0.1 1 10 100 Favours Heparin Favours Control

Median assumed risk = 7.7%

Outcomes	Illustrative comparat Cl)	Illustrative comparative risks* (95% Cl)		
	Assumed risk Correct no treatment hep	esponding risk arin	(95% CI)	
Death	Medium risk populat	ion	RR 0.73	839
	8 per 100 6 pe	r 100	(U.39 to 1.36)	(3)
	(3 to	10)		

Corresponding Risk = Assumed Risk X Relative Risk

Relative Risk 0.73

7.7 per 100 X 0.73 = 5.621 = 6 per 100

Confidence intervals (0.39 to 1.36) 7.7 per 100 X 0.39 = 3.003 = 3 per 100 7.7 per 100 X 1.36 = 10.472 = 10 per 100

Note: in this case we used "per 100", in some cases "per 1000" may illustrate the differences between the groups better

Odds ratio

Respiratory-	Low risk popula	OR 0.64	966		
related hospital admissions	10 per 100	7 per 100 (5 to 9)	(0.47 to 0.89)	(8)	
(follow-up: 3 to 12 months)	High risk popula				
	50 per 100	39 per 100 (32 to 47)			

Need to first convert the OR to an RRBased on formula in handbook

RR =
$$\frac{OR}{1 - (R_{as} \times (1 - OR))}$$

CONTINUOUS OUTCOMES Mean Difference

Outcomes	Illustrative comparative	Relative	No of Destisionents	
	Assumed risk	Corresponding risk	(95% Cl)	(studies)
	usual care 🛛 🤇	self management		
Quality of Life	The mean quality of life	The mean Quality of Life in		698
St George's Respiratory	ranged across control	the intervention groups was		(7)
Questionnaire. Scale	groups from	2.58 lower		
from: 8 to 100.	38 to 60 points	(5.14 to 0.02 lower) 🥖		
(follow-up: 3 to 12				
months)				

Self management programmes to improve quality of life in people with COPD

Outcome: Quality of Life scale (0 to 100 scale)

Results from meta-analysis: Mean differences (WMD or SMD)

Results presented as: points on a scale

CONTINUOUS OUTCOMES

Mean Difference



Step 1: Assumed Risk

In people who don't do a self management programme, what is their score on the Quality of Life scale?

- Based on the range of mean scores in the control groups from the studies
- or, range from observational studies

In this case, there were 7 studies in the meta-analysis, range of scores was from

• 38 to 60 points

CONTINUOUS OUTCOMES Mean Difference



Step 2: Effect

The effect is expressed as the Mean Difference between the Quality of life score with a self management programme and the score without self management.

MD = -2.58 (-5.14, -0.02)

When doing a self management programme, the score on the Quality of Life scale is 2.58 points better on average.

CONTINUOUS OUTCOMES Mean Difference

Patient or population: patients with chronic obstructive pulmonary disease Settings: primary care, community, outpatient

Intervention: self management¹ Comparison: usual care

Outcomes	Illustrative comparative	Relative	No of	
	Assumed risk	ned risk Corresponding risk 🥻		Participants (studies)
	usual care	self management		
Quality of Life	The mean quality of life	The mean Quality of Life in		698
St George's Respiratory	ranged across control	the intervention groups was		(7)
Questionnaire. Scale	groups from	2.58 lower		
from: 0 to 100.	38 to 60 points	(5.14 to 0.02 lower)		
(follow-up: 3 to 12				
months)				

Example: compression stockings to prevent thrombosis in people flying – outcome oedema



Oedema scale from 0 to 10

Summary of Findings for compression stockings to prevent thrombosis in people flying – outcome oedema

Oedema	The mean oedema	The mean Oedema in	1246
Post-flight values	ranged across	the intervention groups	(6)
Scale from: 0 to 10.	control groups from	was	
	6 to 9	4.7 lower	
		(4.9 to 4.5 lower)	

CONTINUOUS OUTCOMES

Re-expressing SMD using a familiar scale

Outcomes	Illustrative comparative r	Relative	No of	
	Assumed risk	Corresponding risk	effect (95% Cl)	Participants (studies)
	no treatment 🛛 🔍	glucosamine		
Pain	The mean pain in the contro	I The mean Pain in the intervention		1111
Scale from: 0 to 10.	groups was	groups was		(8)
(follow-up: 1-3 months)	6.6	0.8 lower		
		(2.1 lower to 0.5 higher)		

Glucosamine to improve arthritis

Outcome: Pain (many scales used)

Results from meta-analysis: Standard Mean difference (SMD)

Results presented as: points on a scale

CONTINUOUS OUTCOMES SMD



Step 1: Assumed Risk

In people who don't take glucosamine, what is their pain score?

• Based on the scores in the control groups of studies using a familiar scale

In this case, the McAlindon study was representative and used the WOMAC pain scale

- pain scale was 0 to 20
- 3 other studies used this scale (Houpt, Hughes, Pavelka)
- second highest and second lowest scores represented assumed risk

CONTINUOUS OUTCOMES SMD



Step 2: Effect

The effect is expressed as a Mean Difference between the pain score with glucosamine and the score without glucosamine. The difference has been standardised because different scales were used in the studies.

 $\underline{SMD} = -0.19 (-0.50, 0.11)$

CONTINUOUS OUTCOMES SMD

	Gluc	osamine	9	Р	lacebo			Std. Mean Difference	Std. Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% Cl	IV, Random, 95% Cl
Cibere 2004	129.72	113.23	71	129.62	118.02	66	13.3%	0.00 [-0.33, 0.34]	_ + _
Houpt 1999	7.14	4.01	45	7.65	4.13	53	12.4%	-0.12 [-0.52, 0.27]	
Hughes 2002	7.5	4.81	39	7.35	1.30	39	11.8%	0.03 [-0.41, 0.48]	
McAlindon 2004	6.8	3.3	101	6.6	4.2	104	14.0%	0.05 [-0.22, 0.33]	
Pavelka 2002	4.61	3.45	101	5.03	3.13	101	14.0%	-0.13 [-0.40, 0.15]	
Reginster 2001	156.1	101.9	106	164.2	104.5	106	14.0%	-0.08 [-0.35, 0.19]	
Rovati 1997	24.3	19.3	79	50	22	77	13.1%	-1.24 [-1.58, -0.89]	_
Zenk 2002	-74.7	26.3	13	-76.5	25.1	10	7.3%	0,07 [-0 76, 0,89]	
Total (95% CI)			555			556	100.0%	-0.19 [-0.50, 0.11]	
Heterogeneity: Tau ² = 0.15; Chi ² = 42.29, df = 7 (P < 0.00001); l ² = 83%									
Test for overall effect:	Z=1.22 ((P = 0.22))					Fa	avours Glucosamine Favours Placebo

Step 3: Corresponding Risk – using familiar scale

What is the difference in pain score with glucosamine?

SMD X SD of representative study = corresponding risk

From meta-analysis, McAlindon study, SD = 4.2

 $-0.19 \times 4.2 = -0.798 = 0.8$ points lower

NOTE: many times the mean and SD may not be included in the metaanalysis – consult original study

CONTINUOUS OUTCOMES

Re-expressing SMD using a familiar scale

Summary of Findings for glucosamine for osteoarthritis - outcome pain

Outcomes	Illustrative com (95% Cl)	Relative effect (95% CD	No of Participants	Quality of the	Comments				
	Assumed risk Corresponding risk		(95% CI)	(studies)			evidence (GRADE)		
	no treatment	glucosamine							
Pain	The mean pain	The mean Pain in		1111	€€00	Scores estimated using			
WOMAC ¹ . Scale	ranged across	the intervention		(8)	low ^{2,3}	a standardised mean			
from: 0, no pain	control groups	groups was				difference of -0.19 (-0.50			
to 20, worst pain.	from	0.8 lower				to 0.11)			
(follow-up: mean	6.8 to 7.1	(2.1 lower to 0.5							
3 months)		higher)							

Example: NSAIDs vs acetaminophen for osteoarthritis – outcome global assessment

	NSAID Acetaminophen		Std. Mean Difference			Std. Mean Difference						
Study or Subgroup	Mean	SD	Total	Mean	SD TO	otal	Weight	IV, Fixed, 95% Cl		IV, Fixed	l, 95% Cl	
Pincus 2001	35.41	18.11	101	43.83	21.63	11	58.6%	-0.42 [-0.69, -0.15]				
Williams 1993	2.31	0.55	74	2.44	9.67	73	41.4%	-0.21 [-0.54, 0.11]			<u> </u>	
										-		
Total (95% CI)			175			184	100.0%	-0.33 [-0.54, -0.12]				
Heterogeneity: Chi ² =	0.92, df	= 1 (P =	: 0.34);	$ ^{2} = 0\%$					+	-0.5 (
Test for overall effect:	Z = 3.13	} (P = 0.)	002)						- 1	Favours NSAID	Favours Acet	aminoph

Pincus representative study (scale 0 to 100)
-0.33 X 21.63 = 7.1379

Summary of Findings for glucosamine for osteoarthritis outcome pain

Outcomes	Illustrative comparat Assumed risk	Relative effect (95% Cl)	No of Participants (studies)	
	acetaminophen	NSAID		
Overall well-being Scale from: 0 to 100. (follow-up: 3-6 months)	The mean overall well- being in the control groups was 44 points	The mean Overall well-being in the intervention groups was 7 lower (12 to 3 lower)		280 (2)

Evidence is GRADEd fromHIGH, MODERATE, LOW, VERY LOW

- $\oplus \oplus \oplus \oplus$ Further research is very unlikely to change our confidence in**High**the estimate of effect.
- E Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

 \oplus **OOO** We are very uncertain about the estimate.

RCT evidence in systematic reviews start at HIGH

Downgraded by a level or two based on

- biases in the studies
- results of the meta-analysis

Biases are organised into 5 categories/criteria

5 criteria

- Limitations of design (Risk of Bias Tables)
- Inconsistency (heterogeneity)
- Indirectness (PICO)
- Imprecision
- Reporting Bias/Publication Bias (Funnel plots)

Consider the criteria and how they impact

the confidence in the effect and the magnitude of the effect

Be transparent!

Footnotes available to let users know how you GRADEd the evidence

¹ Self-management is a term applied to any formalized patient education programme aimed at teaching skills needed to carry out medical regimens specific to the disease, guide health behaviour change, and provide emotional support for patients to control their disease and live functional lives. Of the 14 studies, there were four in which the education delivery mode consisted of group education; nine which were individual education and one study which was written education material only. In six studies the use of an action plan for self-treatment of exacerbations was assessed.

² Seven other studies were not pooled and some showed non-significant effects.

³ No allocation concealment in 1 study. Incomplete follow-up.

⁴ Sparse data.

⁵ Different definitions of exacerbations used and studies could not be pooled.

⁶ The low and high risk values are the two extreme numbers of admissions in the control groups from two studies (8% was rounded to 10% and 51% to 50%).

⁷ Two studies with very severe COPD patients weighted heavily in meta-analysis. Therefore, there is some uncertainty with the applicability of effect to all risk groups.

⁸ Unexplained heterogeneity.

HOW DO I CREATE a SUMMARY of FINGINGS TABLE?

- GRADEpro software to create SoF
- Import data from RevMan 5 into GRADEpro
- Create table author makes decisions about information to present and GRADEs the evidence
- Export table from GRADEpro and import into RevMan 5

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- All cause hospital admissions

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About Imprecision for Authors of Systematic Reviews

In systematic reviews each outcome is considered separately.

For dichotomous outcomes

We suggest downgrading the quality of evidence for either of the following three reasons:

- 1. total (cumulative) sample size is lower than the calculated optimal information size (OIS)
- total number of events is less than 300 (based on: Mueller, Montori, Bassler, Koenig, Guyatt. Ethical Issues in Stopping Randomized Trials Early Because of Apparent Benefit. <u>Ann Intern Med. 2007;146:878-881</u>)
- 95% confidence interval (or alternative estimate of precision) around the pooled or best estimate of effect includes both negligible effect and appreciable benefit or appreciable harm. GRADE suggests that threshold for "appreciable benefit" or "appreciable harm" that warrants downgrading is a relative risk reduction (RRR) or relative risk increase (RRI) greater than 25%.



Exception

When event rates are very low, 95% confidence intervals around relative effects can be very wide, but 95% confidence intervals around absolute effects may be narrow. Under such circumstances one may not downgrade the quality of evidence for imprecision.

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🗣 🥅 Tables	Summary of findings @								
 Characteristics of studies Summary of findings tables 	Self management for patients with chronic obstructive pulmonary disease								
🕶 🛄 Additional tables	Patient or population: patients with chronic obstructive pulmonary disease								
► 100 Studies and references	Settings: primary care	e, community, o	utpatient						
A Data and analyses	Intervention: self mar	nagement ¹							
🕶 🐯 Sources of support	incervencion, sen mai	nayement							
– 😲 Feedback	Comparison: usual care								
— 🔄 Appendices	Outcomes Illustrative comparative			Relative No of effect Participa	No of Participants	Quality of the	Comments		
Summary				(95% CI)	(studies)	evidence			
of Findings		Assumed risk	Corresponding risk			(GRADE)			
of Findings									
table is		usual care	management						
imported	Quality of Life	The mean	The mean Quality		698	@@@ @	Lower score		
into the	St George's	quality of life	of Life in the		(7)	moderate	indicates		
muo me	Respiratory	ranged	Intervention			2	better quality		
RevMan 5	from: 0 to 100.	control	2.58 lower				change of less		
file	(follow-up: 3 to 12	groups from	(5.14 to 0.02				than 4 points		
	,			-		-			

Resources

- Cochrane Handbook
 - Chapter 11: Presenting results and 'Summary of findings' tables
 - Chapter 12: Interpreting results and drawing conclusions

www.cochrane-handbook.org (See Part 2)

 GRADEpro software and other resources at <u>http://www.cc-ims.net/gradepro</u>

Resources

- BMJ series of papers in press.
- Schunemann, et al. An official ATS statement: Grading the quality of evidence and strength of recommendations in ATS guidelines and recommendations.
 <u>American Journal of Respiratory and Critical Care</u> <u>Medicine. 174(5):605-14, 2006</u>
- GRADE Working Group. Grading quality of evidence and strength of recommendations. BMJ 2004; 328: 1490-1494.

Support at support@gradepro.org