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 management
Comparison: usual care

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Illustrative comparative risks</th>
<th>Relative effect</th>
<th>No of participants (studies)</th>
<th>Quality of the evidence (GRADE)</th>
<th>Comments</th>
</tr>
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<tbody>
<tr>
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<td>St George’s Respiratory Questionnaire. Scale from: 0 to 100. (follow-up: 3 to 12 months)</td>
<td>The mean quality of life ranged across control groups from 38 to 60 points</td>
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<td>Dyspnoea Borg Scale. Scale from: 0 to 10. (follow-up: 3 to 6 months)</td>
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<td>See comment Effect is uncertain</td>
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<td>Respiratory-related hospital admissions (follow-up: 3 to 12 months)</td>
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<td></td>
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<td>The mean emergency department visits for lung diseases in the intervention groups was 0.02 lower (1 to 1 higher)</td>
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</tr>
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<td></td>
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<td>626 (5)</td>
<td>moderate*</td>
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Note: 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)
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

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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**

**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 1995a; Bourbeau 2003; Monninkhof 2003; Martin 2004; Boxall 2005; (Coul tas 2005a; Coul tas 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; CI: -5.14 to -0.02)) and impact scores (WMD -2.83; 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; 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; 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%).

*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; 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 1997, five points.
### 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

<table>
<thead>
<tr>
<th>Study</th>
<th>Treatment N</th>
<th>Treatment Mean(SD)</th>
<th>Control N</th>
<th>Control Mean(SD)</th>
<th>Weighted Mean Difference (Fixed)</th>
<th>Weight (%)</th>
<th>Weighted Mean Difference (Fixed) 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bourbeau 2003</td>
<td>88</td>
<td>50.60 (17.80)</td>
<td>76</td>
<td>54.20 (17.60)</td>
<td>0.21</td>
<td>21.4</td>
<td>-3.60 [-4.14, 1.94]</td>
</tr>
<tr>
<td>Bocci 2005</td>
<td>23</td>
<td>50.70 (11.80)</td>
<td>33</td>
<td>59.60 (12.30)</td>
<td>0.24</td>
<td>12.4</td>
<td>-8.90 [-16.17, -1.63]</td>
</tr>
<tr>
<td>Coulter 2005a</td>
<td>49</td>
<td>50.60 (20.40)</td>
<td>26</td>
<td>55.00 (16.40)</td>
<td>0.09</td>
<td>9.1</td>
<td>-0.20 [-3.71, 3.31]</td>
</tr>
<tr>
<td>Coulter 2005b</td>
<td>64</td>
<td>51.10 (14.40)</td>
<td>23</td>
<td>58.60 (14.60)</td>
<td>0.24</td>
<td>10.6</td>
<td>-3.70 [-15.55, 4.15]</td>
</tr>
<tr>
<td>Gallea 1999a</td>
<td>23</td>
<td>40.00 (16.00)</td>
<td>27</td>
<td>43.10 (21.00)</td>
<td>0.16</td>
<td>6.5</td>
<td>-2.10 [-3.13, 0.92]</td>
</tr>
<tr>
<td>Mennikhof 2003</td>
<td>122</td>
<td>37.40 (18.80)</td>
<td>113</td>
<td>37.70 (17.00)</td>
<td>0.50</td>
<td>31.3</td>
<td>-0.30 [-4.88, 4.28]</td>
</tr>
<tr>
<td>Watson 1997</td>
<td>29</td>
<td>39.00 (17.00)</td>
<td>27</td>
<td>39.00 (16.00)</td>
<td>0.78</td>
<td>8.8</td>
<td>0.00 [-8.64, 8.64]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>381</td>
<td></td>
<td>317</td>
<td></td>
<td>1.00</td>
<td>100.0</td>
<td>-2.58 [-5.14, -0.02]</td>
</tr>
</tbody>
</table>

Test for heterogeneity: chi-square = 4.72, df = 6, p = 0.58 (I² = 0.0%)
Test for overall effect: z = 1.98, p = 0.05
### Summary of key information from systematic reviews: Bias

#### Risk of Bias Tables

<table>
<thead>
<tr>
<th></th>
<th>Adequate sequence generation</th>
<th>Allocation concealment</th>
<th>Blinding (trials-concealed outcomes)</th>
<th>Blinding (mortality)</th>
<th>Incomplete outcome data addressed (Short-term outcomes (2-6 wks))</th>
<th>Incomplete outcome data addressed (Long-term outcomes (&gt; 6 mths))</th>
<th>Free of selective reporting</th>
<th>Free of other bias</th>
</tr>
</thead>
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<tr>
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<td>❌</td>
<td>✔</td>
<td>❌</td>
<td>❌</td>
<td>❌</td>
<td>✗</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Baylis 1989</td>
<td>✔</td>
<td>✔</td>
<td>❌</td>
<td>✗</td>
<td>✔</td>
<td>✗</td>
<td>✔</td>
<td>✔</td>
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<tr>
<td>Cooper 1987</td>
<td>❌</td>
<td>✔</td>
<td>❌</td>
<td>✗</td>
<td>✔</td>
<td>✗</td>
<td>✔</td>
<td>✔</td>
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<tr>
<td>Dodd 1985</td>
<td>❌</td>
<td>✔</td>
<td>❌</td>
<td>✗</td>
<td>✔</td>
<td>✗</td>
<td>✔</td>
<td>✔</td>
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<tr>
<td>Goodwin 1986</td>
<td>✔</td>
<td>✔</td>
<td>❌</td>
<td>✗</td>
<td>✔</td>
<td>✗</td>
<td>✔</td>
<td>✔</td>
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<tr>
<td>Sanders 1983</td>
<td>✔</td>
<td>✔</td>
<td>❌</td>
<td>✗</td>
<td>✔</td>
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<td>✔</td>
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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-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 constituent 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 (-3.14 to -1.92) and impact domain (WMD -2.83; 95% CI (-3.65 to -2.02)), but these differences 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 content 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

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<th>Outcomes</th>
<th>Illustrative comparative risks*</th>
<th>Corresponding risk self management</th>
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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
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<td>Effect is uncertain</td>
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<td>Low risk population</td>
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<td></td>
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</tr>
<tr>
<td>10 per 100</td>
<td></td>
<td>OR 0.64</td>
<td>966 (8)</td>
<td>Moderate</td>
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<td>High risk population</td>
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<td></td>
<td></td>
<td></td>
<td></td>
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Primary outcomes – up to 7

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<tr>
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<th>Illustrative comparative risks (95% CI)</th>
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<td>⬤⬤⬤⬤ moderate ²</td>
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</tr>
<tr>
<td>Number and severity of exacerbations ⁵</td>
<td>See comment</td>
<td>See comment</td>
<td>Not estimable ⁵</td>
<td>501 (3)</td>
<td>See comment</td>
<td>Effect is uncertain</td>
</tr>
<tr>
<td>Respiratory-related hospital admissions (follow-up: 3 to 12 months)</td>
<td>Low risk population ⁶</td>
<td>10 per 100</td>
<td>7 per 100 (5 to 9)</td>
<td>OR 0.64 (0.47 to 0.89)</td>
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</tr>
<tr>
<td>Doctor and nurse</td>
<td>The mean</td>
<td>The mean</td>
<td></td>
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</tr>
</tbody>
</table>
### 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

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<tr>
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<td></td>
</tr>
<tr>
<td>St George’s Respiratory</td>
<td>The mean quality of life ranged across</td>
<td>The mean quality of life</td>
<td>608 (7)</td>
<td>2 moderate</td>
<td>Lower score indicates better quality of life. A change of less than 4 points is not shown to be important to patients.</td>
</tr>
<tr>
<td>Questionnaire. Scale from: 0 to 100. (follow-up: 3 to 12 months)</td>
<td>control groups from 38 to 60 points to 100. (follow-up: 3 to 12 months)</td>
<td>in the intervention groups was 2.58 lower (5.14 to 0.02 lower)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dyspnoea</strong></td>
<td>The mean dyspnoea ranged across control</td>
<td>The mean dyspnoea was 0.53 lower (0.96 to 0.1 lower)</td>
<td>144 (2)</td>
<td>3 moderate</td>
<td>Lower score indicates improvement</td>
</tr>
<tr>
<td>Borg Scale. Scale from: 0 to 10. (follow-up: 3 to 6 months)</td>
<td>across control groups from 1.2 to 4.1 points</td>
<td>in the intervention groups was 0.53 lower (0.96 to 0.1 lower)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Number and severity of exacerbations</strong></td>
<td>See comment</td>
<td>See comment</td>
<td>591 (3)</td>
<td>Not estimable</td>
<td>Effect is uncertain</td>
</tr>
<tr>
<td><strong>Respiratory-related hospital admissions</strong></td>
<td>low risk population: OR 0.64 (0.47 to 0.89)</td>
<td>OR 0.64 (0.47 to 0.89)</td>
<td>606 (8)</td>
<td>3 moderate</td>
<td></td>
</tr>
<tr>
<td>(follow-up: 3 to 12 months)</td>
<td>10 per 100 to 7 per 100 (5 to 9)</td>
<td>10 per 100 to 7 per 100 (5 to 9)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>High risk population</strong></td>
<td>39 per 100 to 39 per 100 (32 to 47)</td>
<td>39 per 100 to 39 per 100 (32 to 47)</td>
<td>500 (5)</td>
<td>3 moderate</td>
<td></td>
</tr>
<tr>
<td>(follow-up: 3 to 12 months)</td>
<td>50 per 100</td>
<td>50 per 100</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Emergency department visits for lung diseases</strong></td>
<td>The mean emergency department visits for lung diseases ranged across control groups from 0.2 to 0.7 visits per person per year</td>
<td>The mean emergency department visits for lung diseases in the intervention groups was 0.1 higher (0.2 lower to 0.3 higher)</td>
<td>328 (4)</td>
<td>4 moderate</td>
<td></td>
</tr>
<tr>
<td>(follow-up: 6 to 12 months)</td>
<td>328 (4)</td>
<td>328 (4)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- 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  
**Comparison:** usual care

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Illustrative comparative risks* (95% CI)</th>
<th>Corresponding risk self management</th>
<th>Relative effect (95% CI)</th>
<th>No of Participants (studies)</th>
<th>Quality of the evidence (GRADE)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of Life</td>
<td>The mean quality of life ranged across control groups from 38 to 60 points</td>
<td>The mean quality of life in the intervention groups was 2.58 lower (5.14 to 0.02 lower)</td>
<td>698 (7)</td>
<td>**** moderate^2^</td>
<td>Lower score indicates better quality of life. A change of less than 4 points is not shown to be important to patients.</td>
<td></td>
</tr>
<tr>
<td>Dyspnoea</td>
<td>The mean dyspnoea ranged across control groups from 1.2 to 4.1 points</td>
<td>The mean dyspnoea in the intervention groups was 0.53 lower (0.96 to 0.1 lower)</td>
<td>144 (2)</td>
<td>**** low^3^4</td>
<td>Lower score indicates improvement</td>
<td></td>
</tr>
<tr>
<td>Number and severity of exacerbations</td>
<td>See comment</td>
<td>See comment</td>
<td></td>
<td>591 (3)</td>
<td>See comment</td>
<td>Effect is uncertain</td>
</tr>
<tr>
<td>Respiratory-related hospital admissions (follow-up: 3 to 12 months)</td>
<td>Low risk population^6^</td>
<td>OR 0.64 (0.47 to 0.89)</td>
<td>666 (8)</td>
<td>**** moderate^7^</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>10 per 100 (5 to 9)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>High risk population^6^</td>
<td>39 per 100 (32 to 47)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emergency department visits for lung diseases (follow-up: 6 to 12 months)</td>
<td>The mean emergency department visits for lung diseases ranged across control groups from 0.2 to 0.7 visits per person per year</td>
<td>The mean emergency department visits for lung diseases in the intervention groups was 0.1 higher (0.2 lower to 0.3 higher)</td>
<td>328 (4)</td>
<td>**** moderate^4^</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Doctor and nurse</td>
<td>The mean doctor</td>
<td>The mean doctor</td>
<td>820</td>
<td>****</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **From meta-analysis**
- **Relative Risks, Odds ratios, Hazard ratios, etc.**
### Results - Baseline risks (Assumed Risk)

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Illustrative comparison</th>
<th>Relative effect (95% CI)</th>
<th>No of Participants (studies)</th>
<th>Quality of the evidence (GRADE)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of Life</td>
<td>The mean quality of life ranged across control groups from 18 to 60 points</td>
<td>The mean quality of life in the intervention groups was 2.58 lower (5.14 to 0.02 lower)</td>
<td>988 (7)</td>
<td>◆◆◆ ◆ ◆ moderate²</td>
<td>Lower score indicates better quality of life. A change of less than 4 points is not shown to be important to patients.</td>
</tr>
<tr>
<td>Dyspnoea</td>
<td>The mean dyspnoea ranged across control groups from 2.2 to 4.1 points</td>
<td>The mean dyspnoea in the intervention groups was 0.53 lower (0.06 to 0.1 lower)</td>
<td>144 (2)</td>
<td>◆◆◆ ◆◆ low¹⁴</td>
<td>Lower score indicates improvement</td>
</tr>
<tr>
<td>Number and severity of exacerbations</td>
<td>Not estimable⁵</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Respiratory-related hospital admissions</td>
<td>Low risk population⁶</td>
<td>OR 0.64 (0.47 to 0.89)</td>
<td>966 (8)</td>
<td>◆◆◆ ◆◆ moderate⁷</td>
<td></td>
</tr>
<tr>
<td>Emergency department visits for lung diseases</td>
<td>High risk population⁷</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **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

**Comparison:** usual care

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Illustrative comparative risks (^a) (95% CI)</th>
<th>Corresponding risk self management</th>
<th>Relative effect (95% CI)</th>
<th>No of Participants (studies)</th>
<th>Quality of the evidence (GRADE)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Quality of Life</strong></td>
<td>Assumed risk usual care</td>
<td>The mean quality of life ranged across control groups from 38 to 60 points</td>
<td>The mean quality of life in the intervention groups was 2.58 lower (5.14 to 0.02 lower)</td>
<td>608 (7)</td>
<td>e,e,e moderate (^2)</td>
<td>Lower score indicates better quality of life. A change of less than 4 points is not shown to be important to patients.</td>
</tr>
<tr>
<td><strong>Dyspnoea</strong></td>
<td>The mean dyspnoea ranged across control groups from 1.2 to 4.1 points</td>
<td>The mean dyspnoea in the intervention groups was 0.53 lower (0.96 to 0.1 lower)</td>
<td>144 (2)</td>
<td>e,e,e low (^4)</td>
<td>Lower score indicates improvement</td>
<td></td>
</tr>
<tr>
<td><strong>Number and severity of exacerbations</strong></td>
<td>See comment</td>
<td>See comment</td>
<td></td>
<td></td>
<td>See comment</td>
<td></td>
</tr>
<tr>
<td><strong>Respiratory-related hospital admissions</strong></td>
<td>Low risk population (^6)</td>
<td>OR 0.64 (0.47 to 0.89)</td>
<td>96 (8)</td>
<td>e,e,e moderate (^2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(follow-up: 3 to 12 months)</td>
<td>10 per 100</td>
<td>(5 to 9)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>High risk population (^6)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(follow-up: 3 to 12 months)</td>
<td>50 per 100</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Emergency department visits for lung diseases</strong></td>
<td>The mean emergency department visits for lung diseases ranged across control groups from 0.2 to 0.7 visits per person per year</td>
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<td></td>
</tr>
<tr>
<td>(follow-up: 6 to 12 months)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **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  
**Comparison:** usual care

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Illustrative comparative risks† (95% CI)</th>
<th>Relative effect (95% CI)</th>
<th>No of Participants (studies)</th>
<th>Quality of the evidence (GRADE)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Quality of Life</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>St George’s Respiratory Questionnaire</td>
<td>The mean quality of life ranged across control groups from 38 to 60 points</td>
<td>The mean quality of life in the intervention groups was 2.58 lower (5.14 to 0.02 lower)</td>
<td>698 (7)</td>
<td>moderate²</td>
<td>Lower score indicates better quality of life. A change of less than 4 points is not shown to be important to patients.</td>
</tr>
<tr>
<td><strong>Dyspnoea</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Borg Scale. Scale from: 0 to 10.</td>
<td>The mean dyspnoea ranged across control groups from 1.2 to 4.1 points</td>
<td>The mean dyspnoea in the intervention groups was 0.53 lower (0.98 to 0.1 lower)</td>
<td>144 (2)</td>
<td>low³/⁴</td>
<td>Lower score indicates improvement</td>
</tr>
<tr>
<td><strong>Number and severity of exacerbations</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>See comment</td>
<td></td>
<td>Not estimable²</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Respiratory-related hospital admissions</strong></td>
<td>Low risk population⁶</td>
<td>OR 0.64 (0.47 to 0.89)</td>
<td>966 (8)</td>
<td>moderate⁷</td>
<td></td>
</tr>
<tr>
<td>(follow-up: 3 to 12 months)</td>
<td>10 per 100</td>
<td>7 per 100 (5 to 9)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>High risk population⁶</td>
<td>50 per 100</td>
<td>39 per 100 (32 to 47)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(follow-up: 3 to 12 months)</td>
<td>The mean emergency department visits for lung diseases ranged across control groups from 0.2 to 0.7 visits per 0.1 higher person per year</td>
<td>The mean emergency department visits for lung diseases in the intervention groups was 0.2 lower to 0.3 higher</td>
<td>328 (4)</td>
<td>moderate⁴</td>
<td></td>
</tr>
<tr>
<td><strong>Emergency department visits for lung diseases</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(follow-up: 8 to 12 months)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Evidence for each outcome is graded
- Based on the GRADE approach
- Uses information from the Risk of Bias tables
### Comments

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

Transpareny
Where do the numbers come from?

Dichotomous and Continuous Outcomes
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

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Treatment</th>
<th>Control</th>
<th>Risk Ratio M-H, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finklea 1987</td>
<td>1/104</td>
<td>11/133</td>
<td>0.12 [0.02, 0.89]</td>
</tr>
<tr>
<td>Payler 1984</td>
<td>3/267</td>
<td>29/269</td>
<td>0.10 [0.03, 0.34]</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>371/402</strong></td>
<td><strong>100.0%</strong></td>
<td><strong>0.11 [0.04, 0.30]</strong></td>
</tr>
</tbody>
</table>

Total events: 4/40

Heterogeneity: Tau² = 0.00; Chi² = 0.01, df = 1 (P = 0.93); I² = 0%

Test for overall effect: Z = 4.30 (P < 0.0001)
### Dichotomous Outcomes: Yes/No

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Illustrative comparative risks* (95% CI)</th>
<th>Relative effect (95% CI)</th>
<th>No of Parti (studies)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Assumed risk Control</td>
<td>Corresponding risk Amantadine</td>
<td></td>
</tr>
<tr>
<td>Cases of Infection with prophylaxis (follow-up: 14-18 weeks)</td>
<td>Medium risk population</td>
<td>RR 0.11</td>
<td>773</td>
</tr>
<tr>
<td></td>
<td>10 per 100</td>
<td>1 per 100</td>
<td>(0.04 to 0.3)</td>
</tr>
</tbody>
</table>

Converting RR to # per 100

**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.
**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

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Treatment</th>
<th>Control</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Events</td>
<td>Total</td>
<td>Events</td>
</tr>
<tr>
<td>Finklea 1967</td>
<td>1</td>
<td>104</td>
<td>11</td>
</tr>
<tr>
<td>Payler 1984</td>
<td>3</td>
<td>267</td>
<td>29</td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>371</strong></td>
<td><strong>402</strong></td>
<td><strong>100.0%</strong></td>
</tr>
</tbody>
</table>

Total events: 4

Heterogeneity: Tau² = 0.00; Chi² = 0.01, df = 1 (P = 0.93); I² = 0%

Test for overall effect: Z = 4.30 (P < 0.0001)
### DICHOTOMOUS OUTCOMES  YES/NO

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Illustrative comparative risks* (95% CI)</th>
<th>Relative effect (95% CI)</th>
<th>No of Parti (studies)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cases of Infection with prophylaxis</td>
<td>Control: 10 per 100</td>
<td>RR 0.11 (0.04 to 0.3)</td>
<td>773</td>
</tr>
<tr>
<td>(follow-up: 14-18 weeks)</td>
<td>Amantadine: 1 per 100 (0 to 3)</td>
<td></td>
<td>(2)</td>
</tr>
</tbody>
</table>

**Step 2: Relative effect**
- RR = 0.11

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

\[
\text{assumed risk} \times \text{relative risk} = \text{corresponding risk}
\]

\[
10 \times 0.11 = 1
\]

- 1 per 100 people have the infection if they take amantadine
Example: Heparin to reduce clots
- outcome death

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Heparin</th>
<th>Control</th>
<th>Risk Ratio</th>
<th>Risk Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Events</td>
<td>Total</td>
<td>Events</td>
<td>Total</td>
</tr>
<tr>
<td>1.1.1 LMWH vs. Control</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Karthaus 2006</td>
<td>4</td>
<td>285</td>
<td>1</td>
<td>140</td>
</tr>
<tr>
<td>Monreal 1996</td>
<td>1</td>
<td>16</td>
<td>1</td>
<td>13</td>
</tr>
<tr>
<td>Verso 2005</td>
<td>13</td>
<td>191</td>
<td>20</td>
<td>194</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>492</td>
<td>347</td>
<td>100.0%</td>
<td></td>
</tr>
</tbody>
</table>

Total events 18 22
Heterogeneity: Tau² = 0.00; Chi² = 0.89, df = 2 (P = 0.64); I² = 0%
Test for overall effect: Z = 0.99 (P = 0.32)

Total (95% CI) 492 347 100.0% 0.73 [0.39, 1.36]
Total events 18 22
Heterogeneity: Tau² = 0.00; Chi² = 0.89, df = 2 (P = 0.64); I² = 0%
Test for overall effect: Z = 0.99 (P = 0.32)

- Median assumed risk = 7.7%
Corresponding Risk = Assumed Risk \times Relative Risk

Relative Risk 0.73

7.7 per 100 \times 0.73 = 5.621 = 6 per 100

Confidence intervals (0.39 to 1.36)

7.7 per 100 \times 0.39 = 3.003 = 3 per 100
7.7 per 100 \times 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

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

\[ RR = \frac{OR}{1 - (R_{as} \times (1 - OR))} \]
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
### 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
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**

<table>
<thead>
<tr>
<th>Self management for patients with chronic obstructive pulmonary disease</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient or population:</strong></td>
<td>patients with chronic obstructive pulmonary disease</td>
</tr>
<tr>
<td><strong>Settings:</strong></td>
<td>primary care, community, outpatient</td>
</tr>
<tr>
<td><strong>Intervention:</strong></td>
<td>self management&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Comparison:</strong></td>
<td>usual care</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Illustrative comparative risks* (95% CI)</th>
<th>Relative effect (95% CI)</th>
<th>No of Participants (studies)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of Life</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>St George's Respiratory Questionnaire. Scale from: 0 to 100, (follow-up: 3 to 12 months)</td>
<td>The mean quality of life ranged across control groups from 38 to 60 points</td>
<td>The mean Quality of Life in the intervention groups was 2.58 lower (5.14 to 0.02 lower)</td>
<td>698 (7)</td>
</tr>
</tbody>
</table>
Example: compression stockings to prevent thrombosis in people flying – outcome oedema

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Mean Difference</th>
<th>Mean Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stockings</td>
<td>No stockings</td>
<td>IV, Fixed, 95% CI</td>
</tr>
<tr>
<td>LONFLIT 4 - Kendall1</td>
<td>2.3 ± 1.1</td>
<td>-6.60 [-5.12, -4.08]</td>
</tr>
<tr>
<td>LONFLIT 4 - Kendall2</td>
<td>3.3 ± 1.2</td>
<td>-4.64 [-5.20, -4.08]</td>
</tr>
<tr>
<td>LONFLIT 4 - Scholl1</td>
<td>2.16 ± 1.1</td>
<td>-4.58 [-5.06, -4.10]</td>
</tr>
<tr>
<td>LONFLIT 4 - Scholl2</td>
<td>2.56 ± 1.5</td>
<td>-5.52 [-6.07, -4.97]</td>
</tr>
<tr>
<td>LONFLIT 4 - Traveno1</td>
<td>2.4 ± 1.3</td>
<td>-4.00 [-4.33, -3.67]</td>
</tr>
<tr>
<td>LONFLIT 4 - Traveno2</td>
<td>2.56 ± 1.3</td>
<td>-6.34 [-6.89, -5.79]</td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>625</td>
<td>-4.72 [-4.91, -4.52]</td>
</tr>
</tbody>
</table>

Heterogeneity: Chi² = 60.81, df = 5 (P = 0.00001); I² = 92%
Test for overall effect: Z = 48.26 (P < 0.00001)

- Oedema scale from 0 to 10
Summary of Findings for compression stockings to prevent thrombosis in people flying

- **outcome oedema**

<table>
<thead>
<tr>
<th>Oedema</th>
<th>The mean oedema ranged across control groups from 6 to 9</th>
<th>The mean Oedema in the intervention groups was 4.7 lower (4.9 to 4.5 lower)</th>
<th>1246 (5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-flight values...</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scale from: 0 to 10.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
CONTINUOUS OUTCOMES

Re-expressing SMD using a familiar scale

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Illustrative comparative risks* (95% CI)</th>
<th>Relative effect (95% CI)</th>
<th>No of Participants (studies)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain</td>
<td>no treatment</td>
<td>glucosamine</td>
<td></td>
</tr>
<tr>
<td>Scale from: 0 to 10. (follow-up: 1-3 months)</td>
<td>Mean pain in the control group was 6.6</td>
<td>Mean Pain in the intervention groups was 0.8 lower (2.1 lower to 0.5 higher)</td>
<td>1111 (8)</td>
</tr>
</tbody>
</table>

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.
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.

\[
SMD = -0.19 (-0.50, 0.11)
\]
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

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Illustrative comparative risks* (95% CI)</th>
<th>Relative effect (95% CI)</th>
<th>No of Participants (studies)</th>
<th>Quality of the evidence (GRADE)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain, WOMAC¹</td>
<td>Assumed risk no treatment</td>
<td>Corresponding risk glucosamine</td>
<td>1111 (8)</td>
<td>☒☒☒ ☓ ☓ ☓ ☓ ☓ ☓ ☓ ☓ ☓ ☓ ☓ ☓ ☓</td>
<td>Scores estimated using a standardised mean difference of -0.19 (-0.50 to 0.11)</td>
</tr>
<tr>
<td></td>
<td>The mean pain ranged across control groups from 6.8 to 7.1</td>
<td>The mean Pain in the intervention groups was 0.8 lower (2.1 lower to 0.5 higher)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

¹ Scale from 0, no pain to 20, worst pain. (follow-up: mean 3 months)
### Example: NSAIDs vs acetaminophen for osteoarthritis – outcome global assessment

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>NSAID Mean</th>
<th>NSAID SD</th>
<th>NSAID Total</th>
<th>Acetaminophen Mean</th>
<th>Acetaminophen SD</th>
<th>Acetaminophen Total</th>
<th>Std. Mean Difference IV, Fixed, 95% CI</th>
<th>Std. Mean Difference IV, Fixed, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pincus 2001</td>
<td>35.41</td>
<td>18.11</td>
<td>101</td>
<td>43.83</td>
<td>21.63</td>
<td>11</td>
<td>-0.42 [-0.69, -0.15]</td>
<td></td>
</tr>
<tr>
<td>Williams 1993</td>
<td>2.31</td>
<td>0.55</td>
<td>74</td>
<td>2.44</td>
<td>0.67</td>
<td>73</td>
<td>-0.21 [-0.54, 0.11]</td>
<td></td>
</tr>
<tr>
<td>Total (95% CI)</td>
<td>175</td>
<td></td>
<td></td>
<td>184</td>
<td>100.0%</td>
<td></td>
<td>-0.33 [-0.54, -0.12]</td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: $\chi^2 = 0.92, df = 1 (P = 0.34)$; $I^2 = 0$
Test for overall effect: $Z = 3.13 (P = 0.002)$

- Pincus representative study (scale 0 to 100)
- $-0.33 \times 21.63 = 7.1379$
Summary of Findings
for glucosamine for osteoarthritis - outcome pain

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Illustrative comparative risks* (95% CI)</th>
<th>Relative effect (95% CI)</th>
<th>No of Participants (studies)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall well-being</td>
<td>Assumed risk: The mean overall well-being in the control groups was 44 points</td>
<td>The mean Overall well-being in the intervention groups was 7 lower (12 to 3 lower)</td>
<td>280 (2)</td>
</tr>
<tr>
<td></td>
<td>Corresponding risk: acetaminophen: NSAID</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
GRADEing the evidence

Evidence is GRADEed from

- **HIGH, MODERATE, LOW, VERY LOW**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Further Research Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>📈شبه</td>
<td>Further research is very unlikely to change our confidence in the estimate of effect.</td>
</tr>
<tr>
<td>🕵️‍♂️‍♂️‍♂️‍♂️ Moderate</td>
<td>Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.</td>
</tr>
<tr>
<td>🕵️‍♂️‍♂️‍♂️ Low</td>
<td>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.</td>
</tr>
<tr>
<td>🕵️‍♂️‍♂️‍♂️ Very low</td>
<td>We are very uncertain about the estimate.</td>
</tr>
</tbody>
</table>
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

---

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 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
Data from the RevMan 5 file is imported:
- outcomes
- meta-analyses results
- bibliographic information
Managing outcomes to include a maximum of 7
Entering/editing information for dichotomous outcomes
Entering/editing information to GRADE the quality of the evidence
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;146:679-681)
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%.

**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.
Footnotes for transparency:

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 lowest and highest values are the two extreme numbers of admissions in the control groups from two studies. 58% was ro...
Previewing the SoF table before exporting and importing into RevMan 5.
## 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  
**Comparison:** usual care

<table>
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<tr>
<th>Outcomes</th>
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<tr>
<td><strong>Quality of Life</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>St George’s Respiratory</td>
<td>The mean quality of life ranged across</td>
<td>2.58 lower (5.14 to 0.02</td>
<td>698 (7)</td>
<td>moderate²</td>
<td>Lower score indicates better quality of life. A change of less than 4</td>
</tr>
<tr>
<td>Questionnaire. Scale from: 0 to</td>
<td>control groups from 38 to 60 points</td>
<td>lower)</td>
<td></td>
<td></td>
<td>points is not shown to be important to patients.</td>
</tr>
<tr>
<td>100. (follow-up: 3 to 12 months)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dyspnoea</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Borg Scale. Scale from: 0 to 10.</td>
<td>The mean dyspnoea ranged across</td>
<td>0.53 lower (0.96 to 0.1</td>
<td>144 (2)</td>
<td>low³,⁴</td>
<td>Lower score indicates improvement</td>
</tr>
<tr>
<td>(follow-up: 3 to 6 months)</td>
<td>control groups from 1.2 to 4.1 points</td>
<td>lower)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>**Number and severity of</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>exacerbations⁵</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Respiratory-related</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low risk population⁶</td>
<td>OR 0.64</td>
<td>966</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Exporting the SoF in a file for RevMan 5
Importing the file into a RevMan 5 file

Summary of findings tables

Additional tables

1 NNTs and ORs

New Summary of Findings Table Wizard

How do you want to create the table?

- Import the table from a file created in GRADEprofiler (table will be read-only)
- Import the template file included with RevMan to edit the table in RevMan
- Create the table using RevMan's table editor

Next >
Importing the file into a RevMan 5 file
Summary of findings tables

Add Summary of Findings Table

New Summary of Findings Table Wizard
Which file do you want to import?

File Name: D:\Nancy Snancy\GRADE\SoF testing\effing\self management SoF sof.scf

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
Comparison: usual care

Finish
## 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 \(^1\)  
**Comparison:** usual care

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<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Assumed risk</td>
<td>Corresponding risk</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>usual care</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>self management</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Quality of Life**  
St George's Respiratory Questionnaire. Scale from: 0 to 100. (follow-up: 3 to 12 years)

The mean quality of life ranged across control groups from 62.9 to 64.0, whereas in the intervention groups was 2.58 lower (5.14 to 0.02).  

Audio: 698 (7)  
**moderate 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  (See Part 2)

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

- BMJ series of papers in press.


- Support at support@gradepro.org