Standards for the reporting of new Cochrane Intervention Reviews

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Preface

The standards below summarize proposed attributes of reporting that we consider should be either mandatory or highly desirable for Cochrane Intervention Reviews, with the rationale for this judgment. These standards are not intended to apply to protocols or updated reviews at this point, and these will be addressed in further work. There is also a separate project ongoing aimed at clarifying expectations for plain language summaries.

In order to provide the user with a succinct and relevant document, the methodology of a review should be reported in such a way that links the methods directly to the results of the present version of the review. Thus, details of methods that were planned in the protocol but were not implemented should generally be reported in the dedicated section for differences between the protocol and the review, or in an appendix.

The Cochrane Collaboration has adopted recommendations provided in the PRISMA statement [http://www.prisma-statement.org/]. We believe the reporting standards below will ensure compliance with these recommendations. Some items have been included specifically to enable this (e.g. the standard relating to mentioning that the review has a published protocol). Extensions to the PRISMA statement may also be relevant to particular reviews, such as reviews addressing equity issues [http://equity.cochrane.org/equity-extension-prisma].

The ordering of the standards reflects the position in which each issue might be expected to be addressed in the main text of the review. In some items we have specified where things should be reported (e.g. for contents of the table of 'Characteristics of included studies'). For other items, review authors should consider whether information should be reported in the main text, in tables, figures or appendices.

Further details of the MECIR project can be found at our website:

www.editorial-unit.cochrane.org/mecir

David Tovey, Editor in Chief of *The Cochrane Library*

Status: Mandatory means that a new review should not be published if this is not reported.
Highly desirable means that this should generally be done, but that there are justifiable exceptions.

Item no.	Status	Item name	Standard	Rationale and elaboration
Title and authors				
R1	Highly desirable	Format of title	Follow the standard template for a Cochrane review title.	See *Handbook* Table 4.2.a.
R2	Mandatory	Authors	List names and affiliations of all authors	See *Handbook* 4.2.2.
Abstract				
R3	Mandatory	Writing the abstract	Prepare a structured abstract to provide a succinct summary of the review. In the interests of brevity it is highly desirable for authors to provide an abstract of less than 700 words, and it should be no more than 1000 words in length.	Abstracts are a prominent, publically accessible summary of the review. They should convey key information about the review question and its findings, and be informative to readers. [PRISMA item 2]
R4	Mandatory	Abstract, Background	Summarize the rationale and context of the review.	See *Handbook* 11.8
R5	Mandatory	Abstract, Objectives	State the main objective(s), preferably in a single concise sentence	The objective(s) should be expressed in terms that relate to the population(s), intervention comparison(s) and, where appropriate, outcomes of interest. See *Handbook* 11.8
R6	Mandatory	Abstract, Search methods	Provide the date of the last search from which records were evaluated and any studies identified were incorporated into the review, and an indication of the databases and other sources searched.	Abstracts should aim to give readers brief but key information about the comprehensiveness of the search and the currency of the information summarised by the review. The abstract must include the month and year of the set of searches up to which the conclusions of the review are valid. This date should reflect the date of the most recent set of searches from which all records have been screened for relevance and any studies meeting the eligibility criteria have been fully incorporated into the review (studies may be awaiting classification if, for example, the review authors are awaiting translation or clarification from authors or sponsors). Abstracts do not need to report on recent repeat or 'catch-up' searches whose results have not been fully incorporated into the review. However, discretion should be applied if such searches identify a large body of evidence whose absence from the review findings may affect the reliability of the conclusions. The amount of information regarding the search should be indicative of the process rather than provide specific details. In the interests of brevity certain details regarding the overall process may need to be moved to the full text of the review. Example: "CENTRAL, MEDLINE, Embase, five other databases and three trials registers were

				searched on [date] together with reference checking, citation searching and contact with study authors to identify additional studies".
R7	Mandatory	Abstract, Selection criteria	Summarize eligibility criteria of the review, including information on study design, population and comparison.	Any extensions to eligibility criteria to address adverse effects, economic issues or qualitative research should be mentioned.
R8	Mandatory	Abstract, Data collection and analysis	Summarize any noteworthy methods for selecting studies, collecting data, evaluating risk of bias and synthesizing findings. For many reviews it may be sufficient to state "We used standard methodological procedures expected by The Cochrane Collaboration."	This section of the abstract should indicate the rigour of the methods that underpin the results reported subsequently in the abstract. It does not need to replicate detailed description of the methods in the main text of the review. Details of how many people were involved in the screening process and collection of information about any included studies are not necessary in the abstract. Key statistical methods may be given if not clear from the results that follow. The abstract should prioritize the disclosure of non-standard approaches. For example, rather than disclosing all domains applied in the assessment of bias, notable variations on the standard approach should be given, such as non-standard tools that were used.
R9	Mandatory	Abstract, Main results: number of studies and participants	Report the number of included studies and participants.	The total number of included studies should be stated. It might be appropriate to provide numbers of studies and participants for specific comparisons and main outcomes if the amount of evidence differs substantially from the total. Numbers of participants *analysed* should generally be presented in preference to numbers *recruited* (e.g. randomized); more important is to be clear which numbers are being reported. For some types of data there may be preferable alternatives to the number of participants (e.g. person-years of follow-up, number of limbs).
R10	Highly desirable	Abstract, Main results: study characteristics	Provide a brief description of key characteristics that will determine the applicability of the body of evidence (e.g. age, severity of condition, setting, study duration).	Summarizing the study characteristics will provide readers of the abstract with important information about the applicability of the included studies. This is particularly important if the included studies reflect a subgroup of those eligible for inclusion in the review, for example, if the review intended to address the effects of interventions across all age groups, but included studies that only recruited adolescents.
R11	Mandatory	Abstract, Main results: bias assessment	Provide a comment on the findings of the bias assessment.	The risk of bias assessments are a key finding and form a fundamental part of the strength of the conclusions drawn in the review. If risks of bias differ substantially for different comparisons and outcomes, this may need to be mentioned.
R12	Mandatory	Abstract, Main results: findings	Report findings for all primary outcomes, irrespective of the strength and direction of the result, and of the availability of data.	Findings should typically include concise information about the quality of the body of evidence for the outcome (such as study limitations, consistency of effect, imprecision, indirectness and publication bias), for example using GRADE. Outcomes should not be selected solely on the basis of the findings. If no studies measured the primary outcomes, then a comment should be made to that effect.
R13	Mandatory	Abstract, Main results: adverse effects	Ensure that any findings related to adverse effects are reported. If adverse effects data were sought, but availability of data was limited, this should be reported.	See *Handbook* 11.8 The abstract of the review should aim to reflect a balanced summary of the benefits and harms of the intervention.
R14	Mandatory	Abstract, Main results: format of numerical results	Present summaries of statistical analyses in the same way as they are reported in the review and in a standard way, ensuring that readers will understand the direction of benefit and the measurement scale used, and	The standard format for reporting the results of statistical analysis includes an indication of the summary measure, point estimate and confidence interval (e.g. odds ratio 0.75 (95% confidence interval 0.62 to 0.89)).

			that confidence intervals are included where appropriate.	
R15	Highly desirable	Abstract, Main results: interpretability of findings	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, NNTs, group means), and outcomes combined with a standardized scale (e.g. SMD) might be re-expressed in units that are more naturally understood.	Absolute effects provide a useful illustration of the likely impact of intervention, and are usually easier to understand than relative effects. Units expressed on a standardized scale reflect the effect estimate as the number of standard deviations. This is not intuitive to many readers who may be more familiar with specific scales. Any re-expressed findings must have been presented in the same way in the main text of the review (see previous standard).
R16	Mandatory	Abstract, Authors' conclusions	State key conclusions drawn.	Authors' conclusions may include both implications for practice and implications for research. Care must be taken to avoid interpreting lack of evidence of effect as evidence of lack of effect (See *Handbook* 12.7.4). *Recommendations* for practice should be avoided (See *Handbook* 11.8).
R17	Mandatory	Completeness of main review text	Ensure that all findings reported in the abstract and plain language summary, including re-expressions of meta-analysis results, also appear in the main text of the review.	See *Handbook* 11.8 and 11.9
R18	Mandatory	Consistency of summary versions of the review	Ensure that reporting of objectives, important outcomes, results, caveats and conclusions is consistent across the text, the abstract, the plain language summary and the 'Summary of findings' table (if included).	Summary versions of the review should be written on the assumption that they are likely to be read in isolation from the rest of the review..
Background				
R19	Mandatory	Background	Provide a concise description of the condition or problem addressed by the review question, definition of the intervention and how it might work, and why it is important to do the review.	Systematic reviews should have a clearly defined and well-reasoned rationale which has been developed in the context of existing knowledge. Outlining the context of the review question is useful to readers and helps to establish key uncertainties that the review intends to address. [PRISMA item 3]
R20	Highly desirable	Background headings	Include the four standard headings when writing the Background.	Four standard headings are included in RevMan ('Description of the condition', 'Description of the intervention', 'How the intervention might work', and 'Why it is important to do this review'). See *Handbook* 4.5
R21	Mandatory	Background references	Back up all key supporting statements with references.	Claims or statements regarding aspects such as disease burden, morbidity, prevalence and mechanisms of action should be substantiated and, where available, supported by external evidence.
R22	Mandatory	Background text	Avoid the use of plagiarized text.	Unacknowledged copying from the work of other people is not acceptable. There may however be situations in which the same text appears in different reviews, for example when the reviews are prepared by the same team. A formal policy on plagiarism in Cochrane reviews is in development. Content that is identical to, drawn or copied from standard texts may be acceptable but must be referenced. Ensure any verbatim quotations of more than a few words are shown in quotation marks and clearly acknowledge (i.e. cite) all sources.

R23	Mandatory	Main objective	State the main objective, where appropriate in a single concise sentence.	The primary objective of a Cochrane review should be to assess the effects of one or more healthcare interventions on stakeholder-important outcomes, both intended and unintended. The objective should be expressed in terms that relate to the population(s), intervention comparison(s) and, where appropriate to specify explicitly, the outcomes of interest. Stakeholders may be patients, carers, policy makers, clinicians or others. *MECIR conduct standard 2* (Define in advance the objectives of the review, including participants, interventions, comparators and outcomes.) Where possible, the format should be of the form "To assess the effects of *[intervention or comparison]* for *[health problem]* for/in *[types of people, disease or problem and setting if specified]*". [PRISMA item 4]
R24	Highly desirable	Secondary objectives	State explicitly (as secondary objectives) any specific questions being addressed by the review, such as those relating to particular participant groups, intervention comparisons or outcomes.	The objectives should be expressed in terms that relate to the population(s), intervention comparison(s) and, where appropriate, outcomes of interest. *MECIR conduct standard 4* (Consider in advance whether issues of equity and relevance of evidence to specific populations are important to the review, and plan for appropriate methods to address them if they are. Attention should be paid to the relevance of the review question to populations such as low socioeconomic groups, low or middle income regions, women, children and older people.)
R25	Mandatory	Economic evidence	*If health economics evidence is being reviewed*, state this explicitly in the Objectives (as secondary objectives).	The primary aim of a Cochrane review should be to assess the effects of one or more healthcare interventions on stakeholder-important outcomes, both intended and unintended. These outcomes may include economic outcomes. If health economics evidence is being reviewed as an integrated economics component (see *Handbook* section 15.2.3), this should be stated as a secondary objective.
R26	Mandatory	Qualitative research evidence	*If qualitative research evidence is being reviewed*, state this explicitly in the Objectives (as secondary objectives).	The primary aim of a Cochrane review should be to assess the effects of one or more healthcare interventions on stakeholder-important outcomes, both intended and unintended. If qualitative research evidence is being included to 'extend' the review (see *Handbook* section 20.2.1), this should be stated as a secondary objective.
Methods				
R27	Highly desirable	Reference protocol	Cite the protocol for the review.	The reader should be made aware that the review is based on a published protocol. This is particularly important if the review has been split into multiple reviews since the protocol was published. Since the protocol is usually no longer included in the CDSR once the review is published, it should be cited using the last publication citation for the protocol. Archived versions of protocols can be accessed via the current version of the review. [PRISMA item 5]
Criteria for considering studies for this review				
R28	Mandatory	Eligibility criteria for types of study: study designs	State eligible study designs, and provide a justification for the choice.	It is not necessary to explain why randomized trials are eligible (if that is the case), although it may be important to explain the eligibility or non-eligibility of other types of study. *MECIR conduct standard 9* (Define in advance the eligibility criteria for study designs in a clear and unambiguous way, with a focus on features of a study's design rather than design labels.) *MECIR conduct standard 11* (Justify the choice of eligible study designs.) [PRISMA item 6]
R29	Mandatory	Eligibility criteria for types of study: study reports	*If studies are excluded on the basis of publication status or language of publication*, explain and justify this.	Studies should be included irrespective of their publication status and language of publication, unless explicitly justified. *MECIR conduct standard 12* (Include studies irrespective of their publication status, unless explicitly justified.) [PRISMA item 6]

R30	Mandatory	Eligibility criteria for types of participants	State eligibility criteria for participants, including any criteria around location, setting, diagnosis or definition of condition and demographic factors, and how studies including subsets of relevant participants are handled.	Any notable restrictions on the eligibility criteria of the review should be given and explained (e.g. exclusion of people under or over a certain age, specific settings of intervention). *MECIR conduct standard 5* (Define in advance the eligibility criteria for participants in the studies.) *MECIR conduct standard 6* (Define in advance how studies that include only a subset of relevant participants will be handled.) [PRISMA item 6]
R31	Mandatory	Eligibility criteria for types of interventions	State eligibility criteria for interventions and comparators, including any criteria around delivery, dose, duration, intensity, co-interventions and characteristics of complex interventions.	*MECIR conduct standard 7* (Define in advance the eligible interventions and the interventions against which these can be compared in the included studies.) [PRISMA item 6]
R32	Mandatory	Role of outcomes	*If measurement of particular outcomes is used as an eligibility criterion*, state and justify this.	Studies should never be excluded from a review solely because no outcomes of interest are *reported*. However, on occasion it will be appropriate to include only studies that *measured* particular outcomes. For example, a review of a multi-component public health intervention promoting healthy lifestyle choices, focussing on reduction in smoking prevalence, might legitimately exclude studies that do not measure smoking rates. *MECIR conduct standard 8* (Clarify in advance whether outcomes listed under 'Criteria for considering studies for this review' are used as criteria for including studies (rather than as a list of the outcomes of interest within whichever studies are included).) [PRISMA item 6]
R33	Mandatory	Outcomes of interest	State primary and secondary outcomes of interest to the review, and define acceptable ways of measuring them.	Explain how multiple variants of outcome measures (e.g. definitions, assessors, scales, time points) are addressed. *MECIR conduct standard 14* (Define in advance which outcomes are primary outcomes and which are secondary outcomes.) Also *MECIR conduct standards 15 – 18*.
Search methods for identification of studies				
R34	Mandatory	Search sources	List all sources searched, including: databases, trials registers, web sites and grey literature. Database names should include platform/provider name and dates of coverage; web sites should include full name and URL. State whether reference lists were searched and whether individuals or organizations were contacted.	*MECIR conduct standard 36* (Document the search process in enough detail to ensure that it can be reported correctly in the review.) *Also MECIR conduct standards 24 – 31*. [PRISMA item 7]
R35	Mandatory	Latest searches	Provide the date of the last search and the issue / version number (where relevant) for each database whose results were evaluated and incorporated into the reviewIf a search was re-run prior to publication, the results of which were not incorporated, explain how the results were dealt with and provide the date.	The review should provide the search date from which studies have been retrieved and assessed for inclusion. This is the date up to which the conclusions of the review are valid. It should reflect the date of the most recent set of searches from which all records have been screened for relevance and any studies meeting the eligibility criteria have been fully incorporated into the review (studies may be awaiting classification if, for example, the review authors are awaiting translation or clarification from authors or sponsors). Since the review is likely to have drawn on searches conducted across multiple databases, it is possible that searches were performed on more than one date. The earliest date of the most recent set of searches should be provided in the review text and as the hard-coded date of the last search. The remaining dates for other databases should be reported in an appendix.

				If a 'catch-up' search was run subsequent to the review being written up, any relevant studies not yet assessed for inclusion should be listed in the section 'Studies awaiting assessment'. *MECIR conduct standard 37* (Rerun or update searches for all relevant databases within 12 months before publication of the review or review update, and screen the results for potentially eligible studies.) *MECIR conduct standard 38* (Incorporate fully any studies identified in the rerun or update of the search within 12 months before publication of the review or review update.) [PRISMA item 7]
R36	Mandatory	Search timeframe	Specify and justify any restrictions placed on the time period covered by the search.	*MECIR conduct standard 35* (Justify the use of any restrictions in the search strategy on publication date, publication format or language.)
R37	Mandatory	Searches for different types of evidence	*If the review has specific eligibility criteria to include additional studies such as studies of adverse effects, health economics evidence or qualitative research evidence*, describe search methods for identifying such studies.	Some reviews extend beyond a focus on the effects of healthcare interventions and address specific additional types of evidence. These are discussed in Chapters 14, 15 and 20 of the *Handbook*. *MECIR conduct standard 26* (*If the review has specific eligibility criteria around study design to address adverse effects, economic issues or qualitative research questions*, undertake searches to address them.)
R38	Mandatory	Search strategies for bibliographic databases	Present the exact search strategy (or strategies) used for each database in an Appendix, including any limits and filters used, so that it could be replicated.	Search strategies that are available elsewhere (e.g. standard methodological filters, or strategies used to populate a specialized register) may be referenced rather than reproduced. Including numbers of hits for each line in the strategy is optional. *MECIR conduct standard 36* (Document the search process in enough detail to ensure that it can be reported correctly in the review.) Also *MECIR conduct standards 32 – 35*. [PRISMA item 8]
R39	Highly desirable	Search strategies for other sources	Report the search terms used to search any sources other than bibliographic databases (e.g. trials registers, the web), and the dates of the searches.	Some of this information might be best placed in an Appendix. *MECIR conduct standard 36* (Document the search process in enough detail to ensure that it can be reported correctly in the review.)
Data collection and analysis				
R40	Mandatory	Inclusion decisions	State how inclusion decisions were made (i.e. from search results to included studies), clarifying how many people were involved and whether they worked independently.	*MECIR conduct standard 39* (Use (at least) two people working independently to determine whether each study meets the eligibility criteria, and define in advance the process for resolving disagreements.) [PRISMA item 9]
R41	Mandatory	Data collection process	State how data were extracted from reports of included studies, clarifying how many people were involved (and whether independently), and how disagreements were handled. Describe data collection process for any reports requiring translation.	*MECIR conduct standard 43* (Use a data collection form, which has been piloted.) *MECIR conduct standard 45* (Use (at least) two people working independently to extract study characteristics from reports of each study, and define in advance the process for resolving disagreements.) [PRISMA item 10]

R42	Highly desirable	Requests for data	Describe attempts to obtain or clarify data from individuals or organizations.	*MECIR conduct standard 49* (Seek key unpublished information that is missing from reports of included studies.) [PRISMA item 10]
R43	Mandatory	Data items	List the types of information that were sought from reports of included studies.	*MECIR conduct standard 44* (Collect characteristics of the included studies in sufficient detail to populate a table of 'Characteristics of included studies'.) [PRISMA item 11]
R44	Mandatory	Transformations of data	Explain any transformations of reported data prior to presentation in the review, along with any assumptions made. Explain any procedures for extracting numeric data from graphs.	*MECIR conduct standard 47* (Collect and utilize the most detailed numerical data that might facilitate similar analyses of included studies. Where 2×2 tables or means and standard deviations are not available, this might include effect estimates (e.g. odds ratios, regression coefficients), confidence intervals, test statistics (e.g. t, F, Z, chi-squared) or P values, or even data for individual participants.)
R45	Highly desirable	Missing outcome data	Explain how missing outcome data were handled.	Describe how assumptions are applied for missing data, e.g. last observation carried forward, or assumptions of particular values such as worst-case or best-case scenarios.
R46	Mandatory	Tools to assess risk of bias in individual studies	State the tool(s) used to assess risk of bias for included studies, how the tool(s) was implemented, and the criteria used to assign studies, for example, to judgements of low risk, high risk and unclear risk of bias.	If the *Handbook* guidance for undertaking risk of bias assessments was followed in its entirety, then a reference to the *Handbook* is sufficient to provide the criteria used to assign judgements (see Sections 8.9 to 8.15*). Justify any deviations from the tool. *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 Cochrane Handbook (version 5 or later).) *MECIR conduct standards 53 – 61*. [PRISMA item12]
R47	Mandatory	Effect measures	State the effect measures used by the review authors to describe effect sizes (e.g. risk ratio, mean difference) in any included studies and/or meta-analyses.	
R48	Mandatory	Quantitative synthesis	Describe any methods for combining results across studies (e.g. meta-analysis, subgroup analysis, meta-regression, sensitivity analysis), including methods for assessing heterogeneity (e.g. I^2, tau-squared, statistical test). Reference the software and command/macro/program used for analyses performed outside of RevMan.	*MECIR conduct standard 63* (Undertake (or display) a meta-analysis only if participants, interventions, comparisons and outcomes are judged to be sufficiently similar to ensure an answer that is clinically meaningful.) *MECIR conduct standard 64* (Assess the presence and extent of between-study variation when undertaking a meta-analysis.) [PRISMA items 12, 13, 14 and 16]
R49	Mandatory	Addressing risk of bias	Describe how studies with high or variable risks of bias are addressed in the synthesis.	*MECIR conduct standard* 60 (Address risk of bias in the synthesis (whether qualitative or quantitative). For example, present analyses stratified according to summary risk of bias, or restricted to studies at low risk of bias.)
R50	Mandatory	Non-standard designs	*If designs other than individually randomized, parallel-group randomized trials are included*, describe any methods used to address clustering, matching or other design features of the included studies.	*MECIR conduct standard 71* (Consider the impact on the analysis of clustering, matching or other non-standard design features of the included studies.)

R51	Mandatory	Studies with more than two groups	*If multi-arm studies are included*, explain how they are addressed and incorporated into syntheses.	*MECIR conduct standard 67* (*If multi-arm studies are included*, analyse multiple intervention groups in an appropriate way that avoids arbitrary omission of relevant groups and double-counting of participants.)
R52	Highly desirable	Risk of reporting bias across studies	Describe any methods used for assessing the risk of reporting biases such as publication bias.	[PRISMA item 15]
R53	Mandatory	Subgroup analyses	*If subgroup analysis (or meta-regression) was performed*, state the potential effect modifiers with rationale for each, stating whether each was defined *a priori* or *post hoc*.	*MECIR conduct standard 22* (Pre-define potential effect modifiers (e.g. for subgroup analyses) at the protocol stage; restrict these in number; and provide rationale for each.) [PRISMA item 16]
R54	Highly desirable	Summary of findings	State any methods for summarizing the findings of the review, including the assessment of the quality of the body of evidence for each outcome.	*MECIR conduct standard 75* (Include a 'Summary of Findings' table according to recommendations described in Chapter 10 of the Cochrane Handbook (version 5 or later). Specifically: •include results for one 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) *MECIR conduct standard 76* (Use the five GRADE considerations (study limitations, 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.) [PRISMA item 12]
Results				
Description of studies				
R55	Mandatory	Flow of studies	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 a flow chart. 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.) [PRISMA item 17]
R56	Highly desirable	Lack of included studies	*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.
R57	Mandatory	Excluded studies	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 it is excluded.

				See *Handbook* 7.2.5.
R58	Highly desirable	Studies awaiting classification	List the characteristics of any 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 which are known to the review team but have not yet been incorporated in to the review. 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.
R59	Mandatory	Ongoing studies	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.
R60	Mandatory	Table of 'Characteristics of included studies'	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'.) [PRISMA item 18]
R61	Mandatory	Included studies	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
R62	Mandatory	Table of 'Characteristics of included studies': sample sizes	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.
R63	Mandatory	Table of 'Characteristics of included studies': methods	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* section 13.2). [PRISMA item 18]
R64	Mandatory	Table of 'Characteristics of included studies': participants	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. [PRISMA item 18]
R65	Mandatory	Table of 'Characteristics of included studies': interventions	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.	For example, for drug interventions, consider dose, route, frequency, and duration; or for complex interventions, specify the core components of the intervention. Lengthy explanations of interventions should be avoided. Citations to sources of detailed descriptions can be included. [PRISMA item 18]
R66	Mandatory	Table of 'Characteristics of included 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.

R67	Highly desirable	Table of 'Characteristics of included studies': dates	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"). [PRISMA item 18]
R68	Mandatory	Table of 'Characteristics of included studies': funding source	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.
R69	Mandatory	Table of 'Characteristics of included studies': declarations of interest	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.
R70	Highly desirable	Choice of intervention groups in multi-arm studies.	*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.)
R71	Mandatory	References to included studies	List all reports of each included study under the relevant Study ID.	[PRISMA item 18]
Risk of bias in included studies				
R72	Mandatory	'Risk of bias' table	Present a 'Risk of bias' table for each included study, with judgements about risks of bias, and explicit supports for these judgements.	The 'Risk of bias' table in RevMan should be used, which 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 Cochrane Handbook (version 5 or later).) Also *MECIR conduct standards 54 – 61*. [PRISMA item 19]
R73	Highly desirable	Summary assessments of risk of bias	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 59* (Summarize the risk of bias for each key outcome for each study.) [PRISMA item 22]
R74	Mandatory	Risk of bias in included studies	Provide a brief narrative summary of the risks of bias among the included	It may be helpful to identify any studies considered to be at low risk of bias for particular key outcomes.

			studies.	[PRISMA items 22 and 25]
Effects of interventions				
R75	Mandatory	Use of 'Data and analysis' headings	Ensure appropriate use of the hierarchy of Comparisons / Outcomes / Subgroups / 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'.
R76	Highly desirable	Presenting data	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 of '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. [PRISMA item 20]
R77	Mandatory	Number of studies and participants	State how many studies and how many participants contributed data to results for each outcome, along with the proportion of the included studies and recruited participants potentially available for the relevant comparison.	It is unlikely that the same number of studies will contribute data to every outcome of interest. Specific studies may 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. Failing to disclose this may be misleading. [PRISMA item 9]
R78	Highly desirable	Source of data	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.
R79	Mandatory	Multiple outcome data	Describe any *post hoc* decisions that might give rise to accusations of selective outcome reporting, for example when there are 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. *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.)
R80	Highly desirable	Ordering of results and 'Data and analysis' section	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 selectively reporting 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.
R81	Mandatory	Pre-specified outcomes	Report synthesis results for all pre-specified outcomes, irrespective of the strength or direction of the result. Indicate whether data were not available for outcomes of interest, including whether harms were	To avoid selective outcome reporting (in truth or in perception), the review should address all outcomes specified in the protocol. [PRISMA item 20]

			identified.	
R82	Mandatory	Statistical uncertainty	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. [PRISMA item 20]
R83	Highly desirable	P values	*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 not be used to divide results into 'significant' or 'non-significant'; exact P values portray the strength of evidence against the null hypothesis. See *Handbook* Section 12.4.2..
R84	Mandatory	Tables and Figures	Link to each Table and Figure.	
R85	Highly desirable	Number of Tables and Figures	Restrict the number of Tables and Figures to a small number 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. Further Tables and Figures can be included as supplementary material (e.g. as 'Data and analysis' forest plots or within appendices).
R86	Mandatory	Consistency of results	Ensure that all statistical results presented in the main review text are consistent between the text and the 'Data and analysis' tables.	
R87	Mandatory	Different scales	Explain how studies measuring an outcome of interest using different scales (such as alternative rating scales that measure symptoms or behaviour) were combined, stating whether positive or negative values reflect benefit or harm.	If data from different scales are combined and presented on a standardized scale (such as a standardized mean difference), it is important to clarify that a positive effect size has the same meaning for every study. The direction of benefit or harm must be stated. . *MECIR conduct standard 62* (*If studies are combined with different scales*, ensure that higher scores for continuous outcomes all have the same meaning for any particular outcome; explain the direction of interpretation; and report when directions were reversed.)
R88	Mandatory	Interpretability of results	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, NNTs, group means), and outcomes combined with a standardized scale (e.g. SMD) might be re-expressed in units that are more naturally understood. If clinically important effect sizes are well understood, these should be provided to aid interpretation.	Absolute effects provide a useful illustration of the likely impact of 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 NNTs 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. Clinically important effect sizes should ideally be specified in the protocol.

R89	Mandatory	Studies without usable data	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, introducing 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 contribute 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.
R90	Highly desirable	Missing outcome data	Discuss the implications of missing outcome data from individual participants (due to losses to follow up or exclusions from analysis).	*MECIR conduct standard 65* (Consider the implications of missing outcome data from individual participants (due to losses to follow up or exclusions from analysis).)
R91	Highly desirable	Skewed data	Discuss the possibility and implications of skewed data when analysing continuous outcomes.	*MECIR conduct standard 66* (Consider the possibility and implications of skewed data when analysing continuous outcomes)
R92	Highly desirable	Forest plots	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. [PRISMA item 20]
R93	Highly desirable	Multiple subgroup analyses and sensitivity analyses	*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.	*[PRISMA item 23]*
R94	Mandatory	Labels on plots	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' as 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.
R95	Highly desirable	Risk of bias across studies	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). [PRISMA item 22]
R96	Highly desirable	Reporting biases	Present results of any assessment of the potential impact of reporting biases on the review's findings.	*MECIR conduct standard 74* (Consider the potential impact of reporting biases on the results of the review or the meta-analyses it contains.) [PRISMA item 22]
R97	Highly desirable	'Summary of findings' table	Present a 'Summary of Findings' table according to recommendations described in Chapter 11 of the Cochrane Handbook (version 5 or later). Specifically: include results for one clearly defined population group (with few exceptions);	*MECIR conduct standard 75* (Include a 'Summary of Findings' table according to recommendations described in Chapter 11 of the Cochrane Handbook (version 5 or later). Specifically: •include results for one 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;

			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.	•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.) [PRISMA item 24]
R98	Mandatory	Assessments of the quality of the body of evidence	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 system.	*MECIR conduct standard 76* (Use the five GRADE considerations (study limitations, 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 77* (Justify and document all assessments of the quality of the body of evidence (for example downgrading or upgrading if using the GRADE tool).)
Discussion				
R99	Highly desirable	Discussion headings	Include the standard 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
R100	Mandatory	Limitations	Discuss limitations of the review at study and outcome level (e.g. regarding risk of bias), and at review-level (e.g. incomplete identification of studies, reporting bias).	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 and/or rare adverse events, the review authors must explicitly state this as a limitation. *MECIR conduct standard 74* (Consider the potential impact of reporting biases on the results of the review or the meta-analyses it contains.) [PRISMA item 25]
Authors' conclusions				
R101	Mandatory	Conclusions: implications for practice	Provide a general interpretation of the evidence so that it can inform healthcare or policy decisions. Avoid making recommendations for practice.	*MECIR conduct standard 79* (Avoid providing recommendations for practice.)
R102	Mandatory	Conclusions: implications for research	*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. *MECIR conduct standard 80* (Structure the implications for research to address the nature of evidence required, including population intervention comparison, outcome, and type of study).

Acknowledgements				
R103	Mandatory	Acknowledgements	Acknowledge the contribution of people not listed as authors of the review, including any assistance from the Cochrane eview Group, non-author contributions to searching, data collection, study appraisal or statistical analysis, and the role of any funders.	[PRISMA item 27]
Contributions of authors				
R104	Mandatory	Contributions of authors	Describe the contributions of each author	See *Handbook* 4.2.2
Declarations of interest				
R105	Mandatory	Declarations of interests	Report any present or past 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.	The nature and extent of the affiliation or involvement (whether financial or non-financial) should be described. An additional consideration for authors of systematic reviews is the declaration of involvement in studies that were included in the review. See *Handbook* 2.6
Differences between protocol and review				
R106	Mandatory	Changes from the protocol	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.)
R107	Highly desirable	Methods not implemented	Document aspects of the protocol that were not implemented (e.g. because no studies, or few studies, were found) in the section 'Differences between protocol and review', rather than in the Methods Section.	See *Handbook* 2.1
Sources of support				
R108	Mandatory	Funding	List sources of funding for the review and the role of the funder, if any.	See *Handbook* 4.10. [PRISMA item 28]

*These Handbook section numbers are specific to Version 5.1. All other section numbers apply equally to the 2008 edition (and 2009 reprints) published by Wiley-Blackwell.