Setting eligibility criteria for including studies in the review (C5-13)

Setting the eligibility criteria for including studies in the review

Cochrane Training resource: defining the review question

Cochrane Interactive Learning (CIL): module 2 - writing the review protocol

	Standard	Rationale and elaboration	Resources
C5	*Predefining unambiguous criteria for participants*	***Mandatory***	
	Define in advance the eligibility criteria for participants in the studies.	Predefined, unambiguous eligibility criteria are a fundamental prerequisite for a systematic review. The criteria for considering types of people included in studies in a review should be sufficiently broad to encompass the likely diversity of studies, but sufficiently narrow to ensure that a meaningful answer can be obtained when studies are considered in aggregate. Considerations when specifying participants include setting, diagnosis or definition of condition and demographic factors. Any restrictions to study populations must be based on a sound rationale, since it is important that Cochrane Reviews are widely relevant.	See *Handbook* 5.2
C6	*Predefining a strategy for studies with a subset of eligible participants*	***Highly desirable***	
	Define in advance how studies that include only a subset of relevant participants will be addressed.	Sometimes a study includes some 'eligible' participants and some 'ineligible' participants, for example when an age cut-off is used in the review's eligibility criteria. If data from the eligible participants cannot be retrieved, a mechanism for dealing with this situation should be prespecified.	See *Handbook* 5.2
C7	*Predefining unambiguous criteria for interventions and comparators*	***Mandatory***	
	Define in advance the eligible interventions and the interventions against which these can be compared in the included studies.	Predefined, unambiguous eligibility criteria are a fundamental prerequisite for a systematic review. Specification of comparator interventions requires particular clarity: are the experimental interventions to be compared with an inactive control intervention (e.g. placebo, no treatment, standard care, or a waiting list control), or with an active control intervention (e.g. a different variant of the same intervention, a different drug, a different kind of therapy)? Any restrictions on interventions and comparators, for example, regarding delivery, dose, duration, intensity, cointerventions and features of complex interventions should also be predefined and explained.	See *Handbook* 5.3
C8	*Clarifying role of outcomes*	***Mandatory***	
	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).	Outcome measures should not always form part of the criteria for including studies in a review. However, some reviews do legitimately restrict eligibility to specific outcomes. For example, the same intervention may be studied in the same population for different purposes (e.g. hormone replacement therapy, or aspirin); or a review may address specifically the adverse effects of an intervention used for several conditions. If authors do exclude studies on the basis of outcomes, care should be taken to ascertain that relevant outcomes are not available because they have not been measured rather than simply not reported.	See *Handbook* 5.1.2
C9	*Predefining study designs*	***Mandatory***	
	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	Predefined, unambiguous eligibility criteria are a fundamental prerequisite for a systematic review. This is particularly important when non-randomized studies are considered. Some labels commonly used to define study designs can be ambiguous. For example a 'double blind' study may not make it	See *Handbook* 5.5, 13.2.2

	than design labels.	clear who was blinded; a ‘case control’ study may be nested within a cohort, or be undertaken in a cross-sectional manner; or a ‘prospective’ study may have only some features defined or undertaken prospectively.	
C10	*Including randomized trials*	***Mandatory***	
	Include randomized trials as eligible for inclusion in the review, *if it is feasible to conduct them to evaluate interventions and outcomes of interest.*	Randomized trials are the best study design for evaluating the efficacy of interventions. If it is feasible to conduct them to evaluate questions that are being addressed by the review, they must be considered eligible for the review. However, appropriate exclusion criteria may be put in place, for example regarding length of follow-up.	See *Handbook* 5.5, 13.1.3
C11	*Justifying choice of study designs*	***Mandatory***	
	Justify the choice of eligible study designs.	It might be difficult to address some interventions or some outcomes in randomized trials. Authors should be able to justify why they have chosen either to restrict the review to randomized trials or to include non-randomized studies. The particular study designs included should be justified with regard to appropriateness to the review question and with regard to potential for bias.	See *Handbook* 13.1.2, 13.2.1.3
C12	*Excluding studies based on publication status*	***Mandatory***	
	Include studies irrespective of their publication status, unless exclusion is explicitly justified.	Obtaining and including data from unpublished studies (including grey literature) can reduce the effects of publication bias. However, the unpublished studies that can be located may be an unrepresentative sample of all unpublished studies.	See *Handbook* 10.3.2
C13	*Changing eligibility criteria*	***Mandatory***	
	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.	Following prespecified eligibility criteria is a fundamental attribute of a systematic review. However unanticipated issues may arise. Review authors should make sensible post hoc decisions about exclusion of studies, and these should be documented in the review, possibly accompanied by sensitivity analyses. Changes to the protocol must not be made on the basis of the findings of the studies or the synthesis, as this can introduce bias.	See *Handbook* 5.2, 5.7