**Put under “risk of bias” section**

**SoF tables in PROTOCOL**

**Overall quality of evidence for main outcomes**

Quality of evidence

We will assess the quality of evidence for the main comparison at the outcome level using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (Guyatt 2011a). This methodological approach considers evidence from randomised controlled trials as high quality that may be downgraded based on consideration of any of five areas: design (risk of bias), consistency across studies, directness of the evidence, precision of estimates and presence of publication bias. (Guyatt 2011a). The GRADE approach results in an assessment of the quality of a body of evidence in one of four grades: 1) High: We are very confident that the true effect lies close to that of the estimate of the effect; 2) Moderate: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different; 3) Low: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect; 4) Very Low: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect (Schünemann 2013).

The review authors will independently assess the quality of the evidence found for outcomes identified as critical or important for clinical decision making. These outcomes include: Author include.

In cases where we consider the risk of bias arising from inadequate concealment of allocation, randomised assignment, complete follow-up or blinded outcome assessment to reduce our confidence in the effect estimates, we will downgrade the quality of evidence accordingly (Guyatt 2011b). Consistency will be evaluated by similarity of point estimates, extent of overlap of confidence intervals and statistical criteria including measurement of heterogeneity (I2). The quality of evidence will be downgraded when large and unexplained inconsistency across studies results is noted (i.e. some studies suggest important benefit and others no effect or harm without a clinical explanation) (Guyatt 2011d). Precision will be assessed based on the width of the 95% confidence interval (CI) and by calculating the optimal information size (OIS). If the total number of patients included in the pooled effect estimation was less than the number of patients generated by a conventional sample size calculation for a single adequately powered trial, we will consider rating down for imprecision (Guyatt 2011c). When trials were conducted in populations other than the target population, we will downgrade the quality of evidence because of indirectness (Guyatt 2011e).

Data (i.e. pooled estimates of the effects and corresponding 95% confidence Interval) and explicit judgments for each of the above aspects assessed will be entered into the Guideline Development Tool, the software used to create ‘Summary of findings’ tables (GRADEpro 2008). All judgements involving the assessment of the study characteristics described above will be explained in footnotes or comments in the ‘Summary of findings’ table.

**For the email:**

It is now a Cochrane methods requirement that all new reviews apply GRADE evaluations to determine the quality of evidence and to report the quality in Summary of Findings (SoF) tables. As such, we are requiring new protocols to include a plan for the use of GRADE and SoF tables. I have pasted the standard language we use to describe this in the Methods section of your protocol under Risk of Bias. You will see that there is a highlighted section. Please fill this in by choosing the clinically relevant outcomes from your primary/secondary outcome list (no more than 6 outcomes) that you will include in the SoF tables.

If you need any guidance regarding SoF tables and/or choosing outcomes, Cochrane has some guidance in the handbook: <http://handbook.cochrane.org/chapter_11/11_5_summary_of_findings_tables.htm>.