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

Article Information: DOI, to be added by journal’s editor.

| Section/Topic | Item No | Checklist item | Reported on  Page/Section/Paragraph(s) |
| --- | --- | --- | --- |
| Title and abstract | | | |
|  | 1a | Identification as a randomised trial in the title | Click or tap here to enter text. |
| 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) | Click or tap here to enter text. |
| Introduction | | | |
| Background and objectives | 2a | Scientific background and explanation of rationale | Click or tap here to enter text. |
| 2b | Specific objectives or hypotheses | Click or tap here to enter text. |
| Methods | | | |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio | Click or tap here to enter text. |
| 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | Click or tap here to enter text. |
| Participants | 4a | Eligibility criteria for participants | Click or tap here to enter text. |
| 4b | Settings and locations where the data were collected | Click or tap here to enter text. |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | Click or tap here to enter text. |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | Click or tap here to enter text. |
| 6b | Any changes to trial outcomes after the trial commenced, with reasons | Click or tap here to enter text. |
| Sample size | 7a | How sample size was determined | Click or tap here to enter text. |
| 7b | When applicable, explanation of any interim analyses and stopping guidelines | Click or tap here to enter text. |
| Randomisation: |  |  | Click or tap here to enter text. |
| Sequence generation | 8a | Method used to generate the random allocation sequence | Click or tap here to enter text. |
| 8b | Type of randomisation; details of any restriction (such as blocking and block size) | Click or tap here to enter text. |
| 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 | Click or tap here to enter text. |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | Click or tap here to enter text. |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | Click or tap here to enter text. |
| 11b | If relevant, description of the similarity of interventions | Click or tap here to enter text. |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes | Click or tap here to enter text. |
| 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | Click or tap here to enter text. |
| 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 | Click or tap here to enter text. |
| 13b | For each group, losses and exclusions after randomisation, together with reasons | Click or tap here to enter text. |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | Click or tap here to enter text. |
| 14b | Why the trial ended or was stopped | Click or tap here to enter text. |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group | Click or tap here to enter text. |
| Numbers analysed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | Click or tap here to enter text. |
| 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) | Click or tap here to enter text. |
| 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended | Click or tap here to enter text. |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory | Click or tap here to enter text. |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | Click or tap here to enter text. |
| Discussion | | | |
| Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | Click or tap here to enter text. |
| Generalisability | 21 | Generalisability (external validity, applicability) of the trial findings | Click or tap here to enter text. |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | Click or tap here to enter text. |
| Other information | | |  |
| Registration | 23 | Registration number and name of trial registry | Click or tap here to enter text. |
| Protocol | 24 | Where the full trial protocol can be accessed, if available | Click or tap here to enter text. |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders | Click or tap here to enter text. |

\*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).