# CONSORT 2010 checklist of information to include when reporting a randomised trial*

| Section/Topic               | Item | Checklist item                                                                 | Reported on page No                             |
|-----------------------------|------|---------------------------------------------------------------------------------|------------------------------------------------|
| **Title and abstract**      | 1a   | Identification as a randomised trial in the title                               | Title, Pg 1, line 1-2                          |
|                             | 1b   | Structured summary of trial design, methods, results, and conclusions           | Abstracts, Pg 2, Line 26-46                     |
| **Introduction**            | 2a   | Scientific background and explanation of rationale                              | Introduction, Pg 3-4, line 51-96               |
| Background and objectives   | 2b   | Specific objectives or hypotheses                                               | Introduction, Pg 4-5, Line 97 - 105            |
| **Methods**                 | 3a   | Description of trial design (such as parallel, factorial) including allocation ratio | Methods, Pg 6, Line 127                        |
| Trial design                | 3b   | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | Methods, pg 6 line 138 - 149                   |
| Participants                | 4a   | Eligibility criteria for participants                                           | Methods, Pg 6 Line 128 - 137                   |
|                             | 4b   | Settings and locations where the data were collected                           | Methods, Pg 7 Line 150 - 153                   |
| Interventions               | 5    | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | Methods, Pg 7 Line 154-158                     |
| Outcomes                    | 6a   | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | N/A                                           |
|                             | 6b   | Any changes to trial outcomes after the trial commenced, with reasons          | N/A                                           |
| Item | Details |
|------|---------|
| **Sample size** | 7a How sample size was determined |
| | 7b When applicable, explanation of any interim analyses and stopping guidelines |
| **Randomisation:** | 8a Method used to generate the random allocation sequence |
| **Sequence generation** | 8b Type of randomisation; details of any restriction (such as blocking and block size) |
| **Allocation concealment mechanism** | 9 Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned |
| **Implementation** | 10 Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions |
| **Blinding** | 11a If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how |
| | 11b If relevant, description of the similarity of interventions |
| **Statistical methods** | 12a Statistical methods used to compare groups for primary and secondary outcomes |
| | 12b Methods for additional analyses, such as subgroup analyses and adjusted analyses |
| **Results** | 13a For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome |
| | 13b For each group, losses and exclusions after randomisation, together with reasons |

*Methods, Pg 7, line 159 - 168*
*N/A*

*Methods, Pg 6-7, Line 139 - 162*
*N/A*

*Methods, Pg 7-8, Line 169 - 198*

*Methods, Pg 7-8, Line 169 - 184*
*N/A*

*Methods, Pg 9-10, Line 199 - 229*

*Methods, Pg 10, Line 230-236*
*N/A*

*Results, Pg 11, Line 250 - 254*

*Results, Pg 11, Line 250-254*
| Category                  | Subcategory | Description                                                                                                                                                                                                 | Page/Line |
|---------------------------|-------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| Recruitment               | 14a         | Dates defining the periods of recruitment and follow-up                                                                                                                                                        |           |
|                           | 14b         | Why the trial ended or was stopped                                                                                                                                                                            |           |
| Baseline data             | 15          | A table showing baseline demographic and clinical characteristics for each group                                                                                                                                 |           |
| Numbers analysed          | 16          | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups                                                                            |           |
| Outcomes and estimation   | 17a         | For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)                                                            |           |
|                           | 17b         | For binary outcomes, presentation of both absolute and relative effect sizes is recommended                                                                                                                     |           |
| Ancillary analyses        | 18          | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory                                                                           | N/A       |
| Harms                     | 19          | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)                                                                                                | N/A       |
| Discussion                |             |                                                                                                                                                                                                              |           |
| Limitations               | 20          | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses                                                                                              |           |
| Generalisability          | 21          | Generalisability (external validity, applicability) of the trial findings                                                                                                                                     |           |
| Interpretation            | 22          | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence                                                                                               |           |
| Other information         | Registration| Registration number and name of trial registry                                                                                                                                                                | Page 16, Line 389-390 |

**CONSORT 2010 checklist**
| Protocol | 24 | Where the full trial protocol can be accessed, if available |
|----------|----|----------------------------------------------------------|
| Funding  | 25 | Sources of funding and other support (such as supply of drugs), role of funders |

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).