# 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 | Page 1/ Line 1-3 | Title/P1 |
| | 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see Table 2) | Page 2/ Line 35-62 | Abstract |
| **Introduction** | | | | |
| Background and objectives | 2a | Scientific background and explanation of rationale | Page 3/ Line 71-87 | Introduction/ P 3 |
| | 2b | Specific objectives or hypotheses | Page 3/ Line 83-96 | Introduction/ P 3 |
| **Methods** | | | | |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio | Page 4/ Line 98-142 | Methods/P 1-3 |
| | 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | N/A | N/A |
| Participants | 4a | Eligibility criteria for participants | Page 3-4/ Line 99-120 | Patients/ P 1-2 |
| | 4b | Settings and locations where the data were collected | Page 3/ Line 100-102 | Patients/ P 1 |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | Page 4-5/ Line 122-142 | Study Design/ P1-2 |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | Page 4-5/ Line 133-143 | Study Design/ P1-2 |
| | 6b | Any changes to trial outcomes after the trial commenced, with reasons | N/A | N/A |
| Sample size | 7a | How sample size was determined | N/A | N/A |
| | 7b | When applicable, explanation of any interim analyses and stopping guidelines | N/A | N/A |
| Randomisation: | | | | |
| Sequence generation | 8a | Method used to generate the random allocation sequence | Page 4/ Line 123-128 | Study Design/ P1 |
| | 8b | Type of randomisation; details of any restriction (such as blocking and block size) | Page 4-5/ Line 123-128 | Study Design/ P1 |
| 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 | Page 4/ Line 123-125 | Study Design/ P1 |

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|---|---|---|---|---|
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | Page 4/ Line 123-129 | Study Design/ P1 |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | Page 4/ Line 123-129 | Study Design/ P1 |
| | 11b | If relevant, description of the similarity of interventions | Page 4/ Line 123-131 | Study Design/ P1 |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes | Page 7-8/ Line 236-243 | Statistical analysis/ P1 |
| | 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | N/A | N/A |
| **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 | Page 8/ Line 247-259 | 3.1. Patients status/ P1 |
| | 13b | For each group, losses and exclusions after randomisation, together with reasons | N/A | N/A |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | Page 8/ Line 247-259 | 3.1. Patients status/ P1 |
| | 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 | Page 18/Table 1 | Patients status/P2-3 |
| Numbers analysed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | In the tables. | In the tables. |
| 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) | Page 8-10/ Line 246-308 | Results |
| | 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended | N/A | N/A |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory | N/A | N/A |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | N/A | N/A |
| **Discussion** | | | | |
| Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | Page 13/ Line 413-418 | Discussion/ P4 |
| Generalisability | 21 | Generalisability (external validity, applicability) of the trial findings | Page 13/ Line 421-435 | Conclusion/ P1 |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | Page 10-13/ Line 311-411 | Discussion/ P1-4 |
| **Other information** | | | | |
| Registration | 23 | Registration number and name of trial registry | Page 2/ Line 63-64 | Abstract/Paragraph 5 |

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|---|---|---|---|---|
| Protocol | 24 | Where the full trial protocol can be accessed, if available | Footnote/Paragraph 1 | Footnote/Paragraph 1 |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders | Page 14/ Line 440-441 | Funding |

*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 | Page 1/ Line 1-3 | Title/P1 |
| Authors * | Contact details for the corresponding author | Page 1/ Line 7-18 | Author information |
| Trial design | Description of the trial design (e.g. parallel, cluster, non-inferiority) | Page 2/ Line 38-50 | Abstract /P1 |
| **Methods** | | | |
| Participants | Eligibility criteria for participants and the settings where the data were collected | Page 2/ Line 38-50 | Abstract /P1 |
| Interventions | Interventions intended for each group | Page 2/ Line 38-50 | Abstract /P1 |
| Objective | Specific objective or hypothesis | Page 2/ Line 35-37 | Abstract /P1 |
| Outcome | Clearly defined primary outcome for this report | Page 2/ Line 51-58 | Abstract /P1 |
| Randomization | How participants were allocated to interventions | Page 2/ Line 38-50 | Abstract /P1 |
| Blinding (masking) | Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment | Page 2/ Line 38-50 | Abstract /P1 |
| **Results** | | | |
| Numbers randomized | Number of participants randomized to each group | Page 2/ Line 38-45 | Abstract /P1 |
| Recruitment | Trial status | Finished | Finished |
| Numbers analysed | Number of participants analysed in each group | Page 2/ Line 53-54 | Abstract /P1 |
| Outcome | For the primary outcome, a result for each group and the estimated effect size and its precision | Page 2/ Line 51-58 | Abstract /P1 |
| Harms | Important adverse events or side effects | No | No |

| | | | |
|---|---|---|---|
| Conclusions | General interpretation of the results | Page 2/ Line 59-62 | Abstract /P1 |
| Trial registration | Registration number and name of trial register | Page 2/ Line 63-64 | Abstract /P1 |
| Funding | Source of funding | Page 14/ Line 440-443 | In main text |

** 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.