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

| Section/Topic | Item No | Checklist item | Reported on Page Number/Line Number | Reported on Section/Paragraph |
|---|---|---|---|---|
| **Title and abstract** | | | | |
| | 1a | Identification as a randomised trial in the title | Page1/Line 3 | Title/Paragraph1 |
| | 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see Table 2) | Page2/Line34-77 | Abstract /Paragraph1-4 |
| **Introduction** | | | | |
| Background and objectives | 2a | Scientific background and explanation of rationale | Page3/Line 72- Page4/Line 114 | Introduction/ Paragraph1-5 |
| | 2b | Specific objectives or hypotheses | Page4/Line 115-120 | Introduction/ Paragraph1 |
| **Methods** | | | | |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio | Page5/Line160- Page6/Line 177 | Study design and patient selection/ Paragraph1-2 |
| | 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | N/A(No changes to methods after trial commencement) | N/A(No changes to methods after trial commencement) |
| Participants | 4a | Eligibility criteria for participants | Page6/Line187- Page7/Line 209 | Study design and patient selection/ Paragraph4-5 |
| | 4b | Settings and locations where the data were collected | Page5/Line160- Page6/Line 169 | Study design and patient selection/ Paragraph1 |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | Page5/Line164- Page6/Line 169 | Study design and patient selection/ Paragraph1 |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | Page8/Line245- Page9/Line 281 | Clinical assessment/ Paragraph1-5 |
| | 6b | Any changes to trial outcomes after the trial commenced, with reasons | N/A(No changes to trial outcomes) | N/A(No changes to trial outcomes) |
| Sample size | 7a | How sample size was determined | Page4/Line127- Page5/Line 156 | Sample size calculation/1-8 |
| | 7b | When applicable, explanation of any interim analyses and stopping guidelines | N/A(Not applicable) | N/A(Not applicable) |
| Randomisation: | | | | |
| Sequence generation | 8a | Method used to generate the random allocation sequence | Page6/Line170-177 | Study design and patient selection/ Paragraph2 |
| | 8b | Type of randomisation; details of any restriction (such as blocking and block size) | Page6/Line170-177 | Study design and patient selection/ Paragraph2 |
| 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 | Page6/Line170-177 | Study design and patient selection/ Paragraph2 |

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| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | Page6/Line173-177 | Study design and patient selection/ Paragraph2 |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | Page6/Line173-177 | Study design and patient selection/ Paragraph2 |
| | 11b | If relevant, description of the similarity of interventions | N/A(Not relevant) | N/A(Not relevant) |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes | Page9/Line285-Page10/Line 309 | Statistical analysis / Paragraph1-4 |
| | 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | N/A(No Methods for additional analyses) | N/A(No Methods for additional analyses) |
| **Results** | | | | |
| Participant flow (a diagram is strongly recommended) | 13a | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome | Page10/Line 313-322 | Results/ Paragraph1 |
| | 13b | For each group, losses and exclusions after randomisation, together with reasons | Page10/Line 313-322 | Results/ Paragraph1 |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | Page5/Line164-166, Page10/Line 313-322 | Study design and patient selection/ Paragraph2, Results/ Paragraph1 |
| | 14b | Why the trial ended or was stopped | N/A | N/A |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group | Page10/Line 322 | Results/ Paragraph1 |
| Numbers analysed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | Page10/Line 322 | Results/ Paragraph1 |
| 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) | Page11/Line 343 | Results/ Paragraph3 |
| | 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended | N/A(No binary outcomes ) | N/A(No binary outcomes ) |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory | N/A(No results of any other analyses) | N/A(No results of any other analyses) |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | N/A(No important harms or unintended effects) | N/A(No important harms or unintended effects) |
| **Discussion** | | | | |
| Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | Page16/Line 508-510 | Discussion/ Paragraph7 |
| Generalisability | 21 | Generalisability (external validity, applicability) of the trial findings | Page15/Line 495-Page16/Line508 | Discussion/ Paragraph7 |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | Page14/Line458-Page15/Line 494 | Discussion/ Paragraph3-6 |
| **Other information** | | | | |
| Registration | 23 | Registration number and name of trial registry | Page2/Line 62 | Abstract/ Paragraph5 |

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| Protocol | 24 | Where the full trial protocol can be accessed, if available | Page17/Line 536 | Footnote/Paragraph 2 |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders | Page16/Line 521-525 | Acknowledgment/ Paragraph1 |

*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.

## Table 2 Items to include when reporting a randomized trial in a journal or conference abstract

| Item | Description | Reported on Page Number/Line Number | Reported on Section/Paragraph |
|---|---|---|---|
| Title | Identification of the study as randomized | Page1/Line 3 | Title/Paragraph1 |
| Authors * | Contact details for the corresponding author | Page1/Line 26-31 | Title/Paragraph1-6 |
| Trial design | Description of the trial design (e.g. parallel, cluster, non-inferiority) | Page1/Line 1-4 | Title/Paragraph1 |
| **Methods** | | | |
| Participants | Eligibility criteria for participants and the settings where the data were collected | N/A | N/A |
| Interventions | Interventions intended for each group | Page2/Line 41-42 | **Abstract**/paragraph2 |
| Objective | Specific objective or hypothesis | N/A | N/A |
| Outcome | Clearly defined primary outcome for this report | Page2/Line48-57 | **Abstract**/paragraph3 |
| Randomization | How participants were allocated to interventions | N/A | N/A |
| Blinding (masking) | Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment | N/A | N/A |
| **Results** | | | |
| Numbers randomized | Number of participants randomized to each group | N/A | N/A |
| Recruitment | Trial status | N/A | N/A |
| Numbers analysed | Number of participants analysed in each group | N/A | N/A |
| Outcome | For the primary outcome, a result for each group and the estimated effect size and its precision | N/A | N/A |
| Harms | Important adverse events or side effects | N/A | N/A |

| | | | |
|---|---|---|---|
| Conclusions | General interpretation of the results | Page2/Line 58-63 | **Abstract**/paragraph4 |
| Trial registration | Registration number and name of trial register | Page2/Line 62 | Abstract/ Paragraph5 |
| Funding | Source of funding | N/A | N/A |

** this item is specific to conference abstracts*

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*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.