

# Preparing Summary of Findings tables for Cochrane Reviews

**Introduction**  
**Translating and presenting numbers**  
**GRADEing the evidence**

Applicability and Recommendations Methods Group  
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# 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 management<sup>1</sup>

**Comparison:** usual care

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk usual care	Corresponding risk self management				
<b>Quality of Life</b> 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)	⊕⊕⊕⊕ moderate <sup>2</sup>	Lower score indicates better quality of life. A change of less than 4 points is not shown to be important to patients.
<b>Dyspnoea</b> 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)	⊕⊕⊕⊕ low <sup>4</sup>	Lower score indicates improvement
<b>Number and severity of exacerbations<sup>5</sup></b>	See comment	See comment	Not estimable <sup>5</sup>	591 (3)	See comment	Effect is uncertain
<b>Respiratory-related hospital admissions</b> (follow-up: 3 to 12 months)	<b>Low risk population<sup>6</sup></b>		OR 0.64 (0.47 to 0.89)	966 (8)	⊕⊕⊕⊕ moderate <sup>7</sup>	
	10 per 100	7 per 100 (5 to 9)				
	<b>High risk population<sup>6</sup></b>					
	50 per 100	39 per 100 (32 to 47)				
<b>Emergency department visits for lung diseases</b> (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)	⊕⊕⊕⊕ moderate <sup>4</sup>	
<b>Doctor and nurse visits</b> (follow-up: 6 to 12 months)	The mean doctor and nurse visits ranged across control groups from 1 to 5 visits 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)	⊕⊕⊕⊕ moderate <sup>8</sup>	

\*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:**

Effing T, Monninkhof EM, van der Valk PDLPM, van der Palen J, van Herwaarden CLA, Partidge MR, Walters EH, Zielhuis GA. Self-management education for patients with chronic obstructive pulmonary disease. *Cochrane Database of Systematic Reviews* 2007, Issue 4. Art. No.: CD002990. DOI: 10.1002/14651858.CD002990.pub2.

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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

1997; Gourley 1998; Martin 2004; Coultas 2005a; two points 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 character-

istics. In the studies by Howland 1986 and Cochrane 1987, general 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

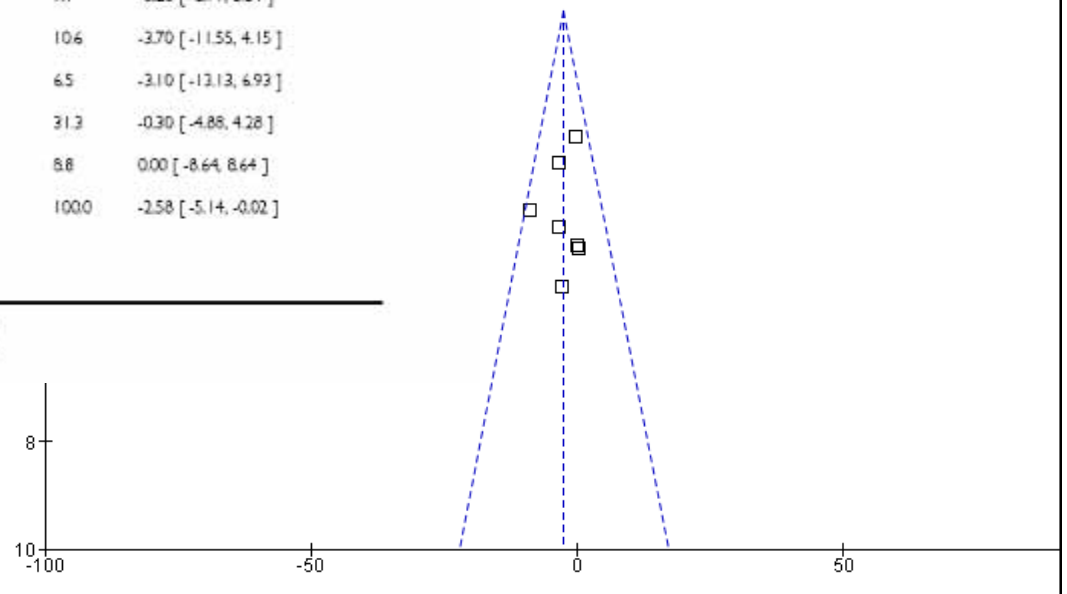
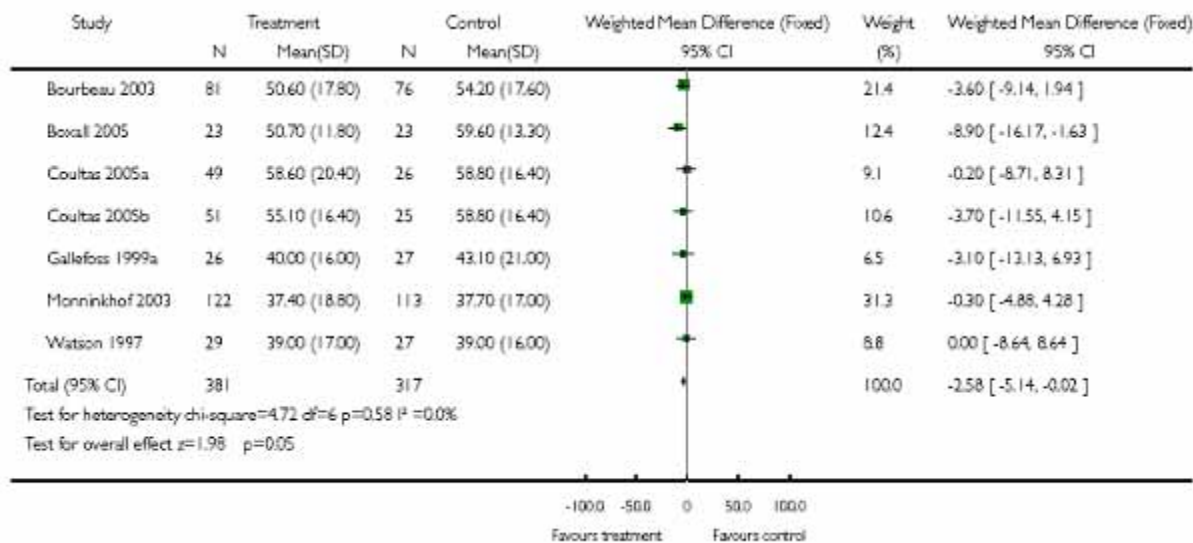
# Summary of key information from systematic reviews: Forest and Funnel Plots

## 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



# Summary of key information from systematic reviews: Bias

	Adequate sequence generation	Allocation concealment	Blinding (Patient-reported outcomes)	Blinding (Mortality)	Incomplete outcome data addressed (Short-term outcomes (2-6 wks))	Incomplete outcome data addressed (Longer-term outcomes (> 6 wks))	Free of selective reporting	Free of other bias
Earry 1988	+	-	+	+	-	-	-	-
Baylis 1989	+	+	+	+	?	?	+	?
Cooper 1987	+	?	-	?	-	-	+	?
Dodd 1985	+	?	+	+	+	-	?	?
Goodwin 1986	+	+	+	+	+	+	+	+
Sanders 1983	+	+	-	?	-	-	-	-

Risk of  
Bias Tables

# Summary of key information from systematic reviews: Abstract

## 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-management 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, exercise 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

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 management <sup>1</sup>						
Comparison: usual care						
Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk usual care	Corresponding risk self management				
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)	⊕⊕⊕⊕ moderate <sup>2</sup>	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)	⊕⊕⊕⊕ low <sup>3,4</sup>	Lower score indicates improvement
Number and severity of exacerbations <sup>5</sup>	See comment	See comment	Not estimable <sup>6</sup>	591 (3)	See comment	Effect is uncertain
Respiratory-related hospital admissions (follow-up: 3 to 12 months)	Low risk population <sup>a</sup>		OR 0.64 (0.47 to 0.89)	966 (8)	⊕⊕⊕⊕ moderate <sup>7</sup>	
	10 per 100	7 per 100 (5 to 9)				
	High risk population <sup>a</sup>					
	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)	⊕⊕⊕⊕ moderate <sup>4</sup>	
Doctor and nurse visits (follow-up: 6 to 12 months)	The mean doctor and nurse visits ranged across control groups from 1 to 5 visits 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)	⊕⊕⊕⊕ moderate <sup>8</sup>	

\*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

- 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 management for patients with chronic obstructive pulmonary disease

**Patient or population:** patients with chronic obstructive pulmonary disease

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<b>Quality of Life</b> 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)		688 (7)	⊕⊕⊕⊕ moderate <sup>2</sup>	Lower score indicates better quality of life. A change of less than 4 points is not shown to be important to patients.
<b>Dyspnoea</b> 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)	⊕⊕⊕⊕ low <sup>3,4</sup>	Lower score indicates improvement
<b>Number and severity of exacerbations<sup>5</sup></b>	See comment	See comment	Not estimable <sup>5</sup>	591 (3)	See comment	Effect is uncertain
<b>Respiratory-related hospital admissions</b> (follow-up: 3 to 12 months)	<b>Low risk population<sup>6</sup></b>		OR 0.64 (0.47 to 0.89)	966 (8)	⊕⊕⊕⊕ moderate <sup>7</sup>	
	10 per 100	7 per 100 (5 to 9)				
	<b>High risk population<sup>6</sup></b>					
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<b>Emergency department visits for lung diseases</b> (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)	⊕⊕⊕⊕ moderate <sup>4</sup>	



# 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 management<sup>1</sup>

Comparison: usual care

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk usual care	Corresponding risk self management				
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)	⊕⊕⊕⊕ moderate <sup>2</sup>	Lower score indicates better quality of life. A change of less than 4 points is not shown to be important to patients.
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Respiratory-related hospital admissions (follow-up: 3 to 12 months)	Low risk population <sup>6</sup>		OR 0.64 (0.47 to 0.89)	966 (8)	⊕⊕⊕⊕ moderate <sup>7</sup>	
	10 per 100	7 per 100 (5 to 9)				
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Doctor and nurse	The mean doctor	The mean doctor		829	⊕⊕⊕⊕	

- 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 management<sup>1</sup>

Comparison: usual care

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
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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)	⊕⊕⊕⊕ moderate <sup>2</sup>	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)	⊕⊕⊕⊕ low <sup>3,4</sup>	Lower score indicates improvement
Number and severity of exacerbations <sup>5</sup>	See comment	See comment	Not estimable <sup>5</sup>	591 (3)	See comment	Effect is uncertain
Respiratory-related hospital admissions (follow-up: 3 to 12 months)	Low risk population <sup>6</sup>		OR 0.64 (0.47 to 0.89)	966 (8)	⊕⊕⊕⊕ moderate <sup>7</sup>	
	10 per 100	7 per 100 (5 to 9)				
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- 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 management<sup>1</sup>

Comparison: usual care

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk usual care	Corresponding risk self management				
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)	⊕⊕⊕⊕ moderate <sup>2</sup>	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)	⊕⊕⊕⊕ low <sup>3,4</sup>	Lower score indicates improvement
Number and severity of exacerbations <sup>5</sup>	See comment	See comment	Not estimable <sup>5</sup>	591 (3)	See comment	Effect is uncertain
Respiratory-related hospital admissions (follow-up: 3 to 12 months)	Low risk population <sup>6</sup>		OR 0.64 (0.47 to 0.89)	966 (8)	⊕⊕⊕⊕ moderate <sup>7</sup>	
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Doctor and nurse	The mean doctor	The mean doctor		829	⊕⊕⊕⊕	

From meta-analysis

Relative Risks, Odds ratios, Hazard ratios, etc.

# Results – Baseline risks (Assumed 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 management<sup>1</sup>

Comparison: usual care

Outcomes	Illustrative comparative risks* (95% CI) Assumed risk usual care	Relative risks* Corresponding risk self management	Relative effect (95% CI)	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 58 to 60 points	The mean quality of Life in the intervention groups was 2.58 lower (5.14 to 0.02 lower)		698 (7)	⊕⊕⊕⊕ moderate <sup>2</sup>	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)	⊕⊕⊕⊕ low <sup>3,4</sup>	Lower score indicates improvement
Number and severity of exacerbations <sup>5</sup>	See comment	See comment	Not estimable <sup>5</sup>	591 (3)	See comment	Effect is uncertain
Respiratory-related hospital admissions (follow-up: 3 to 12 months)	Low risk population <sup>6</sup> 10 per 100	7 per 100 (5 to 9)	OR 0.64 (0.47 to 0.89)	966 (8)	⊕⊕⊕⊕ moderate <sup>7</sup>	
	High risk population <sup>6</sup> 60 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)	⊕⊕⊕⊕ moderate <sup>4</sup>	

- 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 management<sup>1</sup>

Comparison: usual care

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Number and severity of exacerbations <sup>5</sup>	See comment	See comment	Not estimable <sup>5</sup>	591 (3)	See comment	Effect is uncertain
Respiratory-related hospital admissions (follow-up: 3 to 12 months)	Low risk population <sup>6</sup> 10 per 100	7 per 100 (5 to 9)	OR 0.64 (0.47 to 0.89)	966 (8)	⊕⊕⊕⊕ moderate <sup>7</sup>	
	High risk population <sup>6</sup> 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)	⊕⊕⊕⊕ moderate <sup>4</sup>	
Doctor and nurse	The mean doctor	The mean doctor		629	⊕⊕⊕⊕	

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 management<sup>1</sup>

Comparison: usual care

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk usual care	Corresponding risk self management				
<b>Quality of Life</b> 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)	⊕⊕⊕⊕ moderate <sup>2</sup>	Lower score indicates better quality of life. A change of less than 4 points is not shown to be important to patients.
<b>Dyspnoea</b> 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)	⊕⊕⊕⊕ low <sup>3,4</sup>	Lower score indicates improvement
<b>Number and severity of exacerbations<sup>5</sup></b>	See comment	See comment	Not estimable <sup>5</sup>	591 (3)	See comment	Effect is uncertain
<b>Respiratory-related hospital admissions</b> (follow-up: 3 to 12 months)	Low risk population <sup>6</sup>		OR 0.64 (0.47 to 0.89)	966 (8)	⊕⊕⊕⊕ moderate <sup>7</sup>	
	10 per 100	7 per 100 (5 to 9)				
	High risk population <sup>6</sup>					
	50 per 100	39 per 100 (32 to 47)				
<b>Emergency department visits for lung diseases</b> (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)	⊕⊕⊕⊕ moderate <sup>4</sup>	

- 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 management<sup>1</sup>

**Comparison:** usual care

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk usual care	Corresponding risk self management				
<b>Quality of Life</b> 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)	⊕⊕⊕⊕ moderate <sup>2</sup>	Lower score indicates better quality of life. A change of less than 4 points is not shown to be important to patients.
<b>Dyspnoea</b> 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)	⊕⊕⊕⊕ low <sup>3,4</sup>	Lower score indicates improvement
<b>Number and severity of exacerbations<sup>5</sup></b>	See comment	See comment	Not estimable <sup>5</sup>	591 (3)	See comment	Effect is uncertain
<b>Respiratory-related hospital admissions</b> (follow-up: 3 to 12 months)	<b>Low risk population<sup>6</sup></b>		OR 0.64 (0.47 to 0.89)	966 (8)	⊕⊕⊕⊕ moderate <sup>7</sup>	
	10 per 100	7 per 100 (5 to 9)				
	<b>High risk population<sup>6</sup></b>					
	50 per 100	39 per 100 (32 to 47)				
<b>Emergency department visits for lung diseases</b> (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)	⊕⊕⊕⊕ moderate <sup>4</sup>	

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

# Footnotes

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<sup>1</sup> 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.

<sup>2</sup> Seven other studies were not pooled and some showed non-significant effects.

<sup>3</sup> No allocation concealment in 1 study. Incomplete follow-up.

<sup>4</sup> Sparse data.

<sup>5</sup> Different definitions of exacerbations used and studies could not be pooled.

<sup>6</sup> 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%).

<sup>7</sup> 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.

<sup>8</sup> Unexplained heterogeneity.

---

- Clarification
- Judgements
- Transparency

**Where do the numbers  
come from?**

**Dichotomous and Continuous  
Outcomes**

# DICHOTOMOUS OUTCOMES YES/NO

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)
	Assumed risk Control	Corresponding risk Amantadine		
<b>Cases of Infection with prophylaxis</b> (follow up: 14-18 weeks)	<b>Medium risk population</b>		<b>RR 0.11</b> (0.04 to 0.3)	773 (2)
	<b>10 per 100</b>	<b>1 per 100</b> (0 to 3)		

## Amantadine to prevent the influenza

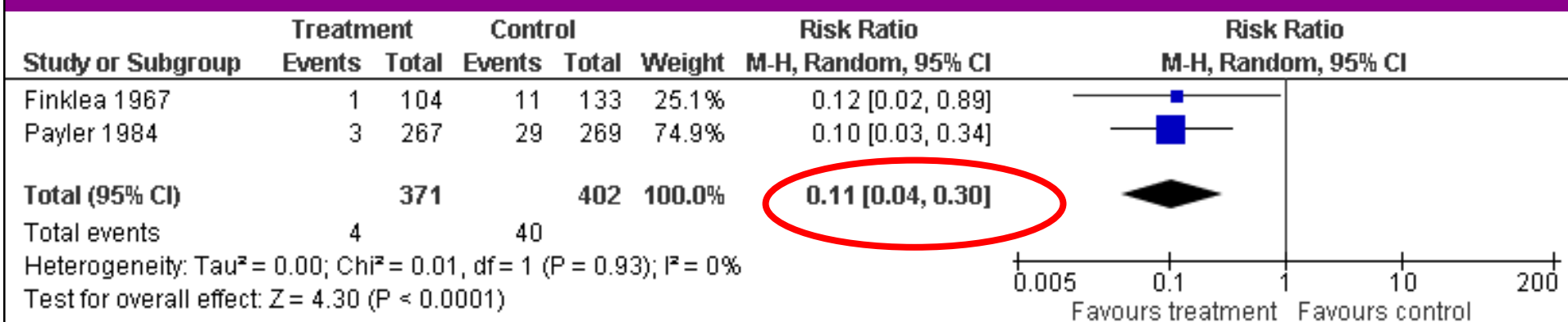
**Outcome:** cases of infection (infection or not)

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

**Results presented as:** #s per 100/1000



# Information from Meta-analysis



# DICHOTOMOUS OUTCOMES YES/NO

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)
	Assumed risk Control	Corresponding risk Amantadine		
Cases of Infection with prophylaxis (follow-up: 14-18 weeks)	Medium risk population		RR 0.11 (0.04 to 0.3)	773 (2)
	10 per 100	1 per 100 (0 to 3)		

## Converting RR to # per 100

$$\text{RR} = 0.11$$

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	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)
	Assumed risk Control	Corresponding risk Amantadine		
Cases of Infection with prophylaxis (follow-up: 14-18 weeks)	Medium risk population		RR 0.11 (0.04 to 0.3)	773 (2)
	10 per 100	1 per 100 (0 to 3)		

## Step 1: Assumed Risk

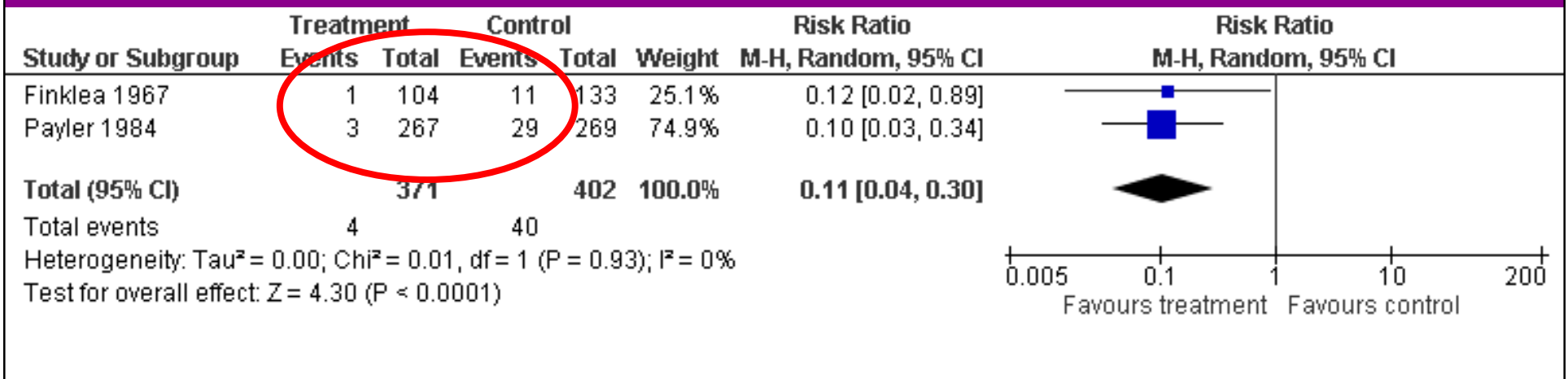
How many people have an infection without amantadine?

- 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 comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)
	Assumed risk Control	Corresponding risk Amantadine		
Cases of Infection with prophylaxis (follow-up: 14-18 weeks)	Medium risk population		RR 0.11 (0.04 to 0.3)	773 (2)
	10 per 100	1 per 100 (0 to 3)		

## Step 2: Relative effect

- RR = 0.11

## Step 3: Corresponding Risk

How many people have an infection with amantadine?

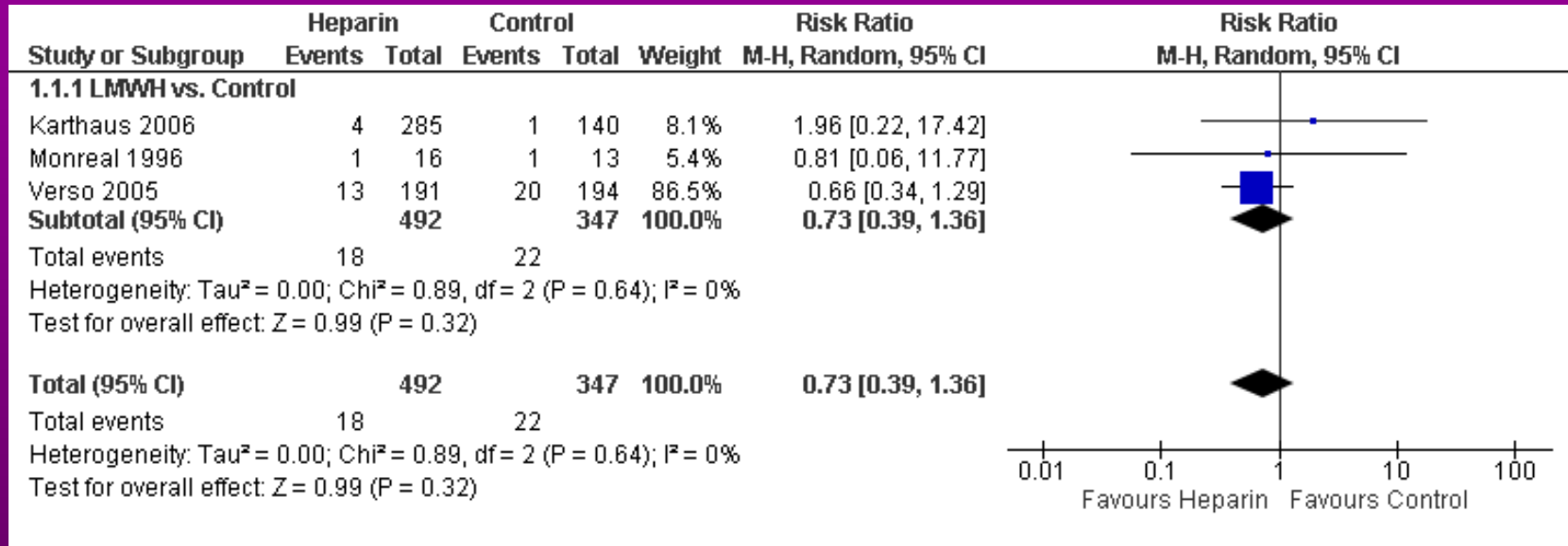
assumed risk X relative risk = corresponding risk

$$10 \quad \times \quad 0.11 \quad = \quad 1$$

- 1 per 100 people have the infection if they take amantadine



# Example: Heparin to reduce clots – outcome death



- Median assumed risk = 7.7%

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)
	Assumed risk no treatment	Corresponding risk heparin		
Death	Medium risk population		RR 0.73 (0.39 to 1.36)	839 (3)
	8 per 100	6 per 100 (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-related hospital admissions (follow-up: 3 to 12 months)	Low risk population <sup>a</sup>		OR 0.64 (0.47 to 0.89)	968 (8)
	10 per 100	7 per 100 (5 to 9)		
	High risk population <sup>a</sup>			
	50 per 100	39 per 100 (32 to 47)		

- Need to first convert the OR to an RR
- Based on formula in handbook

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

# CONTINUOUS OUTCOMES

Mean Difference

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)
	Assumed risk usual care	Corresponding risk <b>self management</b>		
<b>Quality of Life</b> 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 <b>38 to 60 points</b>	The mean Quality of Life in the intervention groups was <b>2.58 lower</b> (5.14 to 0.02 lower)		698 (7)

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

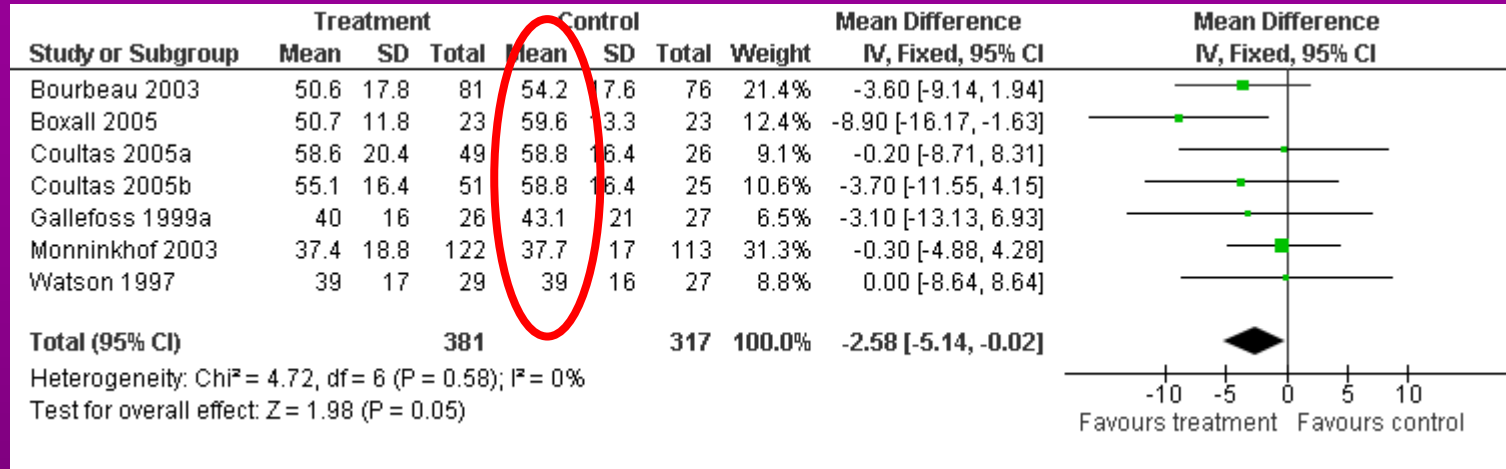
**Outcome:** Quality of Life scale (0 to 100 scale)

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

**Results presented as:** points on a scale

# CONTINUOUS OUTCOMES

Mean Difference



## Step 1: Assumed Risk

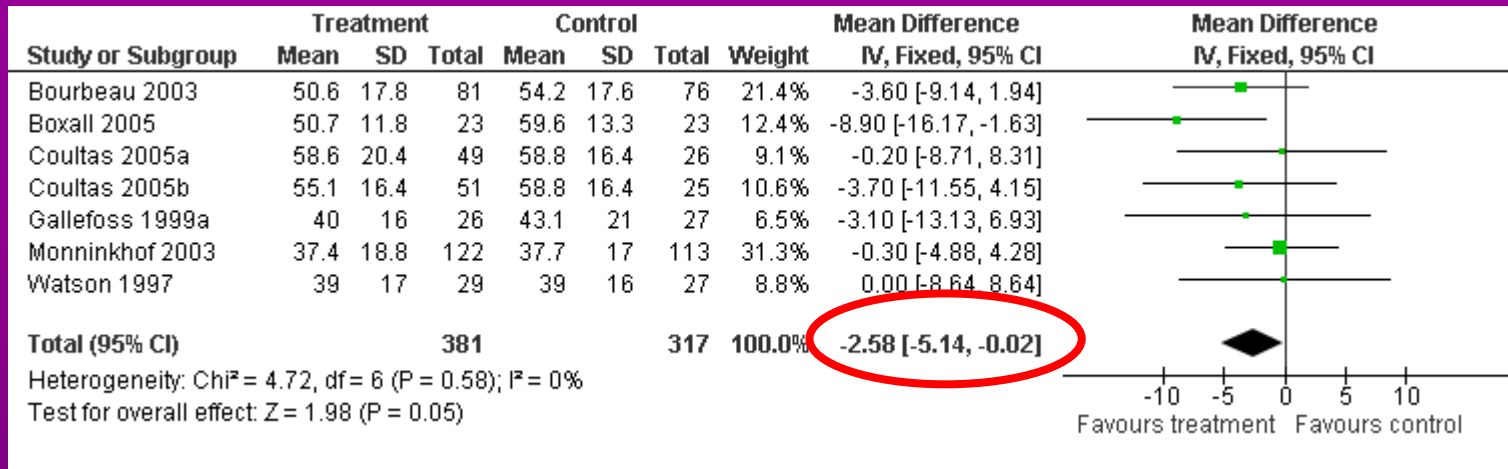
In people who don't do a self management programme, what is their score on the Quality of Life scale?

- 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

## Self management for patients with chronic obstructive pulmonary disease

**Patient or population:** patients with chronic obstructive pulmonary disease

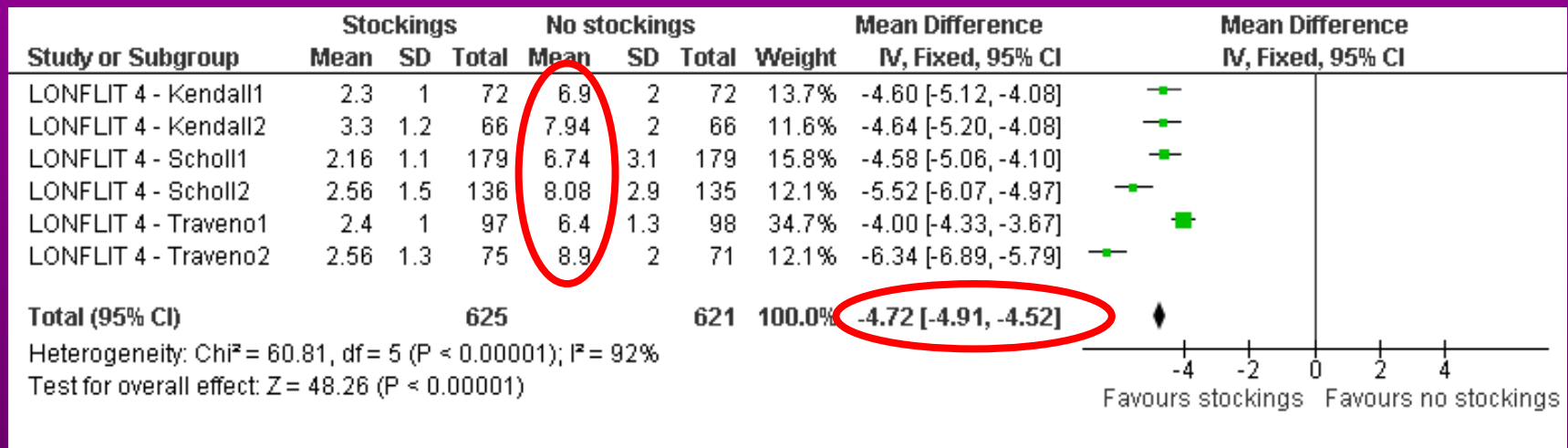
**Settings:** primary care, community, outpatient

**Intervention:** self management<sup>1</sup>

**Comparison:** usual care

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)
	Assumed risk usual care	Corresponding risk self management		
<b>Quality of Life</b> 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 <b>38 to 60 points</b>	The mean Quality of Life in the intervention groups was <b>2.58 lower</b> (5.14 to 0.02 lower)		698 (7)

# 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

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

# CONTINUOUS OUTCOMES

## Re-expressing SMD using a familiar scale

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)
	Assumed risk no treatment	Corresponding risk glucosamine		
<b>Pain</b> Scale from: 0 to 10. (follow-up: 1-3 months)	The mean pain in the control groups was <b>6.6</b>	The mean Pain in the intervention groups was <b>0.8 lower</b> (2.1 lower to 0.5 higher)		1111 (8)

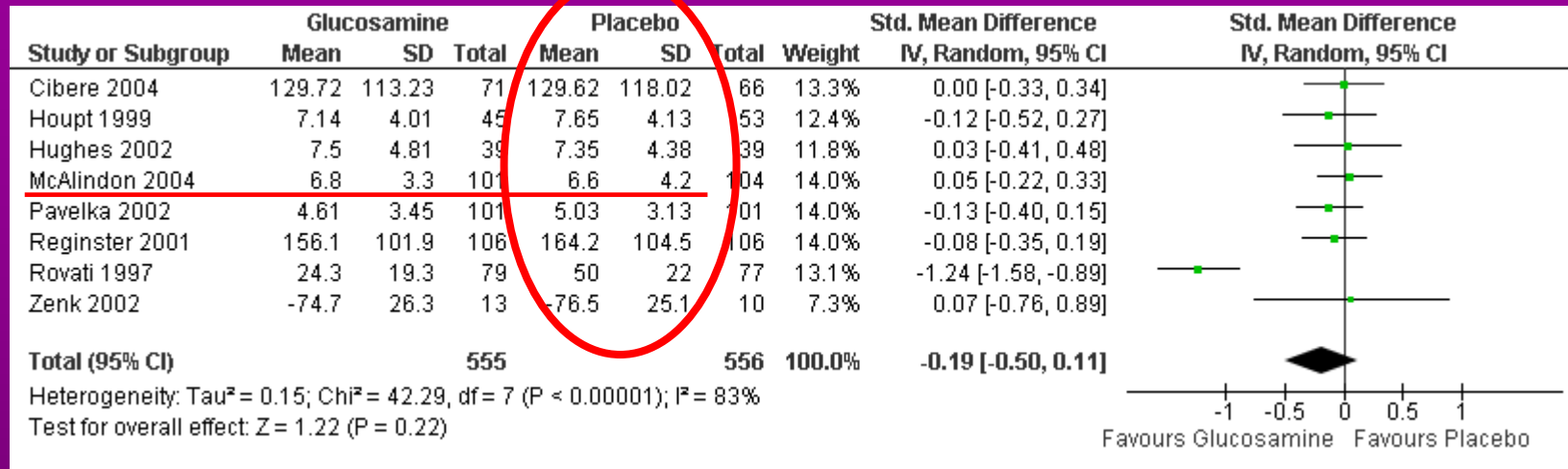
### Glucosamine to improve arthritis

**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

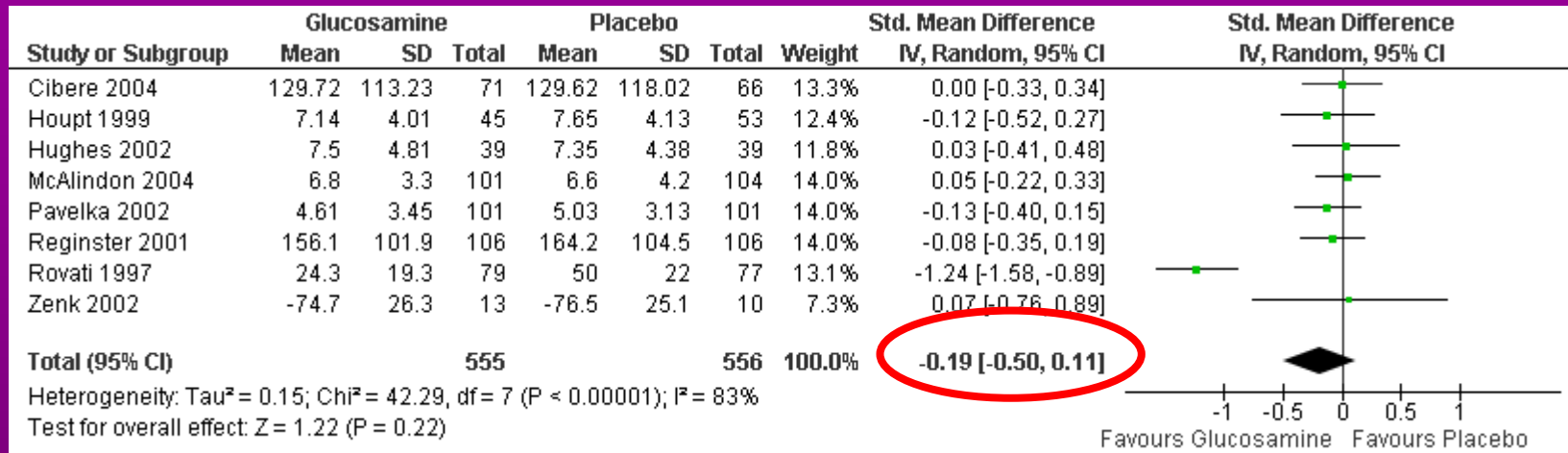
In people who don't take glucosamine, what is their pain score?

- 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



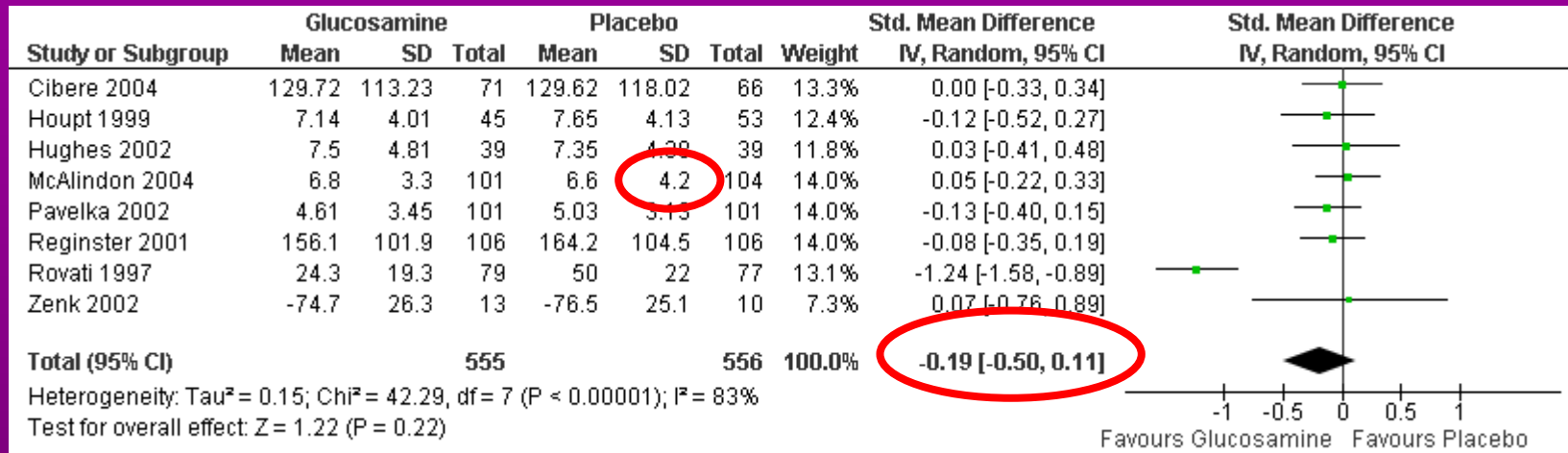
## Step 2: Effect

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.

SMD = - 0.19 (- 0.50, 0.11)



# CONTINUOUS OUTCOMES SMD



## 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

$$-0.19 \times 4.2 = -0.798 = 0.8 \text{ points lower}$$

*NOTE: many times the mean and SD may not be included in the meta-analysis – consult original study*

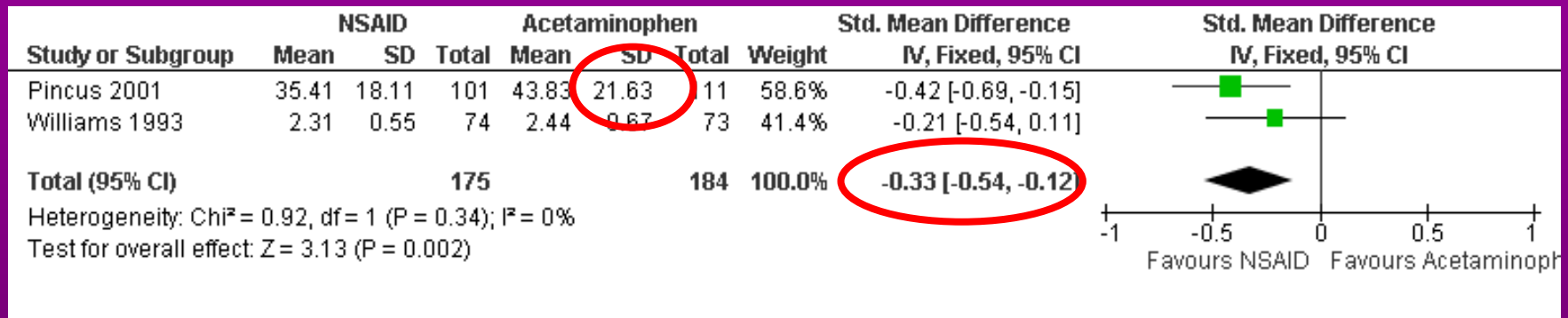
# CONTINUOUS OUTCOMES

## Re-expressing SMD using a familiar scale

### Summary of Findings for glucosamine for osteoarthritis - outcome pain

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

# Example: NSAIDs vs acetaminophen for osteoarthritis – outcome global assessment



- Pincus representative study (scale 0 to 100)
- $-0.33 \times 21.63 = 7.1379$

# Summary of Findings for glucosamine for osteoarthritis - outcome pain

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

# GRADEing the evidence

Evidence is GRADEd from

- HIGH, MODERATE, LOW, VERY LOW

⊕⊕⊕⊕  
**High**

Further research is very unlikely to change our confidence in the estimate of effect.

⊕⊕⊕○  
**Moderate**

Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

⊕⊕○○  
**Low**

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.

⊕○○○  
**Very low**

We are very uncertain about the estimate.

# GRADEing the evidence

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



# GRADEing the evidence

## 5 criteria

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

# **GRADEing the evidence**

**Consider the criteria and how they  
impact**

**the confidence in the effect  
and  
the magnitude of the effect**

# GRADEing the evidence

## Be transparent!

Footnotes available to let users know  
how you GRADEd the evidence

---

<sup>1</sup> 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.

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<sup>3</sup> No allocation concealment in 1 study. Incomplete follow-up.

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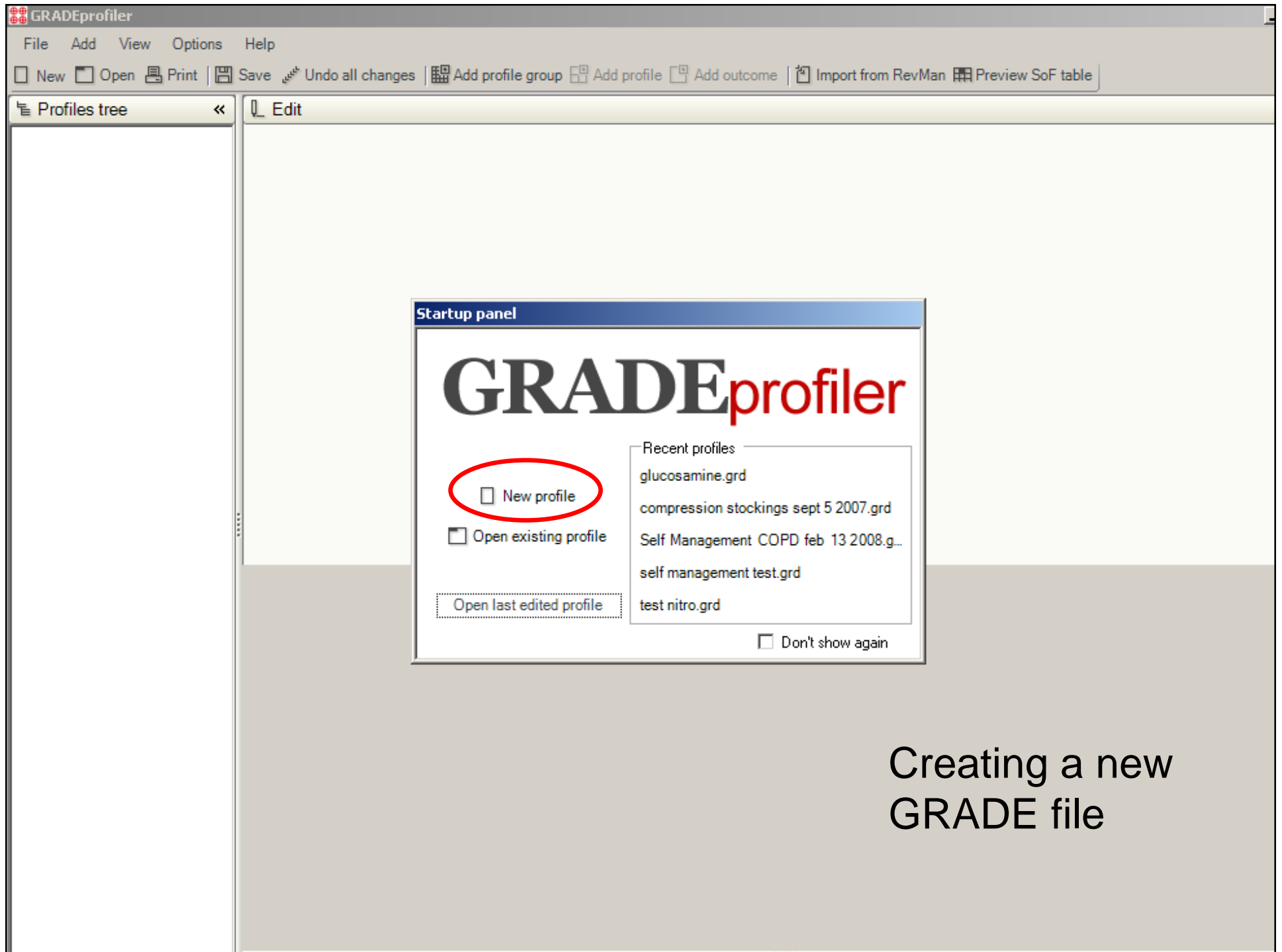
<sup>7</sup> Two studies with very severe COPD patients weighted heavily in meta-analysis. Therefore, there is some uncertainty with the applicability of effect to all risk groups.

<sup>8</sup> Unexplained heterogeneity.

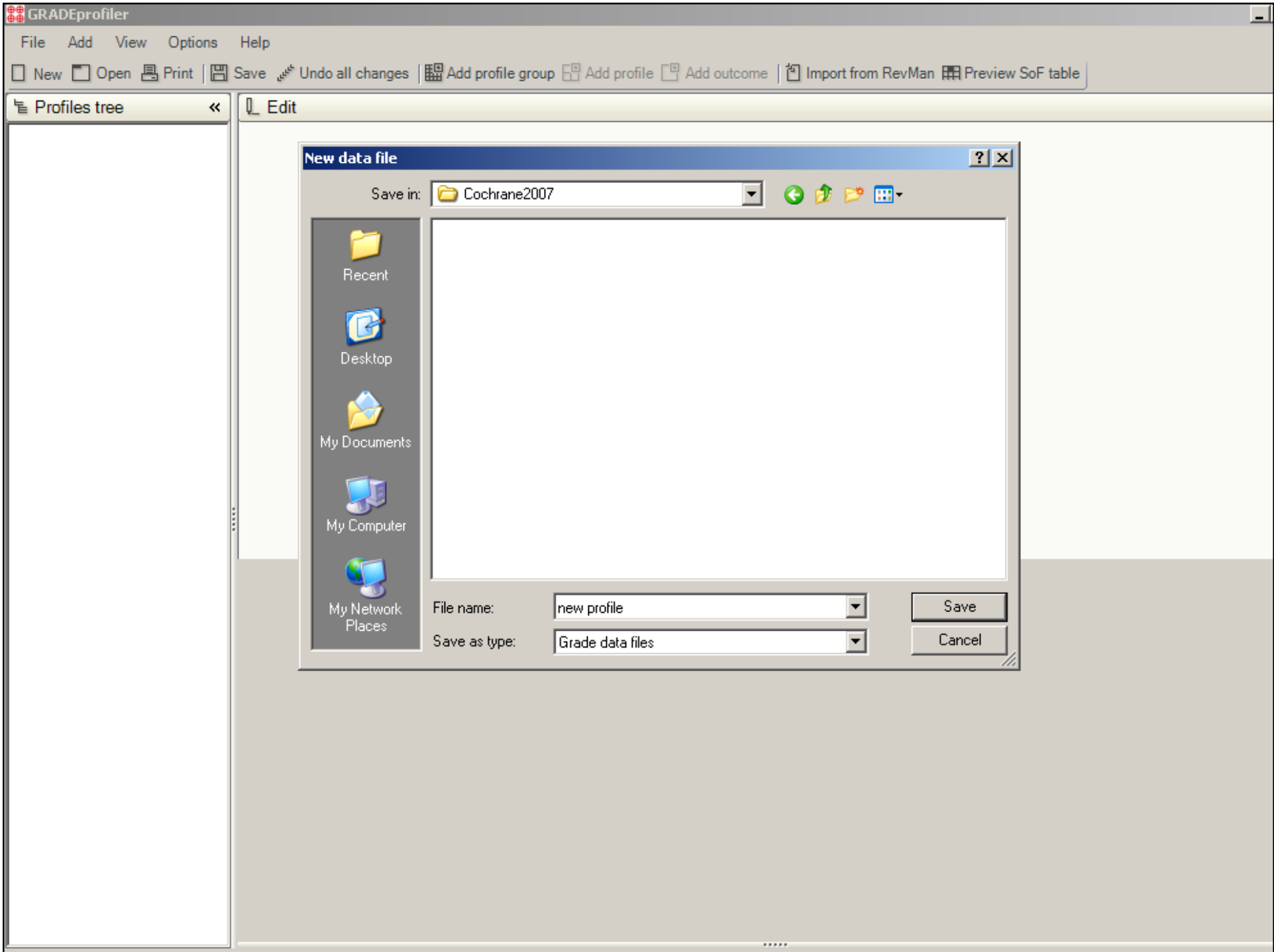
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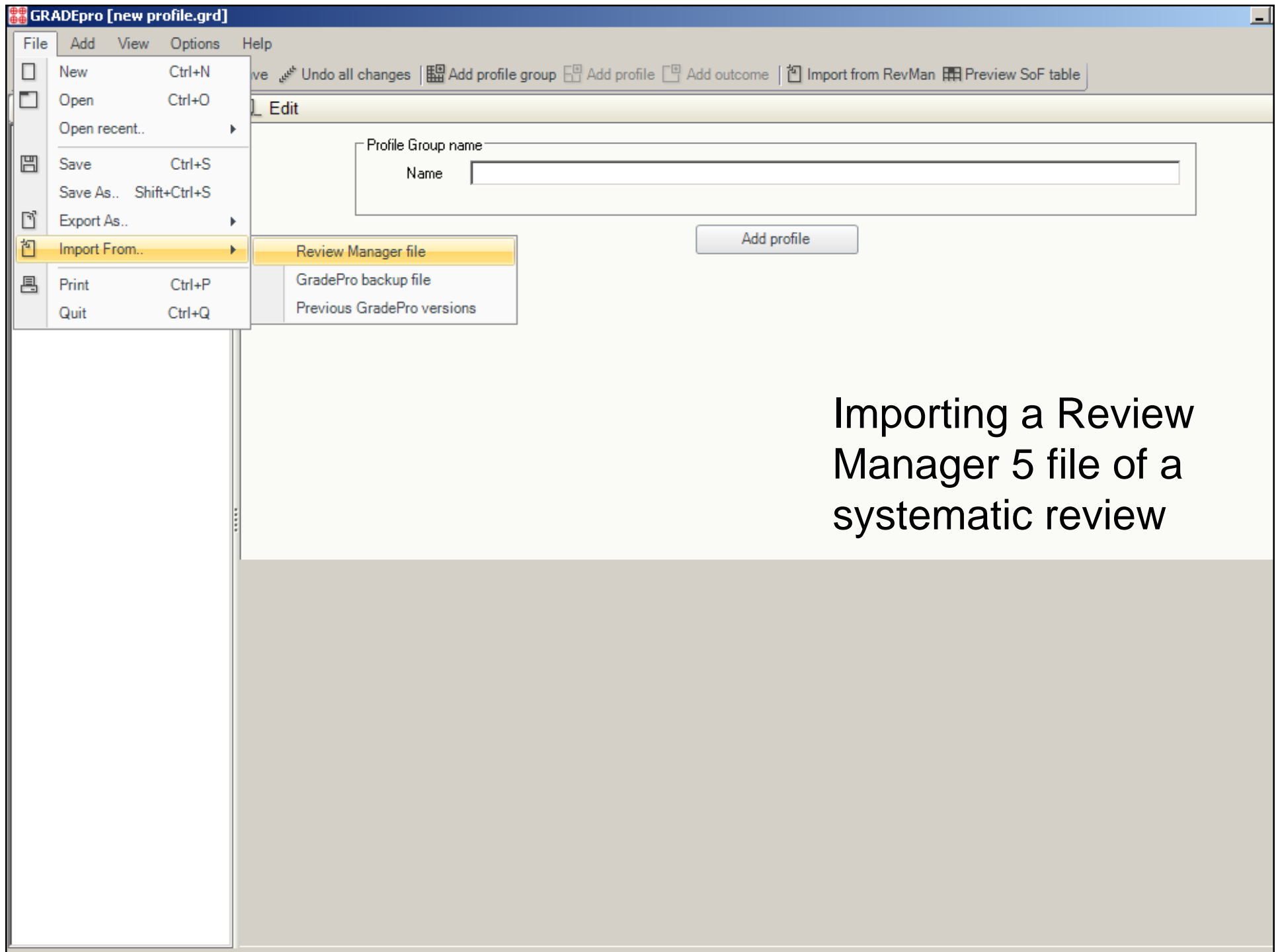
# HOW DO I CREATE a SUMMARY of FINDINGS TABLE?

- 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



Creating a new  
GRADE file





Importing a Review Manager 5 file of a systematic review





GRADEpro [new profile.grd]

File Add View Options Help

New Open Print Save Undo all changes Add profile group Add profile Add outcome Import from RevMan Preview SoF table

Profiles tree

- Self-management education for patients with chronic obstructive pulmonary disease
  - Self-management versus control for patients with chronic obstructive pulmonary disease
    - HRQOL: SGRQ total
    - HRQOL: SGRQ symptoms
    - HRQOL: SGRQ activity
    - HRQOL: SGRQ impacts
    - HRQOL: CRQ dyspnea
    - HRQOL: CRQ fatigue
    - HRQOL: CRQ emotional function
    - HRQOL: CRQ mastery
    - General HRQOL: SIP Total score**
    - General HRQoL: SIP physical
    - General HRQoL: SIP psychosocial
    - HRQOL: SF-36 Total + domains
    - HRQOL: SF-36 Total + domains
    - HRQOL: SF-36 Total + domains - SF-36
    - HRQOL: SF-36 Total + domains - SF-36
    - HRQOL: SF-36 Total + domains - SF-36
    - HRQOL: SF-36 Total + domains - SF-36
    - HRQOL: SF-36 Total + domains - SF-36
    - HRQOL: SF-36 Total + domains - SF-36
    - Borg score dyspnoea
    - Patients using at least one course of oral corticosteroids
    - Patients using at least one course of oral corticosteroids
    - Respiratory-related hospital admissions
    - All cause hospital admissions
    - Emergency department visits per person
    - Emergency department visits per person
    - Doctor and nurse visits: mean number per person
    - Doctor and nurse visits: mean number per person
    - Days lost from work: mean number per person
    - Lung function: FEV1% pred
    - Exercise capacity: 6MWT
    - Smokers (number of smokers)
  - Subgroup analyses for patients with chronic obstructive pulmonary disease
    - Respiratory-related hospital admissions
    - Respiratory-related hospital admissions
    - Respiratory-related hospital admissions

Edit

Outcome: General HRQOL: SIP Total score  dichotomous  continuous pooled Importance: --

No of studies: 3 Study design: -- choose -- Quality of evidence:

Add outcome  
Delete outcome  
Duplicate outcome  
Copy

Delete Revert Go to Summary of findings

Profile: Self-management versus control for patients with chronic obstructive pulmonary disease

General HRQOL: SIP Total score	The mean general hrqol: sip total score in the intervention groups was	-	249 (3)		
General HRQoL: SIP physical	The mean general hrqol: sip physical in the intervention groups was 0 higher	-	201 (2)		
General HRQoL: SIP psychosocial	The mean general hrqol: sip	-	201 (2)		

Footnotes

Add new Change order Edit Delete

Managing outcomes to include a maximum of 7

GRADEpro [new profile.grd]

File Add View Options Help

New Open Print Save Undo all changes Add profile group Add profile Add outcome Import from RevMan Preview SoF table

Profiles tree

- Self-management education for patients with chronic obstructive pulmonary disease
  - Self-management versus control for patients with chronic obstructive pulmonary disease
    - HRQoL: SGRQ total
    - HRQoL: SGRQ symptoms
    - HRQoL: SGRQ activity
    - HRQoL: SGRQ impacts
    - HRQoL: CRQ dyspnea
    - HRQoL: CRQ fatigue
    - HRQoL: CRQ emotional function
    - HRQoL: CRQ mastery
    - General HRQoL: SIP Total score
    - General HRQoL: SIP physical
    - General HRQoL: SIP psychosocial
    - HRQoL: SF-36 Total + domains - SF-36
    - HRQoL: SF-36 Total + domains - SF-36
    - HRQoL: SF-36 Total + domains - SF-36
    - HRQoL: SF-36 Total + domains - SF-36
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    - HRQoL: SF-36 Total + domains - SF-36
    - Borg score dyspnoea
    - Patients using at least one course of or more courses of antibiotics
    - Respiratory-related hospital admissions**
    - All cause hospital admissions
    - Emergency department visits per person
    - Emergency department visits per person
    - Doctor and nurse visits: mean number per person
    - Doctor and nurse visits: mean number per person
    - Days lost from work: mean number per person
    - Lung function: FEV1% pred
    - Exercise capacity: 6Mw
    - Smokers (number of smokers)
  - Subgroup analyses for patients with chronic obstructive pulmonary disease
    - Respiratory-related hospital admissions
    - Respiratory-related hospital admissions
    - Respiratory-related hospital admissions

Edit

Outcome: **Respiratory-related hospital admissions** assessed with: [ ]

Length of follow-up: [ 0 ]

Number of participants: Intervention with event 95 total 528 18 %

Control with event 112 total 438 25.6 %

Range of control group risks in individual studies [ 8 ] % to [ 50.5 ] %

Control risk:  Low [ 0 ] %  Medium [ 17.4 ] %  High [ 0 ] %

Estimate of the effect Relative: OR of 0.64 95% CI from 0.47 to 0.89

Auto absolute effect calculation Absolute: 82 fewer per 1000 95% CI from 24 to 124

Delete Revert Go to Quality Assessment

Profile: Self-management versus control for patients with chronic obstructive pulmonary disease

Patients using at least one course of antibiotics	See comment	See comment	Not estimable	105 (1)		
Respiratory-related hospital admissions	174 per 1000	119 per 1000 (90 to 158)	OR 0.64 (0.47 to 0.89)	966 (8)		
All cause hospital	154 per 1000	220 per 1000	OR 1.55 (0.87 to	286		

Footnotes

Enter information for dichotomous outcomes

Add new Change order Edit Delete



- Welcome to GRADEprofiler
- Getting started
- Overview of GRADE Approach
  - The GRADE approach
    - Purpose
    - Separation of quality and s
    - Clinical question
    - Importance of outcomes
    - Summarizing the evidence
  - Quality of evidence
    - Factors determining the
      - Study design
      - Study limitations
      - Inconsistent results
      - Indirectness of evic
    - Imprecision
      - Imprecision in s
      - Imprecision in g
    - Reporting bias
    - Large or very large
    - Plausible biases un
    - Dose-response gre
    - Examples of quality
  - Levels of evidence
  - Quality of evidence dia
  - Overall quality of evide
- Going from evidence to rec

- Creating evidence profiles
- Creating a SoF Tables
- Viewing evidence tables
- Managing evidence profiles
- Screenshots
- References to articles about GRAD
- Glossary of terms and concepts
- Additional resources
- Alphabetical list of topics
- System requirements
- Technical support
- GRADE Working Group

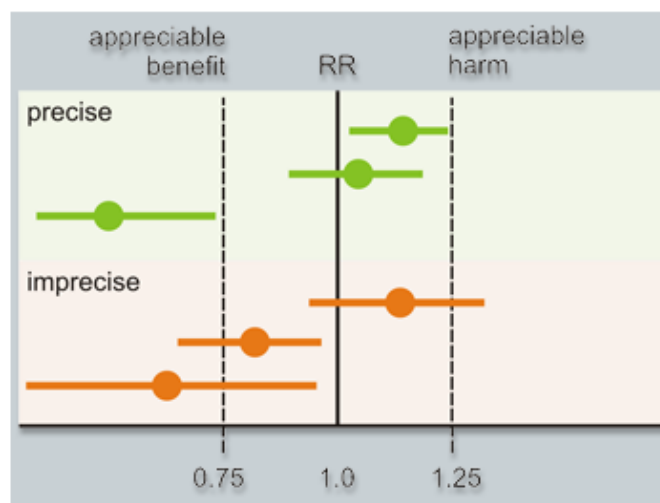
## About Imprecision for Authors of Systematic Reviews

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)
2. 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. Ann Intern Med. 2007;146:878-881)
3. 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%.



**HELP files  
when  
GRADEing  
the  
evidence**

### 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.

GRADEpro [Self Management COPD feb 13 2008.grd]

File Add View Options Help

New Open Print Save Undo all changes Add profile group Add profile Add outcome Import from RevMan Preview SoF table

Profiles tree

- Self-management education
  - Self-management for pa
  - Subgroup analyses for p
  - self management vs usu
    - Quality of Life**
    - Dyspnoea
    - Number and severit
    - Respiratory-related I
    - Emergency departr
    - Doctor and nurse vi
  - not included for

Edit

Outcome: Quality of Life  dichotomous  continuous pooled Importance: ..

No of studies: 7

Study design: randomised trial Quality of evidence: MODERATE

Decrease quality of evidence

- Limitations in design: no
- Inconsistency: no
- Indirectness: no
- Imprecision: no
- Reporting bias: likely (-1)

Increase quality of evidence

- Large effect: no
- Plausible confounding would change the effect: no
- Dose-response gradient: no

Delete Revert Go to Summary of findings

Profile: self management vs usual care for chronic obstructive pulmonary disease

Patient or population: patients with chronic obstructive pulmonary disease  
 Settings: primary care, community, outpatient  
 Intervention: self management<sup>1</sup>  
 Comparison: usual care

Outcome	Assumed risk [usual care]	Corresponding risk [self management]	Relative effect (95% CI)	No of participants (studies)	Quality (GRADE)	Comments
Quality of Life St George's Respiratory Questionnaire. Scale from: 0 to 100.	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)	⊕⊕⊕○ moderate <sup>2</sup>	Lower score indicates better quality of life. A change of less than 4 points is not shown to be important to patients.

Footnotes

1. Self-management is a term applied to any formalized patient education programme aimed at teaching skills needed to carry...
2. Seven other studies were not pooled and some showed non-significant effects.
3. Sparse data.
4. No allocation concealment in 1 study. Incomplete follow-up.
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 10% was ro...

Add new Change order Edit De

## Footnotes for transparency

GRADEpro [Self Management COPD feb 13 2008.grd]

File Add View Options Help

New Open Print Save Undo all changes Add profile group Add profile Add outcome Import from RevMan **Preview SoF table**

Profiles tree << Edit

- Self-management education
  - Self-management for pa
  - Subgroup analyses for p
  - self management vs usu
    - Quality of Life**
    - Dyspnoea
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6. The low and high risk values are the two extreme numbers of admissions in the control groups from two studies (9% use re...

Add new Change ord Edit De

Previewing the SoF table before exporting and importing into RevMan 5



**Export as Html**

Selected Profile(s)

Self-management for patients with chronic obstructive pulmonary disease  
 Subgroup analyses for patients with chronic obstructive pulmonary disease  
**self management vs usual care for chronic obstructive pulmonary disease**  
 not included for

Select format

GRADE evidence table

Summary of findings table

Overview of findings table

Options

Export empty layout

Rows no:

Save

Select Outcomes

Close

Hide preview <<

[Help](#)

### 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 management<sup>1</sup>

**Comparison:** usual care

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk usual care	Corresponding risk self management				
<b>Quality of Life</b> 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 <b>38 to 60 points</b>	The mean Quality of Life in the intervention groups was <b>2.58 lower</b> (5.14 to 0.02 lower)		698 (7)	⊕⊕⊕○ <b>moderate</b> <sup>2</sup>	Lower score indicates better quality of life. A change of less than 4 points is not shown to be important to patients.
<b>Dyspnoea</b> Borg Scale. Scale from: 0 to 10. (follow-up: 3 to 6 months)	The mean dyspnoea ranged across control groups from <b>1.2 to 4.1 points</b>	The mean Dyspnoea in the intervention groups was <b>0.53 lower</b> (0.96 to 0.1 lower)		144 (2)	⊕⊕○○ <b>low</b> <sup>3,4</sup>	Lower score indicates improvement
<b>Number and severity of exacerbations</b> <sup>5</sup>	See comment	See comment	Not estimable <sup>5</sup>	591 (3)		Effect is uncertain
<b>Respiratory-related</b>	<b>Low risk population</b> <sup>6</sup>		<b>OR 0.64</b>	966	⊕⊕⊕○	

6. The low and high risk values are the two extreme numbers of admissions in the control groups from two studies (8% was ro...



GRADEpro [Self Management COPD feb 13 2008.grd]

File Add View Options Help

Undo all changes | Add profile group | Add profile | Add outcome | Import from RevMan | Preview SoF table

Edit

Outcome: Quality of Life  dichotomous  continuous pooled Importance: ..

Review Manager SoF

Word document

HTML file

Image

XML file

7 studies

design randomised trial

Quality of evidence MODERATE

Inconsistency no

Indirectness no

Imprecision no

Reporting bias likely (-1)

Increase quality of evidence

Large effect no

Plausible confounding would change the effect no

Dose-response gradient no

Delete Revert Go to Summary of findings

Profile: self management vs usual care for chronic obstructive pulmonary disease

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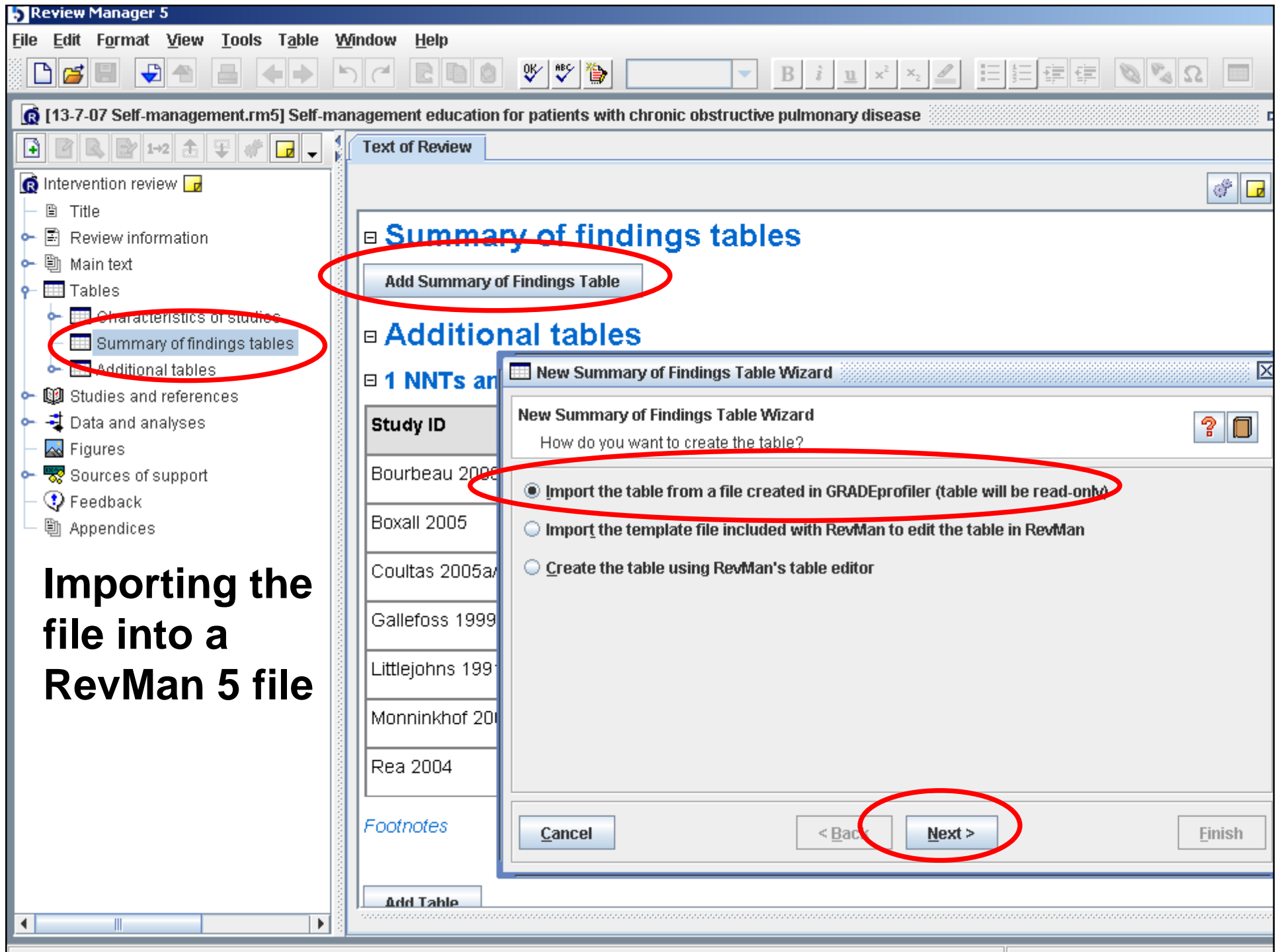
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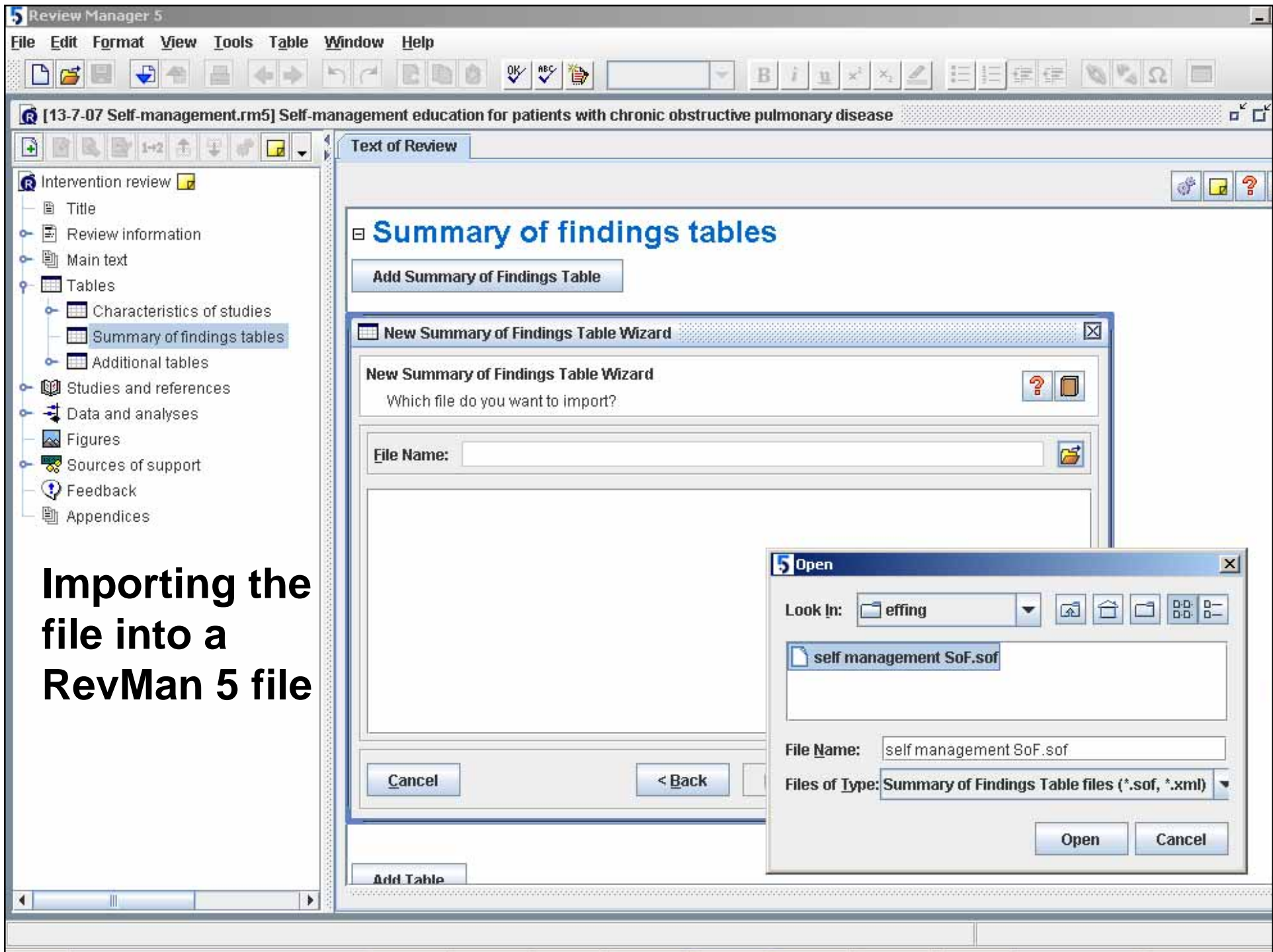
Footnotes

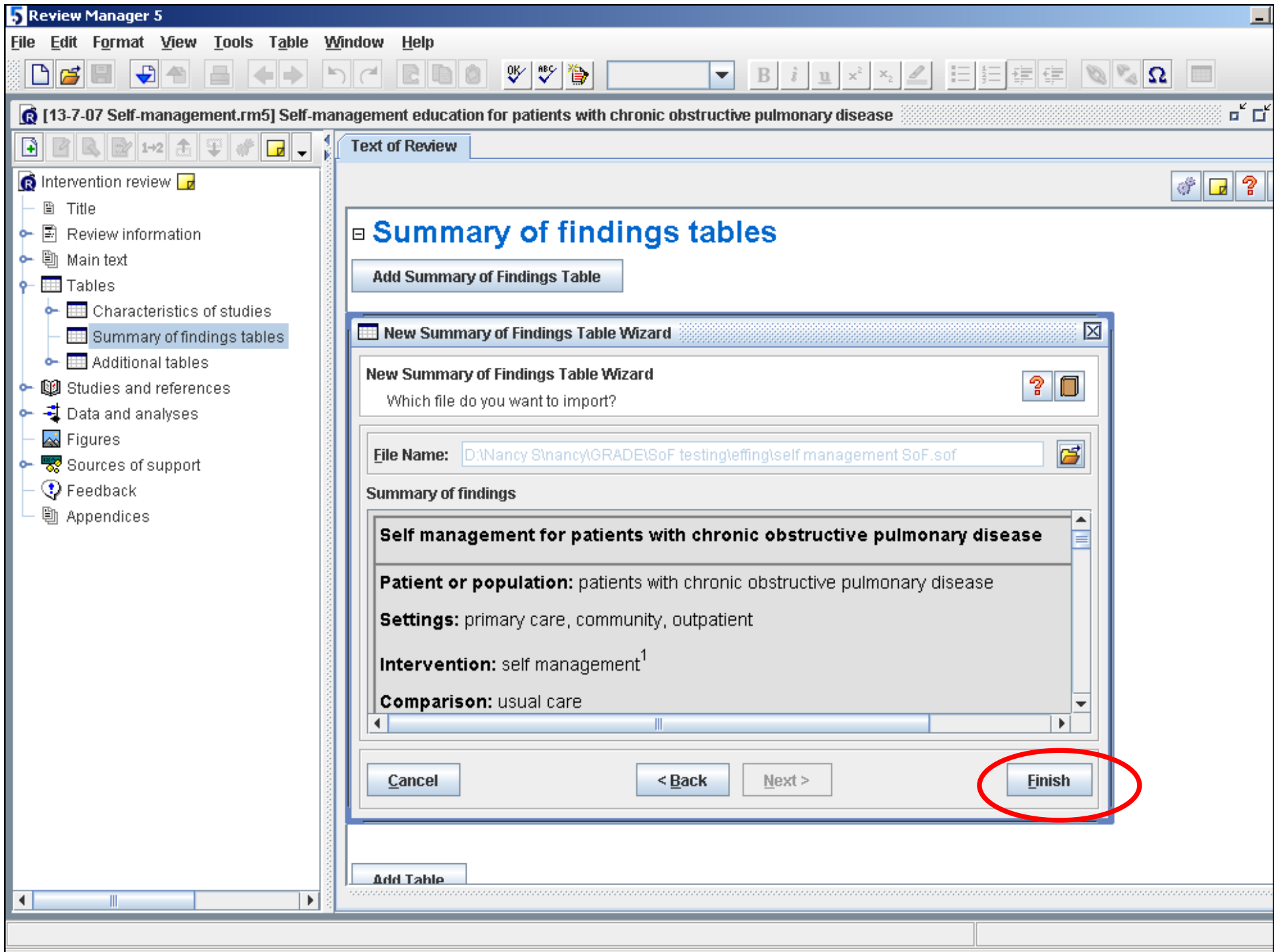
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Add new Change order Edit Delete

## Exporting the SoF in a file for RevMan 5







Review Manager 5

File Edit Format View Tools Table Window Help

[13-7-07 Self-management.rm5] Self-management education for patients with chronic obstructive pulmonary disease

Text of Review

Intervention review

- Title
- Review information
- Main text
- Tables
  - Characteristics of studies
  - Summary of findings tables
  - Additional tables
- Studies and references
- Data and analyses
- Figures
- Sources of support
- Feedback
- Appendices

**Summary of Findings table is imported into the RevMan 5 file**

**Summary of findings tables**

**1 Summary of findings**

**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 management<sup>1</sup>

**Comparison:** usual care

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	usual care	self management				
<b>Quality of Life</b> St George's Respiratory Questionnaire. Scale from: 0 to 100. (follow-up: 3 to 12	The mean quality of life ranged across control groups from	The mean Quality of Life in the intervention groups was <b>2.58 lower</b> (5.14 to 0.02		698 (7)	⊕⊕⊕⊕ <b>moderate</b> 2	Lower score indicates better quality of life. A change of less 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](http://www.cochrane-handbook.org) (See Part 2)

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

# 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.  
American Journal of Respiratory and Critical Care Medicine. 174(5):605-14, 2006
- GRADE Working Group. Grading quality of evidence and strength of recommendations.  
BMJ 2004; 328: 1490-1494.
- Support at [support@gradeapro.org](mailto:support@gradeapro.org)