Cochrane Breast Cancer Group

Version and date: V3.2, September 2013

Intervention Cochrane Protocol – checklist for authors

This checklist is designed to help you (the authors) complete your Cochrane Protocol. Please complete each item in the checklist before checking your Cochrane Protocol into Archie, and email the completed checklist to: Melina Willson, Managing Editor, at Melina.Willson@ctc.usyd.edu.au. The editorial team may return your Cochrane Protocol to you if the form is incomplete or not received. There is a 'Notes' section at the end of the form to alert the editorial team to the reason for any incomplete checks.

The checklist should be used in conjunction with The Cochrane Handbook of Systematic Reviews of Interventions (www.handbook.cochrane.org) and the Methodological Expectations of Cochrane Intervention Reviews (MECIR; www.editorial-unit.cochrane.org/mecir). MECIR includes methodological standards for the *conduct* of reviews (items C1-C80) and for the *reporting* of reviews (items R1-R108).

Cochrane Review title:

Contact person:

Date:

1. General

1.1 ☐ All the authors listed on the Cochrane Protocol have seen and approved this version and take full responsibility for the accuracy of the contents.

1.2 ☐ Addressed questions outlined in the protocol template, particularly those related to methodological approaches

1.3 ☐ Activated the relevant headings in RevMan and completed each section.

1.4 ☐ Completed a validation check in RevMan (File menu > Reports > Validation report), and made corrections where possible.

1.5 ☐ Completed a spell check in RevMan (Tools menu > Check spelling).

1.6 ☐ The text is clearly written and all technical and medical terms are explained for non-expert readers.

2. Title and review information

(see Cochrane Handbook Section 4.2)

2.1 ☐ Title is the same as the registered title, unless a change has been agreed with the Breast Cancer Group

2.2 ☐ Authors are listed in the correct order and have agreed to the order in which they are listed.

2.3 ☐ Names and details of all authors and the contact person appear correctly, or the Breast Cancer Group has been notified of any necessary corrections.

2.4 ☐ Completed the 'Date next stage expected' field, estimating when the Cochrane Review will be completed.

3. Background

(see Cochrane Handbook Section 4.5; see MECIR standards C1 to C4, and R19 to R26)

3.1 ☐ Described the condition or health issue to be addressed, including how it occurs, where it occurs, who is affected (including high risk groups), diagnosis, symptoms and consequences.

3.2 ☐ Described 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.

3.3 ☐ Described any likely differences in the use or outcomes of the intervention for specific populations and have defined those populations where necessary.

3.4 ☐ Described how the intervention might work to achieve the desired outcomes.

3.5 ☐ Explained why it is important to do this Cochrane Review in the context of the factors described above.

3.6 ☐ Supported all facts, figures and statements with references and avoided the use of plagiarised text.

3.7 ☐ Referred to other systematic reviews which have been conducted on the topic, and also other Cochrane Reviews relevant to this topic.

4. Objectives

(see Cochrane Handbook Section 4.5; see MECIR standards C1 to C4, R23 to R26)

4.1 ☐ Where possible, phrased as 'To assess the effects of [intervention or comparison] for [health problem] for/in [types of people, disease or problem and setting if specified]'.

If relevant, stated explicitly (as secondary questions) any specific objectives such as those relating to particular participant groups, comparisons or outcomes

4.2 ☐ If cost effectiveness questions are addressed, stated this explicitly in the Objectives (as secondary questions)

4.3 ☐ If qualitative research questions are addressed, stated this explicitly in the Objectives (as secondary questions)

5. Methods

(see Cochrane Handbook Section 4.5)

5.1 Style

5.1.1 ☐ Used the future tense and active voice.

5.2 Criteria for considering studies for this Cochrane Review

Types of studies (see MECIR standards C9, C10, C11, C12)

5.2.1 ☐ Included study designs that are consistent with the objectives of the Cochrane Review, and the Breast Cancer Group has approved these designs. Provided a justification for eligible study designs

Types of participants (see MECIR standards C4, C5)

5.2.2 ☐ Pre-defined eligibility criteria (e.g. disease stage). Considered equity and specific populations.

Types of interventions (see MECIR standard C7)

5.2.3 ☐ Described the intervention and included any criteria around dose, duration, intensity, delivery, co-interventions and features of the intervention

5.2.4 ☐ Listed comparators for the intervention that are consistent with the objectives of the Cochrane Review (e.g. comparison with a placebo addresses a different objective from comparison with an active intervention).

Types of outcome measures (see MECIR standards C8, C14, C15, C16, C17, C18, C75)

5.2.5 ☐ Listed the outcomes you plan to report in the Cochrane Review, and stated whether any of the outcomes listed are required as part of the eligibility criteria for including studies.

5.2.6 ☐ Identified primary and secondary outcomes. The primary outcomes should be as few as possible

5.2.7 ☐ Included adverse effects and toxicities among the outcomes to be reported. Where these are likely to be measured differently, the measurement tools used have been described

5.2.8 ☐ Considered including outcomes relevant to special populations (e.g. subgroup analysis).

5.2.9 ☐ Defined acceptable methods of measuring each outcome (e.g. validated tools, meaningful process measures) and appropriate time points for measurement. Explained how multiple variants on outcome measures (e.g. definitions, assessors, scales, time-points) are addressed

5.2.10 ☐ Considered the minimally important difference or threshold for appreciable change for each outcome.

5.2.11 ☐ Selected a maximum of seven important outcomes, including adverse effects, to be included in the Summary of findings table(s) when the Cochrane Review is complete (see Cochrane Handbook Section 11.5.2).

5.3 Search methods for identification of studies

(see MECIR standards C19 to C38)

5.3.1 ☐ Consulted Fergus Tai, Trials Search Co-ordinator, at Fergus.Tai@ctc.usyd.edu.au regarding the development of the search strategies.

5.3.2 ☐ Search strategy is consistent with the inclusion criteria for the Cochrane Review, including the types of studies to be included.

5.3.3 ☐ Search incorporates the Cochrane Breast Cancer Group's Specialised Register, MEDLINE, EMBASE, CENTRAL and ongoing trial registries (that is, the WHO ICTRP and ClinicalTrials.gov). Plus any subject-specific databases, contact with experts, references and citations, handsearching

5.3.4 ☐ Mentioned if there are any limits to year of publication, language or publication type. Explained and justified if studies are excluded on the basis of publication status or language of publication

5.4 Data collection and analysis

Selection of studies (see MECIR standards C39, C40, C41)

5.4.1 ☐ Stated that at least two authors will conduct selection of studies for inclusion in the Cochrane Review, and described a strategy for resolving disagreements.

Data extraction and management (see MECIR standards C42, C43, C44, C45, C46, C47, C48, C49, C50, C51, C67)

5.4.2 ☐ Described methods for extracting and managing data (e.g. using a data collection form).

Assessment of risk of bias in included studies (see MECIR standards C52, C53, C54, C55, C56, C57, C58, C59, C61)

5.4.3 ☐ Stated that at least two authors will conduct the assessment of risk of bias, and described a strategy for resolving disagreements.

5.4.4 ☐ Methods are consistent with Chapter 8 of the Cochrane Handbook for randomised controlled trials

5.4.5 ☐ For non-randomised study designs, methods are consistent with the Cochrane Collaboration's risk of bias tool, the EPOC risk of bias criteria (http://epoc.cochrane.org/epoc-resources, under the subheading "Risk of Bias – EPOC specific") and recommendations by Norris et al (see: Norris SL, Moher D, Reeves BC, Shea B, Loke Y, Garner S, et al. Issues relating to selective reporting when including non-randomized studies in systematic reviews on the effects of healthcare interventions. *Research Synthesis Methods* 2013; 4 (1): 36-4). The Breast Cancer Group has approved any additional items

5.4.6 ☐ Described a strategy for using the risk of bias assessment in interpreting the results of the Cochrane Review (e.g. narrative description, stratified analysis, exclusion of high risk trials from analysis).

Measures of treatment effect (see MECIR standards C62, C66)

5.4.7 ☐ Described the measures of effect that will be used to measure outcomes (e.g. odds ratio, risk ratio, mean difference).

NB. For outcomes such as overall survival and progression-free survival, it is preferred that these are expressed as **Hazard Ratios**. Described the methods by which Hazard Ratios will be derived

5.4.8 ☐ Explained any possible transformations of data

Unit of analysis issues (see MECIR standard C71)

5.4.8 ☐ If the Cochrane Review is likely to identify study designs such as crossover trials and cluster-randomised trials, analysis of these designs to avoid unit-of-analysis errors has been described. Refer to Chapter 16 of the Cochrane Handbook for Systematic Reviews of Interventions

Dealing with missing data (see MECIR standard C65)

5.4.9 ☐ Described a strategy for dealing with missing data and following intention-to-treat principles, if appropriate.

Assessment of heterogeneity (see MECIR standard C63, C64)

5.4.10 ☐ Clearly differentiated the strategies for assessing clinical and statistical heterogeneity, and determining whether meta-analysis is appropriate.

Assessment of reporting biases (see MECIR standards C74)

5.4.11 ☐ Described a strategy for assessing reporting biases. If funnel plots will be used, it is clear that asymmetric funnel plots are not necessarily caused by publication bias. Refer to Chapter 10 (section 10.4.3.1)

Data synthesis (see MECIR standards C63, C73, C75, C76, C77)

5.4.12 ☐ Described the methods that will be used for meta-analysis, and how results will be synthesised if meta-analysis is not appropriate.

5.4.13 ☐ If the Cochrane Review will include non-randomised studies, the pooling and the analysis of these studies has been described. **Please ensure that this has been checked by a statistician familiar with pooling data from non-randomised studies

5.4.14 ☐ Mentioned that a Summary of Findings Table (SoFs) using GRADE Profiler will be used to summarise the findings of the review

Subgroup analysis and investigation of heterogeneity (see MECIR standards C68, C69, C70)

5.4.15 ☐ Described planned subgroup analyses, including analysis of the effects in different populations where possible.

Sensitivity analysis (see MECIR standards C60, C72)

5.4.16 ☐ Described planned sensitivity analyses to determine whether conclusions are robust to decisions made during the review process (e.g. choice of meta-analysis method, exclusion of studies from analysis).

6. Acknowledgements

(see Cochrane Handbook Section 4.5)

6.1 ☐ Acknowledged those people who contributed to the Cochrane Protocol but are not named as authors, and included the reasons for acknowledging each person.

6.2 ☐ Permission has been granted from all the people named to include them in this section.

6.3 ☐ A comment should be added to Acknowledge who designed each search strategy

7. Contributions of authors

(see Cochrane Handbook Section 4.5)

7.1 ☐ Described each author's contribution to the design and development of the Cochrane Protocol.

8. Declarations of interest

(see Cochrane Handbook Section 4.5)

8.1 ☐ Completed for each author, noting present or past affiliations that that may lead to a real or perceived conflict of interest, including whether authors are investigators on studies likely to be included in the review. If no potential conflicts are identified for a particular author, "None known" has been stated.

9. Tables (Additional tables)

(see Cochrane Handbook Section 4.6.7)

9.1 ☐ Each table has a brief and informative heading.

9.2 ☐ Included links to each table from the appropriate part of the main text.

9.3 ☐ Included explanations of any abbreviations in footnotes.

9.4 ☐ If footnotes are used, these are referenced in the text using superscript letters (e.g. [a]).

9.5 ☐ Where possible, non-essential tables moved to the 'Appendices'.

10. References

All sources of information in the Cochrane Protocol must be appropriately referenced to prevent plagiarism. Reference citation IDs and the reference list must be consistent with the Cochrane Style Guide (http://www.cochrane.org/sites/default/files/uploads/Cochrane-Style-Guide_4-1-edition.pdf). In particular, please check the following items:

10.1 In the text

10.1.1 ☐ Checked that a link has been created wherever a reference citation ID appears in the text of the Cochrane Protocol using the 'Find and Mark Links' tool.

10.1.2 ☐ Grouped reference citation IDs and links in the text in alphabetical or chronological order, surrounded by round brackets and separated by semi-colons.

10.2 In the reference lists

(see Cochrane Handbook Section 4.7)

References to studies subheading

10.2.7 ☐ None included in the Cochrane Protocol.

Additional references subheading

10.2.1 ☐ Reference citation IDs are in the correct format (first author or group abbreviation and year of publication, e.g. Smith 1983 or UKPDS 1990)

10.2.2 ☐ Included each journal title in full, with no abbreviations.

10.2.3 ☐ Checked how each reference is displayed to remove unnecessary punctuation.

10.2.4 ☐ Where applicable, listed the first six authors before using 'et al.'

10.2.5 ☐ Written the page numbers correctly (e.g. 354-7).

10.2.6 ☐ Included the date accessed in any references to web pages.

Other published versions of this review

10.2.8 ☐ Included references to any previous or derivative published versions of this Cochrane Protocol.

11. Figures

(see Cochrane Handbook Section 4.9 and the RevMan User Guide for specifications on size and resolution)

11.1 ☐ Permission received to reproduce any figures included in the Cochrane Protocol.

11.2 ☐ Each figure has a brief caption describing the purpose of the figure, and acknowledging its source.

11.3 ☐ All figures used are scaled so that a reader can see the complete picture within the RevMan window.

11.4 ☐ All figures are of a sufficient resolution and quality for publication.

12. Sources of support

(see Cochrane Handbook Section 4.10)

12.1 ☐ Listed all sources of funding and in-kind support, including internal sources (e.g. the home institution of any author) and external sources (e.g. grant funding).

13. Appendices

(see Cochrane Handbook Section 4.12)

13.1 ☐ The titles of any appendices are clear and informative. These should include the proposed search strategies on each database (excluding the Specialised Register) and ongoing trial registries

14. Style

(see Cochrane Style Guide at http://www.cochrane.org/training/authors-mes/cochrane-style-resource)

14.1 ☐ Proofread the Cochrane Protocol carefully in accordance with the Cochrane Style Guide Basics.

14.2 ☐ If additional subheadings have been added, the appropriate Heading Style has been selected using the drop-down box on the RevMan toolbar.

14.3 ☐ Used either UK or US English consistently throughout the review (e.g. either 'randomised' or 'randomized')

14.4 ☐ Explained all acronyms and abbreviations (e.g. World Health Organization (WHO)).

14.5 ☐ Written numbers up to and including nine as words, and numbers 10 or higher as numerals (excluding those at the start of a sentence and numbers appearing in tables or figures).

14.6 ☐ Included a space before and after each unit of measurement or mathematical symbol (e.g. 5 mL, P = 0.03)

15. Amended Cochrane Protocols

(see Cochrane Handbook Chapter 3)

If you are submitting an amendment to an already published Cochrane Protocol, please address these additional criteria:

15.1 ☐ Added an event in the 'What's New' section to describe all relevant changes since the last published version of the Cochrane Protocol.

15.2 ☐ In the 'What's New' section, selected whether the new version is an Amendment or New Citation Version, and the selection is consistent with Section 3.2 of the Handbook.

15.3 ☐ Updated the methods of the Cochrane Protocol to reflect the latest guidance in the Cochrane Handbook.

15.4 ☐ If you received any feedback on your Cochrane Protocol via *The Cochrane Library*, you have included the comments received and your response in the 'Feedback' section.

16. Queries or notes for the Breast Cancer Group

List here any notes for the editorial team, including difficulties with completing any of the checklist items: