

**COCHRANE CONSUMERS AND COMMUNICATION REVIEW GROUP**

**Standard Protocol Text and Additional Guidance for Review Authors**

Last updated: 1st December 2016

**Sections to leave blank at protocol stage:**

* Plain Language Summary
* Abstract (and all subheadings).
* Results (and all subheadings).
* Discussion.
* Authors’ conclusions.
* References to studies (but do complete ‘Additional References’)
* Characteristics of included/excluded/ongoing studies tables.
* Data and Analysis tables.
* Risk of bias and ‘Summary of findings’ tables.

**background**

See the [Cochrane Handbook](http://www.cochrane-handbook.org/) section 4.5

Support all numbers and key supporting statements with references.

**Please refer to the Cochrane Handbook for the content under each of these headings. Below are key points that should be included but these are not necessarily a comprehensive list of everything that needs to be covered under each heading.**

* Description of the condition or health issue:
	+ including how and where it occurs, who is affected, diagnosis, symptoms and consequences.
* Description of the intervention
	+ including for whom it is intended, its context in usual practice, comparison interventions, the treatment regimen or intervention components, and known adverse effects. Describe any likely differences in the use or outcomes of the intervention for specific populations (eg children, disadvantaged groups).
	+ If you are proposing particular subgroups for analysis (under the Methods section), mention these subgroups and provide their rationale here.
* How the intervention might work.
	+ including an overview of the existing studies in the area, and what they show.
	+ Also consider addressing any relevant equity issues here.
* Why it is important to do this review
	+ Cite all relevant Cochrane reviews (and other systematic reviews), addressing areas of overlap.

**Objectives**

Refer to the [Cochrane Handbook](http://www.cochrane-handbook.org/) section 4.5.

Use the format:

‘To assess the effects of [intervention or comparison] for [health problem] for/in [types of people, disease or problem and setting if specified].’

This might be followed by a series of specific objectives relating to different participant groups, different comparisons of interventions or different outcome measures. It is not necessary to state specific hypotheses.

For example:

 “The effects of Intervention A compared with intervention B or usual care, for health condition in population, on outcomes X and Y...”

Some examples from CC&CRG reviews:

‘To compare the effects of personalised and general risk communication in deciding whether to participate in health screening, on people's cognitive, affective and behavioural outcomes. These include their knowledge, risk perception, satisfaction with decision-making and decisional conflict, emotional wellbeing and behaviour (ie taking screening tests).’ (Edwards 2006)

‘To assess the effects of 'extended discussion' compared with conventional methods of informed consent for participation in clinical trials for understanding, willingness to participate and anxiety.’ (Hon 2012)

 ‘To assess the effects of mobile phone messaging for communicating results of medical investigations on people's healthcare-seeking behaviour and health outcomes. Secondary objectives include assessment of participants' evaluation of the intervention, direct and indirect healthcare costs and possible risks and harms associated with the intervention.’ (Gurol-Urganci et al 2012)

If you are including economic evidence or qualitative research evidence, state this explicitly in the secondary objectives.

**Methods**

See the [Cochrane Handbook](http://www.cochrane-handbook.org/) chapter 4.5.

*Use the future tense and active voice (eg ‘We will search…’ rather than ‘Searches will be conducted…’).*

**Criteria for considering studies for this review**

See the [Cochrane Handbook](http://www.cochrane-handbook.org/) chapter 4.5 and chapter 5.

Even if your review does not focus specifically on health equity, there may be issues that you should consider in relation to equity. Refer to the CCRG Quick Guide ‘Equity’ (available at <http://cccrg.cochrane.org/author-resources>)and consider items on the Cochrane Equity Checklist in relation to the selection criteria (<http://equity.cochrane.org/our-publications>).

***Types of studies***

See the [Cochrane Handbook](http://www.cochrane-handbook.org/) chapter 4.5 and chapter 5 and the Review Group’s *Study Design Guide* (available at <http://cccrg.cochrane.org/author-resources>). Please note: if you don’t know very much about different study designs and those that may be included in Cochrane reviews, we strongly recommend that you refer to the Group’s Study Design Guide.

Define the eligibility criteria for study designs clearly and unambiguously. Eg.

‘We will include randomised controlled trials (RCTs).’

Note: if you are only including RCTs, then you should state that you will exclude all studies rated at a ‘high risk of bias’ for the random sequence generation item of the risk of bias tool. This is because these studies are quasi-RCTs; refer to the Study Design Guide. If you do not intend to do so, then you must plan and state here how you will manage the situation where ‘true’ RCTs and those at unclear or high risk of bias for sequence generation (some of which may not be RCTs but instead be quasi-RCTs) are included. This might include specifying either of the following options here (and also in Methods sections):

* Restricting meta-analysis to those trials with a ‘low risk of bias’ rating on sequence generation.
* Including in meta-analysis all randomised trials irrespective of their rating for sequence generation, but conducting sensitivity analyses, excluding those at unclear or high risk of bias, to examine the robustness of the meta-analysis results to methodological limitations of the included studies.

For some interventions it may be impractical or impossible to use RCTs to evaluate effectiveness (eg policy or mass media interventions). However, if it is practical to use an RCT then it is difficult to justify the inclusion of other study designs, as they are at a higher risk of bias. If including studies other than randomised controlled trials (RCTs), justify this here with regard to appropriateness of the study design to the review question, and the potential for bias.

If you plan to include quasi-RCTs, define them eg.

‘We will include randomised controlled trials (RCTs) and quasi-RCTs (a trial in which randomisation is attempted but subject to potential manipulation, such as allocating participants by day of the week, date or birth, or sequence of entry into trial) as we anticipate that few, if any, properly RCTs will have been conducted in the [topic area].’

If you intend to include controlled before and after studies (CBAs) and interrupted time series (ITS), provide a strong rationale for their inclusion (with empirical justification if possible).

**If appropriate, use the following wording:**

‘We will include Controlled Before and After (CBA) studies which meet the following criteria:

* There are at least two intervention sites and two control sites
* The timing of the periods for study for the control and intervention groups is comparable (that is, the pre- and post- intervention periods of measurement for the control and intervention groups should be the same); and
* The intervention and control groups are comparable on key characteristics.

We will include Interrupted Time Series (ITS) which meet the following criteria:

* The intervention occurred at a clearly defined point in time, and this was specified by the researchers.
* There were at least three data points before and three data points after the intervention was introduced.’

***Types of participants***

See chapter 4.5 and chapter 5 of the [Cochrane Handbook](http://www.cochrane-handbook.org/).

Define clearly the eligibility criteria for participants. Consider whether (and how) to specify participants in terms of: age, setting, diagnosis or definition of condition, and demographic factors. Provide a sound rationale for any restrictions to study populations. For example:

‘We will include adults (aged 18+) considering consenting to participate in a clinical trial.’

‘We will include children (aged 0 to 12 years) receiving hospital care, but excluding premature neonates because their care needs are substantively different to those of other children.’ (Shields 2012)

Define in advance how studies that include only a subset of relevant participants will be handled. For example:

‘Children: infants (less than 1 year) or preschool-aged children (1 to 5 or 6 years). RCTs including school-aged children will only be included if the main focus of the intervention is those vaccines whose primary series begins in infancy or for preschool-aged children.’ (Kaufman 2012)

‘Children and/or adolescents with a parent, a sibling or a grandparent diagnosed with cancer. The definition of childhood and adolescence can vary. We were as inclusive as possible and defined it as up to and including 18 years of age. Studies were eligible for inclusion if the majority of participants fell into this age group.’ (Scott 2003)

***Types of interventions***

See chapter 4.5 and chapter 5 of the [Cochrane Handbook](http://www.cochrane-handbook.org/).

Define the interventions clearly. Specify and justify any restrictions on interventions, such as delivery, dose duration, intensity, co-interventions and features of complex interventions. For example:

‘We will include face to face interventions conducted in cluster RCTs in the context of a mass vaccination campaign if it is possible to isolate and report the effects of the face to face communication interventions delivered to parents for the vaccination of young children or infants from the larger campaign. Similarly, we will include multi-component interventions with a face to face element if the outcomes of the face to face intervention alone can be determined from the reported data.’ (Kaufman 2012)

‘Interventions in which face-to-face communication with a healthcare practitioner was manipulated. We will include simulation studies in which videos of patient-provider communication are shown to patients, or where healthy subjects were used instead of patients.’ (Verheul 2010)

Specify the comparisons to be made in the review. Ensure these are consistent with and address the review objectives directly. For example:

We will include studies which compare audiovisual information provision with standard forms of information provision.

We will compare the text messaging reminder to a posted reminder letter.

Reviews may assess several comparisons, for example:

We will include the following comparisons:

* Interventions to support people versus no intervention.
* Interventions to support people versus standard or usual care.
* One form of intervention to support people versus another - including simple versus complex interventions.

If appropriate, specify how you plan to disentangle complex or multifaceted interventions and what the appropriate comparison(s) might be. For example, if the review will assess an educational intervention, but education is often delivered together with other intervention components or co-interventions, state which comparisons you will include. So: *Education delivered as part of a complex intervention package (support, reminders and counselling) versus complex package alone* – would enable the effects of education alone to be isolated from the rest of the complex intervention. However the following would not enable the effects of the education intervention alone to be determined:

* *Education as part of a complex package versus control*
* *Education as part of a complex package versus education alone.*

State clearly what you will include and what you will exclude.

For more information on comparisons in reviews of complex interventions, please refer to the CCCG guide on ‘Identifying comparisons in CCCG reviews’, available at <http://cccrg.cochrane.org/author-resources>

***Types of outcome measures***

See chapter 4.5, chapter 5 and chapter 7 of the [Cochrane Handbook](http://www.cochrane-handbook.org/).

1. *Identifying outcomes*

Identifying outcomes for reviews of interventions covered by the Consumers and Communication Group’s scope can be a challenging step. Our guidance below aims to help you plan as much as possible for what you will do in your review but taking into account that you may find a more complex set of data once you identify the trials.

List the outcomes that you will look for in each study. This should include the most important outcomes that need to be considered to make decisions about the effects of the intervention.

Primary outcomes should be kept to a minimum, and should reflect at least one potential benefit and at least one potential harm (or adverse effect). Conventionally, there are up to six primary or main outcomes, including harms or adverse events, and up to a similar number of secondary outcomes. When choosing the primary outcomes you should bear in mind that the review should be able to synthesise these outcomes if eligible studies are identified with combinable data. The conclusions that the review makes will also be based heavily on the effects of the interventions on the primary outcomes. The review’s Summary of Findings tables and conclusions will be based largely on the effects of the interventions on these outcomes, principally the primary outcomes.

At protocol stage the outcomes (up to a total of seven) that will be used as the basis for assessing the quality of evidence (with GRADE) and presented in the Summary of findings table need to be clearly identified.

While complex reviews may justify the inclusion of a greater number of outcomes than simpler reviews, authors should keep the total number of outcomes as small as possible, avoiding trivial outcomes and process outcomes. Numerous outcomes, while sometimes necessary, can lead to a review that lacks focus, is unmanageable for the user, and may be more prone to selective outcome reporting bias.

Draw upon relevant literature in your topic area as well as the Consumers and Communication Review Group’s outcomes taxonomy (http://cccrg.cochrane.org/author-resources) to identify important outcomes. Try to bear in mind that those outcomes that are likely to be most important to decision makers (to support clinical decisions and policy decisions), as well as health care consumers, should be evaluated by the review. This can include patient-reported outcomes, as well as process or intermediate outcomes.

When thinking about the outcomes that are relevant, particularly for complex interventions, it may be helpful to consider the aims of the interventions your review will examine. Sometimes the aims can be simple, for instance, an informational pamphlet aiming to improve knowledge or understanding about a particular health condition or its treatment. Often the aims of a complex intervention might be multiple: pharmacist-delivered medicines review might, for example, aim to improve consumers’ knowledge of their medicines but also to improve people’s skills to administer their medicine, adherence and clinical outcomes. All of these aims could be reflected in the outcomes measured by the trial, and may or may not all be relevant for a review that includes this trial – depending on the review’s question.

At protocol stage, you should state whether the listed outcomes will be used as criteria for including studies. Although this is not recommended, if you plan to exclude studies on the basis of the outcomes reported, then state this and you will have to provide a rationale. Sometimes, however, the measurement of particular outcomes is to be used as an eligibility criterion and this should be stated and defined at protocol stage. For example, a review of educational interventions to promote healthy lifestyle choices, focussing on a reduction in smoking prevalence, might exclude studies that do not measure smoking status.

1. *Outcomes and outcome categories*

This is another challenging issue in our reviews and these are some of the issues you will need to consider.

The first major issue is whether your selected outcomes are actually outcome categories. This is commonly the case in complex reviews. For example, behaviour change and adherence are both outcome categories. The latter may be a sub-set of the former, but not necessarily. These outcomes could have been measured legitimately in different ways in the same trial or across different trials.

Continuing the example, in a trial of multi-faceted self-management, the *outcome category* of behaviour change could have been measured by the *outcomes* of:

* Walking rate
* Adherence to self-management plans
* Adherence to medicines.

You may wish to collect and report all these outcomes in the review, as this can be meaningful for understanding the effects of complex interventions.

Additionally, in another trial of self-management, the three outcomes (walking rate, adherence to self-management plans and adherence to medicine) might be reported. However, in this trial, one of the outcomes - adherence to medicines - could have been *measured* in different ways: by pill count, self-report, and physiological drug levels. You may wish to collect all this data, but at the review Results stage, if one trial has collected adherence to medicines with three separate measures, and you report all these data, then you are at risk of over-representing the impact on this outcome. Equally, there is also the unintended risk that you might decide to report only the measurement with a positive effect and ignore the lack of effect in the other measures.

A number of approaches are available to help you plan how to select outcomes where more than one outcome measure is available in one trial for the same outcome. One approach is to:

* Select the primary outcome which has been identified by the publication authors.
* Where no primary outcome has been identified, select the one specified in the sample size calculation.
* If there are no sample size calculations, rank the effect estimates (ie list them in order from largest to smallest) and select the median effect estimate. Where there is an even number of outcomes the outcome whose effect estimate is ranked n/2, where n is the number of outcomes, can be selected (Brennan 2009).

However, selecting the primary outcome of each included study and combining these (statistically or narratively) may not be appropriate for complex interventions. As stated above, with complex interventions there are often many outcomes, measured in many different ways, and lumping them together may make them less meaningful than considering them individually or in groups of outcomes that have a theoretical basis or clear logic.

Another approach may be to list the outcomes for each trial (without considering either the size of the effect or its statistical significance) and a decision then made about which is most ‘clinically’ important. In such a case this process should be described clearly, and details such as whether two review authors will independently make these decisions before discussions and consensus decisions.

Another possible way to approach this – focused more at the level of the outcome measures (rather than outcome categories) - is to state that objective outcome measures (eg pharmacy records, blood medication levels) will be selected for analysis in preference to subjective measures (eg self-reported medicine taking) wherever possible. Again a process for identifying these outcomes, ideally involving two authors independently making the decisions, should be described if this approach is to be used.

Please bear in mind that although the protocol should describe the processes for objectively deciding which outcomes are to be selected and reported in the review, a highly selective approach is not always appropriate where complex interventions are being evaluated. Sometimes reporting data for several outcomes that reflect different aspects of an outcome category is necessary and meaningful (see the example in section 2). Care needs to be taken however not to over-report several different *measures* of the same outcome – whether or not there is one or more than one outcome in a given category.

So in thinking about the types of outcomes for your review, there are several steps that should be described at protocol stage:

1. Identifying which outcomes are most important – see section 1 above.
2. Categorising outcomes (together with examples of likely outcomes within each category): at review stage, two authors should independently assign the outcomes reported in each included study to the review’s outcome categories and resolve any differences in categorization by the involvement of a third author. This may mean that more than one outcome is assigned to each outcome category at review stage. See section 2 above.
3. Selecting *outcomes* on which to report data:
	1. In the Results and
	2. In the Summary of Findings tables.

Note that these may be similar (for example, if only one outcome is reported for a given category (eg vaccination uptake as a measure of behavior change); or may differ if several outcomes are reported for that category e.g. medicines adherence, exercise adherence, self-management plan adherence for the category of behavior change). The Results of the review should report data on all key outcomes you have listed at protocol stage (where reported by included studies), whereas the Summary of Findings table selects from the outcomes to report those most important for decision makers.

1. Selecting *outcome measures* with which to report data in both the Results and Summary of Findings tables. If the outcome of interest is reported in only one way (eg adherence by pill counts) by each of the included trials then no selection is needed. However, if an outcome (e.g. adherence) is measured in multiple different ways (eg pill count, prescription refill, blood levels, self-report) within a trial you will need to have a method for selecting one measure so as not to over-represent this data – see section 2 above.
2. It is also possible that you may identify some outcomes that you did not anticipate at the protocol stage but which you feel should be included in the review because they are important to someone making a decision. It is possible to do this but justification will be required and the difference reported in the ‘Differences between protocol and review’ section at review stage.

Further information and examples:

* Grimshaw J et al. Systematic reviews of the effectiveness of quality improvement strategies and programmes. Quality and Safety in Health Care 2003;12(4):298-303.
* Brennan et al. Continuous quality improvement: effects on professional practice and healthcare outcomes (Protocol).Cochrane Database of Systematic Reviews 2009, Issue 4.
* Horvat L, et al. Cultural competence education for health professionals (Protocol). Cochrane Database of Systematic Reviews 2011, Issue 10.
* Atherton H, et al. Email for the coordination of healthcare appointments and attendance reminders. *Cochrane Database of Systematic Reviews* 2012, Issue 8.
* Tables from the Cochrane EPOC review on “Audit and feedback: effects of professional practice and health care outcomes” may be useful for providing guidance on how to potentially present the results. (see http://www.epoc.cochrane.org/en/newPage2.html).
* Hrobjartsson A, et al ‘Placebo interventions for all clinical conditions’ Cochrane Database of Systematic Reviews 2010, Issue 1.

*Timing of outcome assessment*

 It may be appropriate to define, in advance, the timing of outcome assessment. For example, some reviews may include all time points, while others might be more specific; but the decision about what is to be included should be guided by what is important for decision making. One strategy can be to group timepoints into short-, medium- and long-term time points and to select no more than one time interval for each outcome from each study. Define in advance the timing of outcome measurement that will be included in the review.

*Main outcomes for the ‘Summary of findings’ table.*

See the [Cochrane Handbook](http://www.cochrane-handbook.org), Sections 11.5.6.2 and 11.5.2.

Pre-specify the review’s ‘main’ outcomes, which are intended for inclusion in the ‘Summary of findings’ table.

* Maximum of seven outcomes per table per comparison.
* Choose outcomes important to stakeholders and their decision making, not based on any expected magnitude of effect;
* Choose primary outcomes as well as harms (and which relate to the rationale presented in the Background);
* At review stage, report findings for all of your selected outcomes, i.e., report data or report no data (if none found)

**Search methods for identification of studies**

See the [Cochrane Handbook](http://www.cochrane-handbook.org/) chapter 4.5 and chapter 6.

Note: Our Information Specialist, John Kis-Rigo, will prepare the OvidSP MEDLINE strategy based on the selection criteria outlined in your draft protocol. This will be appended to the published protocol.

You should receive an email outlining the processes around the development of search strategies shortly after the registration of your title. If you have not, or if you have any questions about searching, please contact the Managing Editor, who will coordinate with John.

***Electronic searches***

**Tailor this text to your protocol:**

‘We will search the following electronic databases:

* The Cochrane Central Register of Controlled Trials (CENTRAL, *The Cochrane Library,* *latest issue*);
* MEDLINE (OvidSP) (*date* to present);
* EMBASE (OvidSP) (*date* to present);
* PsycINFO (OvidSP) (*date* to present); and
* *[List other databases].*

We present the strategy for MEDLINE (*specify platform, e.g. OvidSP*)) in Appendix *X*.

We will tailor strategies to other databases and report them in the review.

There will be no language nor date restrictions *[or specify any restrictions, giving reasons].’*

***Searching other resources***

**Tailor this text to your protocol:**

‘We will search *[list grey literature sources, such as reports and conference proceedings].*

 We will handsearch the following journals: Title (dates), Title (dates), etc.

We will contact experts in the field and authors of included studies for advice as to other relevant studies. We will also search reference lists of relevant studies and *(add other sources, eg personal collections of articles).*

We will also search online trial registers *(list them)* for ongoing and recently completed studies.’

Specify any other search activities.

**Data collection and analysis**

See the [Cochrane Handbook](http://www.cochrane-handbook.org/) section 4.5.

These methods should spell out, in advance, how decisions will be made and by whom. The methods should be detailed enough so that anyone else could read and follow the protocol and come to similar decisions/ conduct the review.

***Selection of studies***

See the [Cochrane Handbook](http://www.cochrane-handbook.org/) section 7.2

* Two people working independently should undertake the initial screening of titles and abstracts against the inclusion criteria.
* The selection of studies based on full text must be done by two people independently.
* Define in advance the process for resolving disagreements.
* Document the selection process in sufficient detail to complete a PRISMA flow chart and a table of ‘Characteristics of excluded studies’.
* Collate multiple reports of the same study ie, identify and report duplicate publications appropriately.

**Use this text (tailored as necessary):**

***‘***Two authors will independently screen all titles and abstracts identified from searches to determine which meet the inclusion criteria. We will retrieve in full text any papers identified as potentially relevant by at least one author. Two review authors will independently screen full text articles for inclusion or exclusion, with discrepancies resolved by discussion and by consulting a third author if necessary to reach consensus. All potentially-relevant papers excluded from the review at this stage will be listed as excluded studies, with reasons provided in the ‘Characteristics of excluded studies’ table. We will also provide citation details and any available information about ongoing studies, and collate and report details of duplicate publications, so that each study (rather than each report) is the unit of interest in the review. We will report the screening and selection process in an adapted PRISMA flow chart (Liberati 2009)\*.’

\*The full citation for this paper should be included in the ‘Other references – Additional references’ list:

Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gotzsche PC, Ioannidis JP, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration. PLoS Medicine 2009; 6: e1000100

***Data extraction and management***

See the [Cochrane Handbook](http://www.cochrane-handbook.org/) chapter 7. See also the Review Group’s *Study Quality Guide* and the *Data Extraction Template,* available at <http://cccrg.cochrane.org/author-resources>

* You must pilot and use a data collection form, and collect characteristics of the included studies in sufficient detail to populate a table of ‘Characteristics of Included Studies’. This should be based on the Review Group’s Data Extraction Template, but please note that this template is more comprehensive and detailed than required for most reviews and so it must be tailored before use. It is essential that the data collection form is piloted and its usability assessed as part of the planning to extract data from included studies.
* As part of data extraction, consider the quality of the intervention in individual trials – see Herbert and Bø, Analysis of quality of interventions in systematic reviews, BMJ 2005; 331; 507-9.
* At least two people working independently should extract study characteristics from reports of each study. Define in advance the process for resolving disagreements.
* It is mandatory that outcome data be extracted independently by at least two people.

**Use this text (tailored as necessary):**

‘Two review authors will extract data independently from included studies. Any discrepancies will be resolved by discussion until consensus is reached, or through consultation with a third author where necessary. We will develop and pilot a data extraction form using the Cochrane Consumers and Communication Review Group Data Extraction Template (available at:  [http://cccrg.cochrane.org/author-resources)](http://www.latrobe.edu.au/cochrane/resource.html%29). Data to be extracted will include the following items: Details of the study (aim of intervention, study design, description of comparison group**…[*please add to this list as appropriate*]).\*\*** All extracted data will be entered into RevMan (RevMan 2012) by one review author, and will be checked for accuracy against the data extraction sheets by a second review author working independently.’

**\*\***An outline or brief description of the data to be extracted from included studies should be given: add to this list and ensure it outlines the information to be extracted that is sufficient to populate a ‘Characteristics of included studies’ table. This information can either be provided in an Additional table, or listed here in the text, and should be based on consideration of the data extraction template. Please also state that outcome data and results of studies will be extracted from included studies during this process.

\* Note that as part of the data extraction process you must collect and report details of the funding source for each included study and the declaration of interests for the primary investigators.

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

Refer to the [Cochrane Handbook](http://www.cochrane-handbook.org/) chapter 8 and to the CC&CRG *Study Quality Guide,* available at <http://cccrg.cochrane.org/author-resources>

* Use the standardised text given below, adapted as needed. In particular:
	+ If you are including quasi-RCTs, cluster RCTs, CBA and/or ITS studies, add the additional standardised text outlining how these different designs will be assessed.
	+ If studies are to be assigned an overall rating as being of ‘higher’ or ‘lower’ risk of bias (for example, as a basis for sensitivity analyses) then you need to describe here the way that these will be defined. See the Cochrane Handbook section 8.8.3.1 for possible options – such as studies meeting particular criteria, or defining a particular threshold point at which studies are considered at lower risk of bias. Note that this point is also relevant to the ‘Sensitivity analysis’ section below.
	+ It is mandatory that at least two people working independently assess the risk of bias of included studies.

**Use this text (tailored as necessary):**

‘We will assess and report on the methodological risk of bias of included studies in accordance with the Cochrane Handbook (Higgins 2011) and the guidelines of the Cochrane Consumers and Communication Review Group (Ryan 2013), which recommends the explicit reporting of the following individual elements for RCTs: random sequence generation; allocation sequence concealment; blinding (participants, personnel); blinding (outcome assessment); completeness of outcome data, selective outcome reporting; and other sources of bias [please specify]. We will consider blinding separately for different outcomes where appropriate (for example, blinding may have the potential to differently affect subjective versus objective outcome measures). We will judge each item as being at high, low or unclear risk of bias as set out in the criteria provided by Higgins 2011, and provide a quote from the study report and a justification for our judgement for each item in the risk of bias table.

Studies will be deemed to be at the highest risk of bias if they are scored as at high or unclear risk of bias for either the sequence generation or allocation concealment domains [*or other domains of the tool; please adapt]*, based on growing empirical evidence that these factors are particularly important potential sources of bias (Higgins 2011).\*

In all cases, two authors will independently assess the risk of bias of included studies, with any disagreements resolved by discussion to reach consensus. We will contact study authors for additional information about the included studies, or for clarification of the study methods as required. We will incorporate the results of the risk of bias assessment into the review through standard tables, and systematic narrative description and commentary about each of the elements, leading to an overall assessment the risk of bias of included studies and a judgment about the internal validity of the review’s results.’

*\*If including quasi-RCTs add:*

‘We will assess and report quasi-RCTs as being at a high risk of bias on the random sequence generation item of the risk of bias tool.

*\*If including cluster RCTs add:*

‘For cluster-RCTs we will also assess and report the risk of bias associated with an additional domain: selective recruitment of cluster participants.’

*\*If including controlled before and after studies add:*

‘We will assess CBA studies against the same criteria as RCTs but report them as being at high risk of bias on both the random sequence generation and allocation sequence concealment items. We will exclude CBA studies that are not reasonably comparable at baseline.’

*\*If including interrupted times series add:*

‘We will assess and report on the following items for ITS studies: intervention independence of other changes; pre-specification of the shape of the intervention effect; likelihood of intervention affecting data collection; blinding (participants, personnel); blinding (outcome assessment); completeness of outcome data, selective outcome reporting; and other sources of bias [please add].’

If you are planning to assess specific items under ‘other’ sources of bias domain this should also be described. Note that assessing other sources of bias is not essential but should be guided by the specific study designs that you plan to include in the review. This might include design-specific issues (such as assessing selective recruitment of cluster participants for cluster-RCTs), baseline imbalances between groups or the likelihood of contamination.

Please refer to the Cochrane Handbook, section 8.15.2 for more information on study-specific issues that may need to be incorporated into the risk of bias assessment under the ‘other’ risk of bias domain.

Do not assess in this domain aspects of conduct of the study, such as those associated with the ‘quality’ of a study. This might include ethical criteria (eg whether the study explicitly sought informed consent or obtained ethics approval), criteria related to precision of the study (eg use of a power calculation), reporting standards or whether the validity and/or reliability of outcome measures was addressed. These aspects of the study can be collected and reported in the ‘Characteristics of included studies’ table.

Note that if the review is to include only RCTs, then all studies rated at a ‘high risk of bias’ for random sequence generation on the risk of bias tool should be excluded from the review. Only reviews that expressly set out to include RCTs plus additional study designs should include any studies at high risk of bias related to random sequence generation.

If you do not intend to specifically exclude studies at high risk of bias on sequence generation in these cases then the protocol should also state how these studies will be dealt with at review stage: ie, either restricting meta-analyses to those studies with a low rating on this item; or conducting sensitivity analyses (excluding studies at unclear or high risk) to investigate the effects of this decision on effect estimates.

***Measures of treatment effect***

See the [Cochrane Handbook](http://www.cochrane-handbook.org) section 9.2.

* For RCTs, quasi-RCTs, cluster RCTs and cross over trials: describe clearly which effect measures you will use to summarise and present the data from included studies, at the study level, for each type of outcome (eg continuous outcomes (SMD, mean difference), dichotomous outcomes (OR, RR, RD) or other outcomes (ordinal, time-to-event)).
* Describe the effect measures that you will use for each different type of included study design (ie RCTs and non-RCTs).
* Provide a measure of variance for each effect measure; usually this is the 95% confidence interval (95% CI).

For cross-over studies other decisions will also be needed, such as what data to include in the review (eg pre-crossover data, post-crossover data). See the Cochrane Handbook section 16.4.

Please note: if you do not understand what is required in this section of the protocol and review, you need to: add someone to your team to assist with this element of the review, and/or to undertake Cochrane training.

Some examples of wording:

* For dichotomous outcomes, we will analyse data based on the number of events and the number of people assessed in the intervention and comparison groups. We will use these to calculate the risk ratio (RR) and 95% confidence interval (CI). For continuous measures, we will analyse data based on the mean, standard deviation (SD) and number of people assessed for both the intervention and comparison groups to calculate mean difference (MD) and 95% CI. If the MD is reported without individual group data, we will use this to report the study results. If more than one study measures the same outcome using different tools, we will calculate the standardised mean difference (SMD) and 95% CI using the inverse variance method in Review Manager 5.

For non-RCTs (CBAs and ITS): clearly describe effect measures for each type of outcome

* For CBAs there are appropriate effect measures for dichotomous outcomes (RR, adjusted RR) and for continuous outcomes (relative % change post intervention, SMD).
* For ITS, effect measures typically include i) change in level of the outcome at the first point after the introduction of the intervention, and ii) the post-intervention slope minus the pre-intervention slope. These estimates are calculated from regression models adjusting for autocorrelation. It is not appropriate to present means and SDs of pre-intervention versus post-intervention time points.

For further information see:

* Brennan S, et al, Continuous quality improvement: effects on professional practice and healthcare outcomes (Protocol). Cochrane Database of Systematic Reviews 2009, Issue 4) – an example of how to structure a section on ITS data analysis.
* Ramsay CR, et al. Interrupted time series designs in health technology assessment: lessons from two systematic reviews of behavior change strategies. International Journal of Technology Assessment in Health Care 2003;19(4):613-23
* Austvoll-Dahlgren A, et al. Pharmaceutical policies: effects of cap and co-payment on rational drug use. Cochrane Database of Systematic Reviews 2008, Issue 1 – for an example of reanalysing data using a regression method.

***Unit of analysis issues***

See the [Cochrane Handbook](http://www.cochrane-handbook.org/) section 9.3 and 16.3.4.

Describe how you will approach analysis if the review is likely to include study designs, such as cluster RCTs and crossover trials, where the unit of analysis must take into the account the unit of randomisation. Describe here how analysis will be conducted to avoid unit-of-analysis errors.

**If appropriate, use this text (tailored as necessary):**

‘If cluster-RCTs are included we will check for unit-of-analysis errors. If errors are found, and sufficient information is available, we will re-analyse the data using the appropriate unit of analysis, by taking account of the intracluster correlation (ICC). We will obtain estimates of the ICC by contacting authors of included studies, or impute them using estimates from external sources. If it not possible to obtain sufficient information to reanalyse the data we will report effect estimates and annotate ‘unit-of-analysis error.’

***Dealing with missing data***

See the [Cochrane Handbook](http://www.cochrane-handbook.org/) section 16.1, 16.2.

Missing outcome data may be imputed using different methods but these need to be specified (and for different study types). For dichotomous outcomes, imputation methods for missing outcome data in meta-analysis have been developed; these do not extend to continuous data. (See Higgins JP, et al. Imputation methods for missing outcome data in meta-analysis of clinical trials. Clinical Trials 2008;5(3):225-39).

**Use this text (tailored as necessary):**

‘We will attempt to contact study authors to obtain missing data (participant, outcome, or summary data). For participant data, we will, where possible, conduct analysis on an intention-to-treat basis; otherwise data will be analysed as reported. We will report on the levels of loss to follow-up and assess this as a source of potential bias.

For missing outcome or summary data we will impute missing data where possible and report any assumptions in the review. We will investigate, through sensitivity analyses, the effects of any imputed data on pooled effect estimates.’

***Assessment of heterogeneity***

Refer to the [Cochrane Handbook](http://www.cochrane-handbook.org/) section 9.5, and the CCRG Quick Guide ‘Heterogeneity & Subgroup Analysis’ available at <http://cccrg.cochrane.org/author-resources>

Describe how you will assess the presence of heterogeneity (variation across studies). This means considering how consistent the effects of an intervention on a particular outcome are across the included studies, which can be assessed formally in Cochrane reviews where meta-analysis has been conducted.

Please note that at review stage you will be expected to report why you decided to pool data using meta-analysis, or not, and exactly what these decisions were based on. This means that you will need to consider and report exactly why studies were too variable to pool (if this is the decision made), or how the studies were similar enough to meta-analyse, so that these important decisions underpinning analyses in the review are transparent to readers.

**Use the following text (tailored as necessary):**

‘Where studies are considered similar enough (based on consideration of [populations, interventions, or other factors; please adapt] to allow pooling of data using meta-analysis, we will assess the degree of heterogeneity by visual inspection of forest plots and by examining the Chi2 test for heterogeneity. We will report our reasons for deciding that studies were similar enough to pool statistically. Heterogeneity will be quantified using the I2 statistic. An I2 value of 50% or more will be considered to represent substantial levels of heterogeneity, but this value will be interpreted in light of the size and direction of effects and the strength of the evidence for heterogeneity, based on the P value from the Chi2 test (Higgins 2011). Where heterogeneity is present in pooled effect estimates we will explore possible reasons for variability by conducting subgroup analysis\*.

Where we detect substantial clinical, methodological or statistical heterogeneity across included studies we will not report pooled results from meta-analysis but will instead use a narrative approach to data synthesis. In this event we will clearly report our reasons for deciding that studies were too dissimilar to meta-analyse. We will also attempt to explore possible clinical or methodological reasons for this variation by grouping studies that are similar in terms of [*populations, intervention features, methodological features, or other factors; please specify and adapt*] to explore differences in intervention effects.’

Note that when few trials are included in a meta-analysis, the Chi2 test has little power to detect heterogeneity. Therefore a non-significant result should not necessarily be interpreted as evidence of no heterogeneity and should be instead interpreted with care.

\* Note that if no subgroup analyses are planned at review stage this sentence should be amended.

***Assessment of reporting biases***

See the [Cochrane Handbook](http://www.cochrane-handbook.org/) section 10.4.3.1. and Sterne JA, et al. Recommendations for examining and interpreting funnel plot asymmetry in meta-analyses of randomised controlled trials. BMJ 2011;343:d4002.

Describe how the review will assess whether reporting biases are likely to have influenced the results. Reporting biases occur when the findings and type of results of a study influence the dissemination of the research (eg statistically significant, positive results are more likely to be published than non-significant results). In systematic reviews we wish to identify and evaluate the entire body of evidence on the effects of a particular intervention (ie those with both statistically non-significant and statistically results), yet reporting biases may make the identification of all available research, and so the assessment of the evidence available, more difficult.

**Use the following text (tailored as necessary):**

‘We will assess reporting bias qualitatively based on the characteristics of the included studies (eg if only small studies that indicate positive findings are identified for inclusion), and if information that we obtain from contacting experts and authors or studies suggests that there are relevant unpublished studies.

If we identify sufficient studies (at least 10) for inclusion in the review we will construct a funnel plot to investigate small study effects, which may indicate the presence of publication bias. We will formally test for funnel plot asymmetry, with the choice of test made based on advice in Higgins 2011, and bearing in mind that there may be several reasons for funnel plot asymmetry when interpreting the results.’

***Data synthesis***

See the [Cochrane Handbook](http://www.cochrane-handbook.org) chapter 9.

Describe how the included studies’ data will be analysed. Specific decisions about how the analysis will proceed are made at the review stage (depending on what is actually included); however the planned analysis should be outlined here. Consider the types of data likely to appear in the review, based on the criteria for inclusion, and how these might be most appropriately synthesised and analysed.

*If meta-analysis is planned and possible*

* The decision whether to meta-analyse data will be based on an assessment of whether participants [settings], intervention, comparison and outcomes are sufficiently similar to ensure a clinically meaningful result. It should not be based on an I2 or Chi2 value.
* If a meta-analysis is performed, decide in advance whether to use a fixed-effect or random-effects model. This choice is not based on the I2 statistic or a statistical test of heterogeneity. For complex reviews (as CC&CRG reviews frequently are), it is reasonable to state that random effects meta-analysis will be used.

**Use this text (tailored as necessary):**

‘We will decide whether to meta-analyse data based on whether the interventions in the included trials are similar enough in terms of participants, settings, intervention, comparison and outcome measures to ensure meaningful conclusions from a statistically pooled result. Due to the anticipated variability in the [populations and interventions; [please adapt] of included studies, we will use a random-effects model for meta-analysis.’

*Further key points for authors if meta-analysis is planned:*

* Please also note (as stated earlier) if the review is restricted to RCTs only then authors should either plan to exclude all studies rated at a high risk of bias on sequence generation; or must plan how the possibility of studies with different ratings on this item will be dealt with in analyses ie, restricting meta-analysis to studies with a low risk of bias only; or conducting sensitivity analysis to investigate the effects of this decision (excluding studies with a high and unclear risk of bias on this item). If relevant, add a statement to the above standard text to cover this point.
* Including study designs other than RCTs adds to the review’s complexity. If you plan to include and meta-analyse results from these studies, describe clearly how this meta-analysis will be done.
* One approach is that you could plan to include only RCTs, quasi-RCTs and cluster RCTs in any meta-analysis, and to provide descriptive statistics for CBA and ITS studies. Descriptive statistics could include median effect sizes, inter-quartile ranges or other measures, and this information could be presented graphically using bar charts or other approaches. Again, including non-RCTs in the review, then add a statement explaining how the analysis will be performed to the above standard text.

*If meta-analysis is not planned and/or likely to be possible*

* In practice it may only be possible to statistically pool some data included in a review; or the data may be unsuitable for pooling statistically. This cannot always be predicted at protocol stage. It is therefore necessary to describe here how data that cannot be meta-analysed will be dealt with.
* You may wish to present such data in graphs, tables, box plots or via a narrative summary and synthesis.
* Where a narrative summary is to be used, it is not sufficient to simply state ‘data will be summarised narratively’. Instead, explain what you mean by a narrative summary, and how it will be structured and presented.
* See the CCRG resources ‘Describing results’ and ‘Narrative data synthesis and analysis’ available at <http://cccrg.cochrane.org/author-resources>

Some examples of how this might be described in the protocol:

‘If we are unable to pool the data statistically using meta-analysis we will provide clear reasons for this decision, and will conduct a narrative synthesis of results. We will present the major outcomes and results, organised by intervention categories according to the major types and/or aims of the identified interventions. Depending on the assembled research, we may also explore the possibility of organising the data by population. Within the data categories we will explore the main comparisons of the review:

* Intervention versus no intervention.
* Intervention versus usual care.
* One form of intervention versus another.

Where studies compare more than one intervention, we will compare each separately to no intervention/ control; and with one another.’

‘If we are unable to pool the data statistically using meta-analysis, we will provide clear reasons for this decision, and will group the data based on the category that best explores the heterogeneity of studies and makes most sense to the reader (ie by interventions, populations or outcomes). Within each category we will present the data in tables and narratively summarise the results.’

***Subgroup analysis and investigation of heterogeneity***

See the [Cochrane Handbook](http://www.cochrane-handbook.org) section 9.5 and 9.6, and the CCRG Quick Guide ‘Heterogeneity & Subgroup Analysis’ available at <http://cccrg.cochrane.org/author-resources>

The intervention’s effects might be expected to vary with different populations or different characteristics of the intervention itself (eg different durations or intensities of delivery). These effect modifiers can be investigated in subgroup analyses (or using meta-regression) in the review. Subgroup analyses split the data from all participants in order to make comparisons between subgroups in the data. These subgroups can be based on factors like participant features (eg low versus high educational levels; younger versus older people) or subsets of studies (eg geographic location).

In the protocol, specify the potential effect modifiers that will be investigated and provide a strong rationale, preferably empirical, for each (See also Background section). For example, why might the effect of the intervention be expected to be different in those with low education levels, older people, or those with more than one concurrent health problem?

The chance of observing spurious results increases as more subgroup analyses are undertaken. Therefore, limit the number of subgroup analyses to those which are most important (meaningful and/or clinically relevant).

Also describe how you will categorise subgroups. For example, how will ‘high’ and ‘low’ education levels be decided or defined?

If enough studies contribute to meta-analysis to justify performing subgroup analysis, you must use a formal statistical test to compare the subgroups.

Since in CC&CRG reviews it may not be possible to pool data statistically, or there may be too few included studies to warrant statistical subgroup analyses, you should plan (at protocol stage) how you will narratively explore relationships in the data ie presenting a narrative form of subgroup analyses where it is not possible to do so statistically.

***Sensitivity analysis***

See the [Cochrane Handbook](http://www.cochrane-handbook.org/) section 9.7.

Sensitivity analysis can be used to assess the robustness of results. This can include exploring the impact of assumptions, imputed data, borderline decisions, choice of meta-analysis method, and inclusion of studies at high risk of bias. Sensitivity analyses repeat the primary analyses of the review, but with different assumptions or decisions, for example, changing the analysis method. The aim is to determine how robust the results of the review are to the decisions that were made in conducting the review.

Describe planned sensitivity analyses in as much detail as possible here.

If sensitivity analysis is planned based on the risk of bias assessment, you must have specified at the ‘Assessment of risk of bias’ section how you will determine whether a study (as opposed to an individual domain) is of high or low risk of bias. See also Section 8.8.3. of the Cochrane Handbook.

* Possible approaches include:
	+ Comparing the results of studies at higher and lower risk of bias (remove lower quality studies from the analysis and see how robust the results are when based only on higher quality studies) – but higher and lower risk of bias need to be defined, see above and also Section 8.7 of the Cochrane Handbook.
	+ Compare results when different analysis methods are used – eg comparing the results from fixed-effects versus random-effects meta-analysis; or comparing results when different effect measures are used – eg comparing RR and OR.
	+ Compare results based on imputed data - eg when ICC values have been taken from external sources (for cluster-RCTs).
	+ For reviews of RCTs only - investigating the effects of excluding high and unclear rated studies on the sequence generation item of the tool.

The effects of interventions according to risk of bias assessments can be compared formally using meta-regression; see sections 8.8.2.3, 9.6.4 and 9.6.5.1 of the Cochrane Handbook. Note, however, that a minimum of 10 studies is recommended for meta-regression for each variable that is included in the model.

Outline as many details of the sensitivity analyses that may happen at review stage in the protocol, but also note that not all decisions will be possible before the review is conducted; some decisions will need to be made based on the assembled data and included studies.

***‘Summary of findings’ table***

See the [Cochrane Handbook](http://www.cochrane-handbook.org/) chapters 11 and 12, particularly section 11.5.

See also Guyatt et al 2012 GRADE guidelines 12. Preparing Summary of Findings tables – binary outcomes. Journal of Clinical Epidemiology ([http://www.gradeworkinggroup.org/index.htm](https://owa.latrobe.edu.au/owa/redir.aspx?C=pzDd_yMVVUa4jY618iafqkEFqLnJn88IBZBaDUiDI_N1NezJW92TGbpU6Tgkw0JKf8mzgSd843g.&URL=http%3a%2f%2fwww.gradeworkinggroup.org%2findex.htm))

See the ‘Summary of Findings’ Guide available at <http://cccrg.cochrane.org/author-resources>

‘Summary of findings’ tables present the review’s main findings in a table format. The methods for summarising and presenting the results in this format, and for assessing the quality of the evidence using GRADE as part of this process, must be described clearly at protocol stage.

Include information about:

* which populations (including the specification of low, medium or high risk populations), interventions and comparisons are being addressed, and why;
* the source of any external information used in the ‘Assumed risk’ column (ie the source of this information and a rationale for each assumed risk to be presented – for each outcome), see Sections 11.5.6.3 and 11.5.6.4 for more information;
* a brief comment that you will use the GRADE approach to assessing the quality of the body of evidence; and
* any departures from the standard methods described in Chapters [11](http://www.mrc-bsu.cam.ac.uk/cochrane/handbook/chapter_11/11_presenting_results_and_summary_of_findings_tables.htm) and [12](http://www.mrc-bsu.cam.ac.uk/cochrane/handbook/chapter_12/12_interpreting_results_and_drawing_conclusions.htm) of the Cochrane Handbook, along with a justification.

List the review’s main outcomes, ie those intended for inclusion in the ‘Summary of findings’ table, at the section ‘Types of outcome measures’. The selection of outcomes to present in the Summary of findings table(s) should be made based on your identification of those outcomes that are most likely to be important to decision makers, including consumers. Outcomes should not be selected based on the assumption that you are likely to see changes, or changes in a certain direction or of a certain size, in these outcomes as a result of the intervention.

**Use this text (tailored as necessary):**

‘We will prepare a 'Summary of findings' table to present the results of meta-analysis and/or narrative synthesis for the major comparisons of the review, for each of the key outcomes, including potential harms, outlined in the ‘Types of outcome measures’ section. We will provide a source and rationale for each assumed risk cited in the table(s), and will use the GRADE criteria to rank the quality of the evidence based on the methods described in chapter 11 of the Cochrane Handbook for Systematic Reviews of Interventions, using the GRADEprofiler (GRADEpro) software (Schünemann 2011). If meta-analysis is not possible, we will present results in a narrative ‘Summary of findings’ table format.’

***Assessing the quality of the evidence (alternative heading to ‘Summary of findings’ table)***

See the ‘How to GRADE’ Guide available at <http://cccrg.cochrane.org/author-resources>

If a formal ‘Summary of findings’ table is not planned, you must still outline methods for assessing the quality of the body of evidence at review stage. Add a subheading (‘Assessing the quality of the evidence’) here instead.

Using the GRADE criteria to assess and summarise the quality of the evidence for each outcome is now compulsory in Cochrane reviews. There are five criteria: risk of bias, inconsistency, imprecision, indirectness and publication bias; these allow conclusions about the quality of the evidence to be drawn consistently across the different outcomes in a review. The GRADE tool should be used as implemented and described in the GRADEprofiler software; and two authors working independently should assess the quality of the evidence by considering each of the five GRADE criteria.

**Use this text (tailored as necessary):**

‘We will assess and report the quality of the evidence, using the GRADE criteria to assess the quality of the evidence for each outcome on each of the following domains: risk of bias, inconsistency, imprecision, indirectness and publication bias. Two authors will independently assess the quality of the evidence as implemented and described in the GRADEprofiler (GRADEpro) software (Schünemann 2011).’

***Ensuring relevance to decisions in health care***

This is the section of the protocol that highlights the vision for Cochrane reviews to inform real world decisions and the principle of assessing healthcare interventions using outcomes that matter to people making choices in health care. When practitioners are authors they bring an awareness of many pertinent issues. This awareness can be broadened by listening to health service users too. For reviews of interventions that require the authority, skills and resources of more than individual practitioners, policy makers and managers can also offer useful insights.

Outline your plans for considering the views of people who make policy or practice decisions, implement decisions or experience the consequences of decisions related to the focus of your review, with the suggested subheading ‘Ensuring relevance to decisions in health care’.

The CC&CRG includes, as part of its editorial processes, input into protocols and reviews from people working in health services and people using health services. We also encourage authors to consider improving the quality of the review, in terms of its relevance to issues and outcomes for these people, in different ways. Listening to other people may help authors become more sensitive to important issues, choose how to frame the review when detailing the populations, interventions, comparators, outcomes and contexts to consider, choose appropriate subgroup analyses, or consider the implications of the findings. This does not have to be onerous but might include undertaking one or more of the following:

* Reading relevant reports and literature produced by organisations on issues for their members.
* Inviting members of relevant organisations or with personal experience to discuss issues pertinent to the review by telephone, email or round a table.
* Inviting members of organisations, including consumer organisations, to be part of the review team and to contribute as authors to drafting of the protocol and/or review.
* Forming an advisory group or panel to provide advice on the review and input to drafts.

None of these options are pieces of research. They broaden the ideas that authors bring to a review so any such input would be acknowledged appropriately in the protocol and/or review.

Another approach is to draw on existing research about people’s views. This may be considered in the background to justify the importance of the review, or in the discussion to draw out the implications of the findings. There are increasing numbers of qualitative syntheses of people’s views that are particularly appropriate to inform an effectiveness review. If so little research exists that there is not a good understanding of the issues authors may choose to undertake additional research, using focus groups, interviews or questionnaires to support the analysis performed in the review. This could lead to important guidance for designing new randomised controlled trials.

Please include a section on ensuring relevance to healthcare decisions at the end of the methods section of your protocol, including (and expanding upon) the following text:

‘The protocol and review will receive feedback from at least one consumer referee in addition to a health professional as part of the Cochrane Consumers and Communication Review Group’s standard editorial process.’

***Acknowledgements***

See the [Cochrane Handbook](http://www.cochrane-handbook.org/) chapter 4.5.

Acknowledge here any people or organisations that you wish. Acknowledge any previous authors of the Cochrane protocol or review or previous sources of support to the review. Obtain permission from persons acknowledged. Please acknowledge the contribution of the Cochrane Consumers and Communication Review Group editors and staff:

‘We thank the editors and staff of the Cochrane Consumers and Communication Review Group, particularly our contact editor [Name] for their input to this protocol. We thank XXXX…’

***Contribution of authors***

See the [Cochrane Handbook](http://www.cochrane-handbook.org/) chapter 4.5.

Describe the author contributions here. Identify which author is the review’s guarantor. All authors should discuss and agree on their respective descriptions of contribution.

Also outline what each review author will do for the full review and who will be responsible for conducting the review update.

***Declarations of interest***

See the [Cochrane Handbook](http://www.cochrane-handbook.org/) chapter 2 and chapter 4.5.

If there are no conflicts of interest, state ‘None known’.

Report any present or past affiliations or other involvement in any organization or entity with an interest in the review that might lead to a real or perceived conflict of interest. Situations that might be perceived by others as being capable of influencing a review author’s judgements include personal, political, academic and other possible conflicts, as well as financial conflicts. You must state if you have been involved in a study which might be included in the review, and how this will be managed (eg the author in question will not be involved in assessing the study for inclusion, or extracting or analysing data from that study).

***Published Notes***

This protocol is based on standard text and guidance provided by the Cochrane Consumers and Communication Review Group (CCCRG 2016).

***Sources of Support***

Complete this section (See the [Cochrane Handbook](http://www.cochrane-handbook.org) section 4.10).

***Appendix 1: MEDLINE search strategy***

How to cite this document in RevMan:

Reference ID: CCCRG 2016

Reference Type: Other

Authors Cochrane Consumers and Communication Review Group

English Title: Standard Protocol Text and Additional Guidance for Review Authors.

Journal/Book/Source: http://cccrg.cochrane.org

Date of Publication: 2016

How to cite the *Cochrane Handbook* in RevMan:

Reference ID: Higgins 2011

Reference Type: Other

Authors: Higgins JPT, Green S (editors)

English Title: Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011

Journal/Book/Source: Available from [www.cochrane-handbook.org](http://www.cochrane-handbook.org)

How to cite the RevMan software in RevMan:

Reference type: Computer program

English title: Review Manager (RevMan)

Date of publication: 2012

Edition: 5.2

Publisher name: The Nordic Cochrane Centre, The Cochrane Collaboration

City of publication: Copenhagen

### How to cite Schünemann 2011 in RevMan:

### Reference ID: Schünemann 2011

### Reference Type: Other

Authors: Schünemann HJ, Oxman AD, Higgins JPT, Vist GE, Glasziou P, Guyatt GH

English Title: Chapter 11: Presenting results and ‘Summary of findings' tables. In: Higgins JPT, Green S (editors), Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011

Journal/Book/Source: Available from www.cochrane-handbook.org.

***We thank Dr Rebecca Ryan, Dr Dell Horey, Prof. Sandy Oliver, Dr. Joanne McKenzie, Dr Megan Prictor, Ms Nancy Santesso and Ms Anneliese Synnot, for developing and refining this guidance.***