

Writing a Cochrane Protocol in RevMan

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[*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). 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.)* 11](#_Toc531341824)

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**Protocol information**

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| **Authors** *R2, Mandatory*  *List names and affiliations of all authors.* *Details: See Handbook 4.2.2.*  [Empty name]1  1[Empty affiliation]  Citation example: [Empty name]. [Intervention] for [health problem] [Protocol]. Cochrane Database of Systematic Reviews [Year], Issue [Issue].  **Contact person**  **Dates**   |  |  | | --- | --- | | **Assessed as Up-to-date:** |  | | **Date of Search:** |  | | **Next Stage Expected:** |  | | **Protocol First Published:** | | **Review First Published:** | | **Last Citation Issue:** |   **What's new**   |  |  |  | | --- | --- | --- | | **Date** | **Event** | **Description** |   Top of Form    Bottom of Form  **History** |

**Background**

***R19, Mandatory***

*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.*

***Details***

*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]*

***Background headings***

***R20, Highly desirable***

*Include the four standard headings when writing the Background.*

***Details***

*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*

***Background references***

***R21, Mandatory***

*Back up all key supporting statements with references.*

***Details***

*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.*

***Background text***

***R22, Mandatory***

*Avoid the use of plagiarized text.*

***Details***

*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.*

**Description of the condition**

**Description of the intervention**

**How the intervention might work**

**Why it is important to do this review**

**Objectives**

### ***Main objective***

***R23, Mandatory***

*State the main objective, where appropriate in a single concise sentence.*

***Details***

*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]*

***Secondary objectives***

***R24, Highly desirable***

*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.*

***Details***

*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.)*

***Economic evidence***

***R25, Mandatory***

*If health economics evidence is being reviewed, state this explicitly in the Objectives (as secondary objectives).*

***Details***

*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.*

***Qualitative research evidence***

***R26, Mandatory***

*If qualitative research evidence is being reviewed, state this explicitly in the Objectives (as secondary objectives).*

***Details***

*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**

**Criteria for considering studies for this review**

**Types of studies**

***Eligibility criteria for types of study: study designs***

***R28, Mandatory***

*State eligible study designs, and provide a justification for the choice.*

***Details***

*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]*

***Eligibility criteria for types of study: study reports***

***R29, Mandatory***

*If studies are excluded on the basis of publication status or language of publication, explain and justify this.*

***Details***

*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]*

**Types of participants**

***Eligibility criteria for types of participants***

***R30, Mandatory***

*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.*

***Details***

*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]*

**Types of interventions**

***Eligibility criteria for types of interventions***

***R31, Mandatory***

*State eligibility criteria for interventions and comparators, including any criteria around delivery, dose, duration, intensity, co-interventions and characteristics of complex interventions.*

***Details***

*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]*

**Types of outcome measures**

***Role of outcomes***

***R32, Mandatory***

*If measurement of particular outcomes is used as an eligibility criterion, state and justify this.*

***Details***

*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]*

***Outcomes of interest***

***R33, Mandatory***

*State primary and secondary outcomes of interest to the review, and define acceptable ways of measuring them.*

***Details***

*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.*

**Primary outcomes**

**Secondary outcomes**

**Search methods for identification of studies**

**Electronic searches**

**Searching other resources**

**Data collection and analysis**

**Selection of studies**

***Inclusion decisions***

***R40, Mandatory***

*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.*

***Details***

*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]*

**Data extraction and management**

***Data collection process***

***R41, Mandatory***

*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.*

***Details***

***Requests for data***

***R42, Highly desirable***

*Describe attempts to obtain or clarify data from individuals or organizations.*

***Details***

*MECIR conduct standard 49 (Seek key unpublished information that is missing from reports of included studies.)  
[PRISMA item 10]*

***Data items***

***R43, Mandatory***

*List the types of information that were sought from reports of included studies.*

***Details***

*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]*

***Transformations of data***

***R44, Mandatory***

*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.*

***Details***

*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.)*

**Assessment of risk of bias in included studies**

***Tools to assess risk of bias in individual studies***

***R46, Mandatory***

*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.*

***Details***

*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]*

**Measures of treatment effect**

***Effect measures***

***R47, Mandatory***

*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.*

**Unit of analysis issues**

### *Dealing with missing data*

### *Missing outcome data*

###### *R45, Highly desirable*

*Explain how missing outcome data were handled.*

#### *Details*

*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.*

**Dealing with missing data**

**Assessment of heterogeneity**

**Assessment of reporting biases**

***Risk of reporting bias across studies***

***R52, Highly desirable***

*Describe any methods used for assessing the risk of reporting biases such as publication bias.*

***Details:*** *[PRISMA item 15]*

**Data synthesis**

***Quantitative synthesis***

***R48, Mandatory***

*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. I2, tau-squared, statistical test). Reference the software and command/macro/program used for analyses performed outside of RevMan.*

***Details***

*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]*

***Addressing risk of bias***

***R49, Mandatory***

*Describe how studies with high or variable risks of bias are addressed in the synthesis.*

***Details***

*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.)*

***Non-standard designs***

***R50, Mandatory***

*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.*

***Details***

*MECIR conduct standard 71 (Consider the impact on the analysis of clustering, matching or other non-standard design features of the included studies.)*

***Studies with more than two groups***

***R51, Mandatory***

*If multi-arm studies are included, explain how they are addressed and incorporated into syntheses.*

***Details***

*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.)*

***Summary of findings***

***R54, Highly desirable***

*State any methods for summarizing the findings of the review, including the assessment of the quality of the body of evidence for each outcome.*

***Details***

*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). 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.)*

**Subgroup analysis and investigation of heterogeneity**

***Subgroup analyses***

***R53, Mandatory***

*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.*

***Details***

*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]*

**Sensitivity analysis**

**Acknowledgements**

***R103, Mandatory***

*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.*

***Details***

*[PRISMA item 27]*

**Contributions of authors**

*R104, Mandatory*

*Describe the contributions of each author*

#### *Details: See Handbook 4.2.2.*

**Declarations of interest**

***R105, Mandatory***

*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.*

***Details***

*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*

**Published notes**

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**Sources of support**

***Funding***

***R108, Mandatory***

*List sources of funding for the review and the role of the funder, if any.*

***Details:*** *See Handbook 4.10. [PRISMA item 28]*

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