

SUPPLEMENTARY FILE 1

QUALITY ASSESSMENT CHECKLISTS

Cochrane Collaboration tool for assessing risk of bias for RCTs

Study ID:

Assessor:

Date:

1. Adequate sequence generation?	Yes	No	Unclear
2. Allocation concealment?	Yes	No	Unclear
3. Blinding?	Yes	No	Unclear
4. Incomplete outcome data addressed?	Yes	No	Unclear
5. Free from selective reporting?	Yes	No	
Unclear			
6. Free from other bias?	Yes	No	Unclear

For crossover trials:

Was use of a crossover design appropriate?

Is it clear that the order of receiving treatments was randomised?

Can it be assumed that the trial was not biased from carry over effects?

Are unbiased data available? (paired analysis, analysis of first period only?)

Summary assessment

Low risk of bias

Unclear

High risk of bias

Controlled before and after ACROBAT quality assessment

Study:

Design type:

Assessor:

From page 10 of the tool:

Signalling questions

A key feature of the tool is the inclusion of signalling questions within each domain of bias. These are reasonably factual in nature and aim to facilitate judgements about the risk of bias. All are phrased such that “yes” indicates low risk of bias.

The **response options for the signalling questions** are:

- (1) Yes (Y);
- (2) Probably yes (PY);
- (3) Probably no (PN);
- (4) No (N); and
- (5) No information (NI).

There is one exception to this: the opening signalling question (1.1, in the assessment of bias due to confounding) does not have a ‘No information’ option.

Some signalling questions are only answered in certain circumstances, for example if the response to a previous question is ‘Yes’ or ‘Probably yes’ (or ‘No’ or ‘Probably no’).

Responses of ‘Yes’ and ‘Probably yes’ (also of ‘No’ and ‘Probably no’) have similar implications.

The former would imply that firm evidence is available in relation to the signalling question; the latter would imply that a judgement has been made. If measures of agreement are applied to answers to the signalling questions, we recommend grouping these pairs of responses.

Free-text boxes alongside signalling questions

There is space for free text alongside each signalling question. This should be used to provide support for each answer. Brief direct quotations from the text of the study report should be used when possible to support responses.” See also page 11-12 for summative interpretation.

	Outcomes assessed						
Domain							
Bias due to confounding							
1.1 Is confounding of the effect of intervention unlikely in this study?							
1.2. If N or PN to 1.1: Were participants analysed according to their initial intervention group throughout follow up?							

<p>1.3. If N or PN to 1.2:</p> <p>Were intervention discontinuations or switches unlikely to be related to factors that are prognostic for the outcome?</p>	
<p>If Y or PY to 1.3, answer questions 1.4 to 1.6, which relate to baseline confounding</p> <p>If N or PN to 1.1 <i>and</i> 1.2 <i>and</i> 1.3, answer questions 1.7 and 1.8, which relate to time-varying confounding</p>	
<p>1.4. Did the authors use an appropriate analysis method that adjusted for all the critically important confounding domains?</p>	
<p>1.5. If Y or PY to 1.4:</p> <p>Were confounding domains that were adjusted for measured validly and reliably by</p>	

the variables available in this study?	
1.6. Did the authors avoid adjusting for post-intervention variables?	
1.7. Did the authors use an appropriate analysis method that adjusted for all the critically important confounding domains and for time-varying confounding?	
1.8. If Y or PY to 1.7: Were confounding domains that were adjusted for measured validly and reliably by the variables available in this study?	

Bias in selection of participants into the study

2.1. Was selection into the study unrelated to intervention or unrelated to outcome?

2.2. Do start of followup and start of intervention coincide for most subjects?

**2.3. If N or PN to 2.1 or 2.2:
Were adjustment techniques used that are likely to correct for the presence of selection biases?**

Bias in measurement of interventions

3.1 Is intervention status well defined?

3.2 Was information on intervention status recorded at the time of intervention?

<p>3.3 Was information on intervention status unaffected by knowledge of the outcome or risk of the outcome?</p>	
<p>Bias due to departures from intended interventions</p>	
<p>4.1. Were the critical cointerventions balanced across intervention groups?</p>	
<p>4.2. Were numbers of switches to other interventions low?</p>	
<p>4.3. Was implementation failure minor?</p>	
<p>4.4. If N or PN to 4,1, 4.2 or 4.3:</p> <p>Were adjustment techniques used that are likely to correct for these issues?</p>	

Bias due to missing data	
5.1 Are outcome data reasonably complete?	
5.2 Was intervention status reasonably complete for those in whom it was sought?	
5.3 Are data reasonably complete for other variables in the analysis?	
5.4 If N or PN to 5.1, 5.2 or 5.3: Are the proportion of participants and reasons for missing data similar across interventions?	
5.5 If N or PN to 5.1, 5.2 or 5.3: Were appropriate statistical methods used to	

account for missing data?							
Bias in measurement of outcomes							
6.1 Was the outcome measure objective?							
6.2 Were outcome assessors unaware of the intervention received by study participants?							
6.3 Were the methods of outcome assessment comparable across intervention groups?							
6.4 Were any systematic errors in measurement of the outcome unrelated to intervention received?							
Bias in selection of the reported result							
Is the reported effect estimate unlikely to be							

<p>selected, on the basis of the results, from... multiple outcome <i>measurements</i> within the outcome domain?</p>							
<p>Is the reported effect estimate unlikely to be selected, on the basis of the results, from... multiple <i>analyses</i> of the intervention-outcome relationship?</p>							
<p>Is the reported effect estimate unlikely to be selected, on the basis of the results, from... different <i>subgroups</i>?</p>							
<p>Overall</p>							

Quality assessment for uncontrolled studies

Taken from Llewellyn et al., 2014. Interventions for adult Eustachian tube dysfunction: a systematic review. Health technology Assessment, 18, 46.

Study ID:

Assessor:

Date:

Possible answers are 'yes', 'no', and where relevant, 'unclear' or 'not applicable'.

	Yes	No	Unclear	NA	Comments
Were the selection/eligibility criteria adequately reported?					
Is the sample likely to be representative?					
If yes, was it a random sample?					
Were patients recruited prospectively?					
Were patients recruited consecutively?					
Was the participation rate adequate (> 80% of those eligible)					
Was there at least 80% follow-up from baseline?					
Was loss to follow-up reported?					
Were relevant prognostic factors reported?					
Were other relevant confounding factors reported? (e.g. use of cointerventions)					
Was an appropriate measure of variability reported?					

