

**Criteria for considering studies for this review (PR9-16)** ..... 2

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### Criteria for considering studies for this review

Cochrane Training resource: [defining the review question](#)

Cochrane Interactive Learning: [module 2 - writing the review protocol](#)

	Standard	Rationale and elaboration	Resources
PR9	<i>Eligibility criteria for types of study: study designs</i>	<b>Mandatory</b>	
	State eligible study designs, using key study characteristics, and provide a justification for the choice.	<p>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.</p> <p>Particular care may be needed to explain whether cross-over trials and cluster-randomized trials are to be considered.</p> <p>Study characteristics might include details such as “with blind assessment of outcomes” or “with prospective identification of participants”, rather than ambiguous labels such as “double blind” or “prospective study”.</p> <p>If ‘conditional’ eligibility criteria are used that are based on absence of particular types of evidence (e.g. when no randomized trials are found), this must be stated unambiguously (and detailed methods for addressing all potentially eligible studies will need to be described).</p> <p><a href="#">MECIR conduct standard 9</a>: 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.</p> <p><a href="#">MECIR conduct standard 11</a>: Justify the choice of eligible study designs.</p>	
PR10	<i>Eligibility criteria for types of study: study reports</i>	<b>Mandatory</b>	
	<i>If studies will be excluded on the basis of publication status or language of publication, explain and justify this.</i>	<p>Studies should be included irrespective of their publication status and language of publication, unless exclusion is explicitly justified.</p> <p><a href="#">MECIR conduct standard 12</a>: Include studies irrespective of their publication status, unless exclusion is explicitly justified.</p>	
PR11	<i>Eligibility criteria for types of participants</i>	<b>Mandatory</b>	
	State eligibility criteria for participants, including any criteria around location, setting, diagnoses or definition of condition and demographic factors, and how studies including subsets of relevant participants will be addressed.	<p><a href="#">MECIR conduct standard 5</a>: Define in advance the eligibility criteria for participants in the studies.</p> <p><a href="#">MECIR conduct standard 6</a>: Define in advance how studies that include only a subset of relevant participants will be addressed.</p>	
PR12	<i>Eligibility criteria for types of interventions</i>	<b>Mandatory</b>	
	State eligibility criteria for	Eligible interventions, and particularly the comparators, must address the stated objectives of the review. For example, inclusion of studies with an active comparator intervention is	

	interventions and comparators, including any criteria around delivery, dose, duration, intensity and cointerventions. Criteria for complex interventions should be made explicit, e.g. by stating mandatory components.	not consistent with an objective to look only at whether an experimental intervention is effective compared with an inactive control.  <a href="#">MECIR conduct standard 7</a> : Define in advance the eligible interventions and the interventions against which these can be compared in the included studies.	
PR13	<i>Role of outcomes</i>	<b>Mandatory</b>	
	Be explicit about the role of outcomes in determining eligibility of studies for the review.	For most Cochrane Reviews of randomized trials of the intended effects of interventions, the aim should be to identify and include all relevant participants who have been randomized to the intervention comparisons of interest. The extent to which outcome data are available for these people can be affected by decisions made by the trialists – i.e. there is a risk of selective outcome reporting bias.  An important distinction should be made between whether outcomes were measured, and whether the measured outcome data are available. Studies should not be excluded from a review solely because no outcome data are available. 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. Often it is difficult to know whether unreported outcomes were measured, so it is generally appropriate to include all studies irrespective of whether outcomes are reported.  <a href="#">MECIR conduct standard 8</a> : 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).	
PR14	<i>Outcome domains of interest</i>	<b>Mandatory</b>	
	State which outcomes are primary outcomes and which are secondary outcomes.	Up to seven outcomes should be prespecified for inclusion in a 'Summary of findings' table (see PR40); it may be convenient to highlight them here.  <a href="#">MECIR conduct standard 14</a> : Define in advance which outcomes are primary outcomes and which are secondary outcomes.  Also <a href="#">MECIR conduct standards 15–18</a>	<a href="#">Planning GRADE and Summary of Findings tables</a>
PR15	<i>Outcome measures of interest</i>	<b>Mandatory</b>	
	Define relevant outcome measures and time points for measurement, and any hierarchy for choosing among them.	Explain how multiple variants of outcome measures (e.g. definitions, assessors, scales, time points) will be addressed.	
PR16	<i>Minimally important difference</i>	<b>Highly desirable</b>	
	Define minimally important differences for key outcome measures.	To facilitate interpretation of the size of effect of an intervention, it is important to understand the size of difference that is important to review users.	Cochrane Training resource: <a href="#">analysing continuous outcomes</a>  CIL: <a href="#">module 6 - analysing the data</a>

