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Results (R56-109)

Description of studies (R56-72)

Description of studies

	Standard	Rationale and elaboration	Resources
R56	*Flow of studies*	***Mandatory***	
	Provide information on the flow of studies from the number(s) of references identified in the search to the number of studies included in the review, ideally using PRISMA type flow diagram. Clarify how multiple references for the same study relate to the individual studies.	MECIR conduct standard 41*:* Document the selection process in sufficient detail to complete a PRISMA flow chart and a table of 'Characteristics of excluded studies'. *MECIR conduct standard 42:* Collate multiple reports of the same study, so that each study, rather than each report, is the unit of interest in the review.	Cochrane Training resource: searching for studies CIL: module 4 - selecting studies and collecting data
R57	*Lack of included studies*	***Highly desirable***	
	If a review identifies no eligible studies, restrict the Results section to a description of the flow of studies and any brief comments about reasons for exclusion of studies.	Under 'Risk of bias in included studies' and 'Effects of interventions', state "No study met the eligibility criteria". Any discussion of evidence not meeting the eligibility criteria of the review should be in the Discussion section.	
R58	*Excluded studies*	***Mandatory***	
	List key excluded studies and provide justification for each exclusion.	The table of 'Characteristics of excluded studies' is intended as an aid to users rather than a comprehensive list of studies that were identified but not included. List here any studies that a user might reasonably expect to find in the review to explain why they are excluded.	See *Handbook* 7.2.5 Cochrane Training resource: selecting studies CIL: module 4 - selecting studies and collecting data
R59	*Studies awaiting classification*	***Highly desirable***	
	List the characteristics of any completed studies that have been identified as potentially eligible but have not been incorporated into the review.	Users of the review will be interested to learn of any potentially relevant studies that have been conducted and are known to the review team, but have not yet been incorporated in to the review irrespective of their publication status. This will help them to assess the stability of the review findings. These should be listed in the table of 'Characteristics of studies awaiting classification', along with any details that are known. Authors should also consider the impact of not including these studies on the review findings as a potential limitation, and the extent to which they affect the implications for research.	Cochrane Training resource: searching for studies CIL: module 3 - searching for studies
R60	*Ongoing studies*	***Mandatory***	
	Provide details of any identified studies that have not been completed.	Users of the review will be interested to learn of any potentially relevant studies that have not been completed. This will help them to assess the stability of the review findings. These should be listed in the table of 'Characteristics of ongoing studies', along with any details that are known. Cochrane Reviews should be mindful of research waste so it is useful to consider how ongoing studies might address the review question under 'Implications for research'.	Cochrane Training resource: searching for studies CIL: module 3 - searching for studies

R61	*Table of 'Characteristics of included studies'*	***Mandatory***	
	Present a table of 'Characteristics of included studies' using a uniform format across all studies.	MECIR conduct standard 44: Collect characteristics of the included studies in sufficient detail to populate a table of 'Characteristics of included studies'.	Cochrane Training resource: collecting data CIL: module 8 - reporting the review
R62	*Included studies*	***Mandatory***	
	Provide a brief narrative summary of any included studies. This should include the number of participants and a summary of the characteristics of the study populations and settings, interventions, comparators and funding sources.		See *Handbook* 4.5 CIL: module 8 - reporting the review
R63	*Table of 'Characteristics of included studies': methods*	***Mandatory***	
	Provide the basic study design or design features (e.g. parallel group randomized trial, cluster-randomized trial, controlled before and after study).	Even if the review is restricted to one study design, these tables should provide a comprehensive summary of each study. It is important that labels used to describe study designs are clearly defined in the review.	See *Handbook* 13.2 Cochrane Training resource: collecting data CIL: module 4 - selecting studies and collecting data
R64	*Table of 'Characteristics of included studies': participants*	***Mandatory***	
	Provide sufficient information about the study populations to enable a user of the review to assess the applicability of the review's findings to their own setting.	Information presented in this table should reflect the baseline demographics of the study sample. In addition, it is helpful to state the eligibility criteria of the study.	Cochrane Training resource: collecting data CIL: module 4 - selecting studies and collecting data
R65	*Table of 'Characteristics of included studies': sample sizes*	***Mandatory***	
	Include the sample size for each included study in the table of 'Characteristics of included studies'.	If sample sizes are available for each intervention group, these should be included. A convenient place is often within the box for Interventions, e.g. inserting "(n =)" after each listed intervention group.	Cochrane Training resource: collecting data CIL: module 4 - selecting studies and collecting data
R66	*Table of 'Characteristics of included studies': interventions*	***Mandatory***	
	Provide sufficient information to enable users of the review to assess the applicability of the intervention to their own setting, and if possible in a way that allows the intervention to be replicated.	The components of all interventions (drug, non-drug, simple or complex) should be reported. Reporting guidelines have been developed for describing interventions used in primary research and review authors may find it useful to structure their description of interventions around the core attributes highlighted by TIDieR (Hoffman 2014). Lengthy explanations of interventions should be avoided. Citations to sources of detailed descriptions can be included.	Cochrane Training resource: collecting data CIL: module 4 - selecting studies and collecting data
R67	*Table of 'Characteristics of included*	***Mandatory***	

	studies': outcomes		
	Provide clear and consistent information about outcomes measured (or reported), how they were measured and the times at which they were measured.	It should be clear whether main outcomes of interest in the review were measured in the study.	Cochrane Training resource: collecting data CIL: module 4 - selecting studies and collecting data
R68	*Table of 'Characteristics of included studies': dates*	***Highly desirable***	
	Include the dates when the study was conducted in the table of 'Characteristics of included studies'.	If dates are not available then this should be stated (e.g. "Study dates not reported").	Cochrane Training resource: collecting data CIL: module 4 - selecting studies and collecting data
R69	*Table of 'Characteristics of included studies': funding source*	***Mandatory***	
	Include details of funding sources for the study, where available.	Details of funding sources should be placed in this table rather than as part of the 'Risk of bias' table. Including an extra row in the table of 'Characteristics of included studies' is encouraged.	Cochrane Training resource: collecting data CIL: module 4 - selecting studies and collecting data
R70	*Table of 'Characteristics of included studies': declarations of interest*	***Mandatory***	
	Include details of any declarations of interest among the primary researchers.	Declarations of interest should be placed in this table rather than as part of the 'Risk of bias' table. Including an extra row in the table of 'Characteristics of included studies' is encouraged.	Cochrane Training resource: collecting data CIL: module 4 - selecting studies and collecting data
R71	*Choice of intervention groups in multi-arm studies*	***Highly desirable***	
	If a study is included with more than two intervention arms, restrict comments on any irrelevant arms to a brief comment in the table of 'Characteristics of included studies'.	Intervention arms that are not relevant to the review question should not be discussed in detail, although it is useful to clarify (in this table) that such arms were present. *MECIR conduct standard 50:* If a study is included with more than two intervention arms, include in the review only intervention and control groups that meet the eligibility criteria.)	Cochrane Training resource: analysing non-standard data and study designs CIL: module 6 - analysing the data
R72	*References to included studies*	***Mandatory***	
	List all reports of each included study under the relevant Study ID.	It is important that all reports are listed, and are grouped by study. Marking one report as the primary reference is helpful where appropriate.	

Risk of bias in included studies (R73-75)

Risk of bias in included studies

Cochrane Training resource: assessing RoB included studies and RoB 2.0 webinar

Cochrane Interactive Learning: module 5 - introduction to study quality and risk of bias

	Standard	Rationale and elaboration	Resources
R73	*"Risk of bias" table*	***Mandatory***	
	Present a 'Risk of bias' table for each included study, with judgements about risks of bias, and explicit support for these judgements.	The 'Risk of bias' table in RevMan should be used, this is an extension of the table of 'Characteristics of included studies'. MECIR conduct standard 52: Assess the risk of bias for each included study. For randomized trials, the Cochrane 'Risk of bias' tool should be used, involving judgements and supports for those judgements across a series of domains of bias, as described in Chapter 8 of the *Handbook* (version 5 or later). *Also* MECIR conduct standards 54 – 61	
R74	*Summary assessments of risk of bias*	***Highly desirable***	
	Summarize the risk of bias across domains for each key outcome for each included study, and ensure that these are supported by the information presented in the 'Risk of bias' tables.	*MECIR conduct standard 58:* Summarize the risk of bias for each key outcome for each study.	
R75	*Risk of bias in included studies*	***Mandatory***	
	Provide a brief narrative summary of the risks of bias among the included studies.	It may be helpful to identify any studies considered to be at low risk of bias for particular key outcomes.	

Effects of interventions (R76-99)

Effects of interventions

Cochrane Interactive Learning: module 8 - reporting the review

	Standard	Rationale and elaboration	Resources
R76	*Use of 'Data and analysis' headings*	***Mandatory***	
	Ensure appropriate use of the heading hierarchy of Comparisons, Outcomes, Subgroups and Study data in the 'Data and analysis' section.	Appropriate use of the hierarchy ensures consistency of structure across reviews. It is confusing for the user if outcomes are listed against the heading 'Comparison' and interventions listed against the heading 'Outcome or subgroup'.	
R77	*Presenting data*	***Highly desirable***	
	Ensure that simple summary data for each intervention group, as well as estimates of effect size (comparing the intervention groups), are available for each study for each outcome of interest to the review. These appear by default when dichotomous or continuous outcome data are analysed within RevMan.	Simple summaries such as numbers of events, means and standard deviations should be presented for each treatment group when available. This is achieved primarily by using the 'Data and analyses' section of the review, for dichotomous and continuous outcomes. For other outcomes, these should typically be presented in tables labelled 'Other data'. When data for each separate intervention group are available for outcomes analysed as 'generic inverse-variance' data, these might be presented in Additional tables.	
R78	*Number of studies and participants*	***Mandatory***	
	State how many studies and how many participants contributed data to	It is unlikely that the same number of studies will contribute data to every outcome of interest. Specific studies may	

	results for each outcome, along with the proportion of the included studies and recruited participants potentially available for the relevant comparison.	contribute different numbers of participants for different outcomes. Therefore, for each comparison, it is helpful to indicate to readers what proportion of the relevant included studies and recruited participants contribute data to each outcome. Failure to disclose this may be misleading.	
R79	*Source of data*	***Highly desirable***	
	State the source of all data presented in the review, in particular, whether it was obtained from published literature, by correspondence, from a trials register, from a web-based data repository, etc.	Transparency of data source enables validation or verification of data by others, including editors or readers of the review.	
R80	*Multiple outcome data*	***Mandatory***	
	Describe any post hoc decisions that might give rise to accusations of selective outcome reporting, for example when there were multiple outcome measures (e.g. different scales), multiple time points or multiple ways of presenting results.	Transparent disclosure of post hoc decisions will enable readers of the review to assess the credibility of the results of the review for themselves. Post hoc decisions to change the definition or priority of outcome measures must be reported and justified under 'Differences between the protocol and review'. MECIR conduct standard 16: Define in advance details of what are acceptable outcome measures (e.g. diagnostic criteria, scales, composite outcomes). *MECIR conduct standard 17:* Define in advance how outcome measures will be selected when there are several possible measures (e.g. multiple definitions, assessors or scales). *MECIR conduct standard 18:* Define in advance the timing of outcome measurement.	
R81	*Ordering of results and 'Data and analysis' section*	***Highly desirable***	
	Organize results to follow the order of comparisons and outcomes specified in the protocol, following in particular the distinction between primary and secondary outcomes.	Review authors must avoid selective reporting of analysis results in a way that depends on the findings. The best way to achieve this is to follow a well-structured protocol and present results as outlined in that protocol. However, sometimes a pragmatic decision needs to be made that an alternative arrangement is preferable, particularly with regard to comparisons. This choice should be explicitly justified.	
R82	*Prespecified outcomes*	***Mandatory***	
	Report synthesis results for all prespecified outcomes, irrespective of the strength or direction of the result. Indicate when data were not available for outcomes of interest, and whether adverse effects data were identified.	To avoid selective outcome reporting (in truth or in perception), the review should address all outcomes specified in the protocol.	
R83	*Statistical uncertainty*	***Mandatory***	
	Accompany all effect size estimates with a measure of statistical uncertainty (e.g. a confidence interval with a specified level of confidence such as 90%, 95% or 99%).	Confidence intervals are the preferred method for expressing statistical uncertainty.	Cochrane Training resource: intro to meta-analysis
R84	*P values*	***Highly desirable***	
	If reporting P values, provide exact P values (e.g. P = 0.08 rather than P > 0.05).	Effect estimates with confidence intervals are the preferred method of presenting numeric results. P values should not be used as an alternative to confidence intervals and should	See *Handbook* 12.4.2

		not be used to divide results into 'significant' or 'non-significant'; exact P values portray the strength of evidence against the null hypothesis.	
R85	*Tables and Figures*	***Mandatory***	
	Link to each Table and Figure.	All tables and figures should have a brief descriptive caption and must be referred to in numerical order in the review text.	
R86	*Number of Tables and Figures*	***Highly desirable***	
	Keep the number of Tables and Figures low to convey key findings without affecting the readability of the review text.	Tables (typically implemented as Additional tables) and Figures (including RevMan flow charts, RevMan forest plots and imported graphics) may be added to reviews and included in the body of the text. Reviews should try and avoid including more than six such Tables and Figures in total. Further Tables and Figures can be included as supplementary material (e.g. as 'Data and analysis' forest plots or within Appendices).	
R87	*Consistency of results*	***Mandatory***	
	Ensure that all statistical results presented in the main review text are consistent between the text and the 'Data and analysis' tables.	Errors can be introduced, particularly when analyses are rerun.	
R88	*Direction of effect*	***Mandatory***	
	State whether findings indicate a clear direction of benefit.	Where results indicate that an intervention is better or worse than another intervention, it is important to make it clear which intervention is favoured. This is the case particularly when different scales are combined using standardized mean differences.	Cochrane Training resource: intro to meta-analysis
R89	*Interpretability of results*	***Mandatory***	
	Ensure that key findings are interpretable, or are re-expressed in an interpretable way. For instance, they might be re-expressed in absolute terms (e.g. assumed and corresponding risks, NNTBs, group means), and outcomes combined with a standardized scale (e.g. standardized mean difference) might be re-expressed in units that are more naturally understood. If minimally important differences were prespecified or are available, these should be provided to aid interpretation.	Absolute effects provide a useful illustration of the likely impact of an intervention, and are usually easier to understand than relative effects. They may need to be accompanied, however, with information about assumed baseline risks. Confidence intervals should be presented for NNTBs and similar summary measures. Re-expressing relative effects as absolute effects often requires the specification of assumed (e.g. untreated) risks, and the source of these should be provided. Results expressed as standardized mean differences reflect the number of standard deviations' difference between mean responses. This is not intuitive to many readers who may be more familiar with specific scales. Ideally, minimally important effect sizes should be specified in the protocol.	Cochrane Training resources: analysing dichotomous outcomes and analysing continuous outcomes
R90	*Studies without usable data*	***Mandatory***	
	Comment on the potential impact of studies that apparently measured outcomes, but did not contribute data that allowed the study to be included in syntheses.	There is good evidence of selective outcome reporting among clinical trials. Outcomes that are believed to have been measured but are not reported in a usable format may therefore be systematically different from those that are usable, and introduce bias. 'Usable' in this sense refers both to incorporation in a meta-analysis and to consideration in non-statistical syntheses of findings. Authors might consider using a table to indicate which studies contributed data to the outcomes of interest in the review. MECIR conduct standard 40: Include studies in the review irrespective of whether measured outcome data are reported in a 'usable' way.	
R91	*Missing outcome data*	***Highly desirable***	

	Discuss the implications of missing outcome data from individual participants (due to losses to follow-up or exclusions from analysis).	*MECIR conduct standard 64:* Consider the implications of missing outcome data from individual participants (due to losses to follow-up or exclusions from analysis).	
R92	*Skewed data*	***Highly desirable***	
	Discuss the possibility and implications of skewed data when analysing continuous outcomes.	MECIR conduct standard 65: Consider the possibility and implications of skewed data when analysing continuous outcomes.	Cochrane Training resource: analysing continuous outcomes CIL: module 6 - analysing the data
R93	*Forest plots*	**Highly desirable**	
	Present data from multiple studies in forest plots (using the 'Data and analyses' structure in RevMan) wherever possible, providing it is reasonable to do so.	Presenting data in forest plots can be useful, even if the studies are not combined in a meta-analysis.	Cochrane Training resource: intro to meta-analysis CIL: module 6 - analysing the data
R94	*Multiple subgroup analyses and sensitivity analyses*	***Highly desirable***	
	If presenting multiple sensitivity analyses or different ways of subgrouping the same studies, present these in summary form (e.g. a single Table or Figure) and not in multiple forest plots.		Cochrane Training resource: exploring heterogeneity CIL: module 6 - analysing the data
R95	*Labels on plots*	***Mandatory***	
	Label the directions of effect and the intervention groups in forest plots with the interventions being compared.	By default, RevMan currently uses 'experimental' and 'control' within labels. It is helpful to replace these with more specific intervention names, and essential if the ordering is swapped (or for head-to-head comparisons). Directions of effect should be used as consistently as possible within a review.	Cochrane Training resource: intro to meta-analysis CIL: module 6 - analysing the data
R96	*Risk of bias across studies*	***Highly desirable***	
	Present results of the assessment of risk of bias across studies (and across domains) for each key outcome, and state whether this leads to concerns about the validity of the review's findings.	Considerations of risk of bias across studies are required for assessments of the quality of the body of evidence (e.g. using GRADE).	Cochrane Training resources: assessing RoB included studies and RoB 2.0 webinar CIL: module 5 - introduction to study quality and risk of bias CIL: module 7 - interpreting the findings
R97	*Reporting biases*	***Highly desirable***	
	Present results of any assessment of the potential impact of reporting biases on the review's findings.	MECIR conduct standard 73: Consider the potential impact of reporting biases on the results of the review or the meta-analyses it contains.	Cochrane Training resource: small study effects and reporting biases CIL: module 7 - interpreting the

			findings
R98	'*Summary of findings' table*	***Mandatory***	
	Present a 'Summary of findings' table according to recommendations described in Chapter 11 of the *Handbook* (version 5 or later).	Specifically: include results for one clearly defined population group (with few exceptions); indicate the intervention and the comparison intervention; include seven or fewer patient-important outcomes; describe the outcomes (e.g. scale, scores, follow-up); indicate the number of participants and studies for each outcome; present at least one baseline risk for each dichotomous outcome (e.g. study population or median/medium risk) and baseline scores for continuous outcomes (if appropriate); summarize the intervention effect (if appropriate); and include a measure of the quality of the body of evidence for each outcome. Efforts should be made to incorporate information presented in 'Summary of findings' tables (such as absolute effects, quality ratings and downgrading decisions) in other parts of the review including the Abstract, Plain language summary, Effects of interventions, Discussion and Authors' conclusions.	Cochrane Training resource: GRADE approach to evaluating evidence quality Incorporating GRADE in Cochrane Reviews CIL: module 8 - reporting the review
R99	*Assessments of the quality of the body of evidence*	***Mandatory***	
	Provide justification or rationale for any measures of the quality of the body of evidence for each key outcome. If a 'Summary of findings' table is used, use footnotes to explain any downgrading or upgrading according to the GRADE approach.	*MECIR conduct standard 74:* Use the five GRADE considerations (risk of bias, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of the body of evidence for each outcome, and to draw conclusions about the quality of evidence within the text of the review. *MECIR conduct standard 75:* Justify and document all assessments of the quality of the body of evidence (for example downgrading or upgrading if using GRADE).	Cochrane Training resource: GRADE approach to evaluating evidence quality Incorporating GRADE in Cochrane Reviews CIL: module 7 - interpreting the findings CIL: module 8 - reporting the review

Discussion (R100-101)

Discussion

Cochrane Interactive Learning: module 8 - reporting the review

	Standard	Rationale and elaboration	Resources
R100	*Discussion headings*	***Highly desirable***	
	Include the standard RevMan headings when writing the Discussion.	Five standard headings are included in RevMan ('Summary of main results', 'Overall completeness and applicability of evidence', 'Quality of the evidence', 'Potential biases in the review process, 'Agreements and disagreements with other studies or reviews').	See *Handbook* 4.5
R101	*Limitations*	***Mandatory***	
	Discuss limitations of the review at study and outcome level (e.g. regarding risk of bias), and at review level (e.g. incomplete	Review authors must explicitly state the limitations of their review. One aspect that is easily overlooked is that of adverse effects. In particular, if the review methods do not allow for detection of serious or rare adverse events, or both,	

	identification of studies, reporting bias).	the review authors must explicitly state this as a limitation. Additional considerations here include currency and completeness of the search, completeness of data collection processes, assumptions made regarding classification of interventions, outcomes or subgroups, and methods used to account for missing data. MECIR conduct standard 74: Consider the potential impact of reporting biases on the results of the review or the meta-analyses it contains.	

Authors' conclusions (R102-103)

Authors' conclusions

Cochrane Interactive Learning: module 8 - reporting the review

	Standard	Rationale and elaboration	Resources
R102	*Conclusions: implications for practice*	***Mandatory***	
	Provide a general interpretation of the evidence so that it can inform healthcare or policy decisions. Avoid making recommendations for practice.	When formulating implications for practice base conclusions only on findings from the synthesis (quantitative or narrative) of studies included in the review. The conclusions of the review should convey the essence of the synthesis of included studies, without selective reporting of the particular findings on the basis of the result, and without drawing on data that were not systematically compiled and evaluated as part of the review.	See *Handbook* 4.5, 12.7 Incorporating GRADE in Cochrane Reviews.
R103	*Conclusions: implications for research*	***Mandatory***	
	If recommending further research, structure the implications for research to address the nature of evidence required, including population, intervention comparison, outcome, and type of study.	Researchers and research funders are an important user group of Cochrane Reviews. Recommendations for future research should offer constructive guidance on addressing the remaining uncertainties identified by the review. This is particularly important for reviews that identify few or no studies. Include any information about completed or ongoing studies that are likely to address the review question.	

Acknowledgements (R104)

Acknowledgements

	Standard	Rationale and elaboration	Resources
R104	*Acknowledgements*	***Mandatory***	
	Acknowledge the contribution of people not listed as authors of the review, including any assistance from the Cochrane Review Group, non-author contributions to searching, data collection, study appraisal or statistical analysis, and the provision of funding.		Cochrane Training resource: writing a protocol

Contribution of authors (R105)

Contribution of authors

	Standard	Rationale and elaboration	Resources
R105	*Contributions of authors*	**Mandatory**	
	Describe the contributions of each author to the review.		See *Handbook* 4.2.2 Cochrane Training resource: writing a protocol

Declarations of interest (R106)

Declarations of interest

	Standard	Rationale and elaboration	Resources
R106	*Declarations of interest*	***Mandatory***	
	Report any present or recent (three years prior to declaration) affiliations or other involvement in any organization or entity with an interest in the review's findings that might lead to a real or perceived conflict of interest. Include the dates of the involvement.	The full policy on conflicts of interest is available in the Cochrane Editorial and Publishing Policy Resource (EPPR). In brief, the nature and extent of the affiliation or involvement (whether financial or non-financial) should be described to promote transparency. Strategies to clarify how commercial and intellectual conflicts of interests (such as review authors who are trialists) were handled in the review process may be needed. Declarations of interest should be stated according to the relevant criteria from the International Committee of Medical Journal Editors (ICMJE), and must be consistent with interests declared on the Disclosure of Potential Conflicts of Interest form.	See Handbook 2.6 Cochrane Training resource: writing a protocol

Differences between protocol & review (R107-108)

Differences between protocol & review

	Standard	Rationale and elaboration	Resources
R107	*Changes from the protocol*	***Mandatory***	
	Explain and justify any changes from the protocol (including any post hoc decisions about eligibility criteria or the addition of subgroup analyses).	*MECIR conduct standard 13:* Justify any changes to eligibility criteria or outcomes studied. In particular, post hoc decisions about inclusion or exclusion of studies should keep faith with the objectives of the review rather than with arbitrary rules.	
R108	*Methods not implemented*	***Mandatory***	
	Document aspects of the protocol that were not implemented (e.g. because no studies, or few studies, were found) in the section	Including a record of methods that were not implemented helps to retain specific details of the protocol. By doing so, the next version of the review can be seen to be coherent with what was planned in the protocol.	See *Handbook* 2.1

	'Differences between protocol and review', rather than in the Methods section.		

Sources of support (R109)

Sources of support

	Standard	Rationale and elaboration	Resources
R109	*Sources of support*	***Mandatory***	
	List sources of financial and non-financial support for the review and the role of the funder, if any.		See *Handbook* 4.10 Cochrane Training resource: writing a protocol