Additional File 1: Checklist for transparent reporting of sample size calculation in trials

- Provide clear statements of the (primary) objective(s) or outcome(s) of the study.
- State the criterion for statistical significance (i.e. the desired level of significance) (eg. 0.01, 0.05, 0.10)
- State the desired power. (eg. 80%, 90%, 95%)
- State the type of summary or test statistic that will be used for analysis.
- State clearly whether the test will be one- or two-tailed.
- State the smallest difference and a clear statement of whether it is
  - the minimal clinically important difference (MCID);
  - the difference that investigators think is worth detecting; or
  - the difference that investigators think is likely to be detected.
- Provide clear justification on
  - how the various prior estimates of the variance and the effect used in the calculations were obtained; and
  - their usefulness in the context of the study.
- Provide clear statements regarding the assumptions made about
  - the distribution of the outcomes; and
  - the variability of the outcomes.
- State the method of analysis assumed for the calcualtion
- Provide clear statements about how the sample size calculation was adjusted for
  - Clustering or design effect
  - the expected response rate;
  - loss to follow up;
  - lack of compliance;
  - any other unforeseen reasons for loss of subjects.
  - multiple primary outcomes,
  - planned interim analyses
- State the software, reference or formula used for the sample size calculation.