

APPENDIX 7: METHODOLOGY CHECKLISTS FOR CLINICAL STUDIES AND REVIEWS

The methodological quality of each study was evaluated using NICE checklists (NICE, 2009d). The checklists for systematic reviews and for RCTs are reproduced below (for other checklists and further information about how to complete each checklist, see *The Guidelines Manual* [NICE, 2009d]).

Methodology checklist: systematic reviews and meta-analyses

Study identification Include author, title, reference, year of publication	
Guideline topic:	Review question no:
Checklist completed by:	
SCREENING QUESTIONS	
In a well-conducted, relevant systematic review:	Circle one option for each question
The review addresses an appropriate and clearly focused question that is relevant to the guideline review question	Yes No Unclear
The review collects the type of studies you consider relevant to the guideline review question	Yes No Unclear
The literature search is sufficiently rigorous to identify all the relevant studies	Yes No Unclear
Study quality is assessed and reported	Yes No Unclear
An adequate description of the methodology used is included, and the methods used are appropriate to the question	Yes No Unclear

Methodology checklist: RCTs

Study identification Include author, title, reference, year of publication		
Guideline topic:		Review question no:
Checklist completed by:		
		Circle one option for each question
A. Selection bias (systematic differences between the comparison groups)		
A1	An appropriate method of randomisation was used to allocate participants to treatment groups (which would have balanced any confounding factors equally across groups)	Yes No Unclear N/A
A2	There was adequate concealment of allocation (such that investigators, clinicians and participants cannot influence enrolment or treatment allocation)	Yes No Unclear N/A
A3	The groups were comparable at baseline, including all major confounding and prognostic factors	Yes No Unclear N/A
Based on your answers to the above, in your opinion was selection bias present? If so, what is the likely direction of its effect?		
Low risk of bias Unclear/unknown risk High risk of bias		
Likely direction of effect:		
B. Performance bias (systematic differences between groups in the care provided, apart from the intervention under investigation)		
B1	The comparison groups received the same care apart from the intervention(s) studied	Yes No Unclear N/A
B2	Participants receiving care were kept 'blind' to treatment allocation	Yes No Unclear N/A
B3	Individuals administering care were kept 'blind' to treatment allocation	Yes No Unclear N/A
Based on your answers to the above, in your opinion was performance bias present? If so, what is the likely direction of its effect?		
Low risk of bias Unclear/unknown risk High risk of bias		
Likely direction of effect:		

C. Attrition bias (systematic differences between the comparison groups with respect to loss of participants)		
C1	All groups were followed up for an equal length of time (or analysis was adjusted to allow for differences in length of follow-up)	Yes No Unclear N/A
C2	a. How many participants did not complete treatment in each group?	
	b. The groups were comparable for treatment completion (that is, there were no important or systematic differences between groups in terms of those who did not complete treatment)	Yes No Unclear N/A
C3	a. For how many participants in each group were no outcome data available?	
	b. The groups were comparable with respect to the availability of outcome data (that is, there were no important or systematic differences between groups in terms of those for whom outcome data were not available).	Yes No Unclear N/A
Based on your answers to the above, in your opinion was attrition bias present? If so, what is the likely direction of its effect?		
<p style="text-align: center;"> Low risk of bias Unclear/unknown risk High risk of bias </p>		
Likely direction of effect:		
D. Detection bias (bias in how outcomes are ascertained, diagnosed or verified)		
D1	The study had an appropriate length of follow-up	Yes No Unclear N/A
D2	The study used a precise definition of outcome	Yes No Unclear N/A
D3	A valid and reliable method was used to determine the outcome	Yes No Unclear N/A
D4	Investigators were kept 'blind' to participants' exposure to the intervention	Yes No Unclear N/A
D5	Investigators were kept 'blind' to other important confounding and prognostic factors	Yes No Unclear N/A
Based on your answers to the above, in your opinion was detection bias present? If so, what is the likely direction of its effect?		
<p style="text-align: center;"> Low risk of bias Unclear/unknown risk High risk of bias </p>		
Likely direction of effect:		