Table 1. CONSORT 2010 checklist of information to include when reporting a clinical trial (adapted from <http://www.consort-statement.org/>).

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| Section/Topic | Item No | Checklist item | Reported on page No | Comments |
| Title and abstract | Title and abstract should clearly indicate the trial design. Each journal has its own requirements on the structure of the abstract. Some journals also require the online clinical trial registration number included in the abstract. |
|  | 1a | Identification as a randomised trial in the title |  |
| 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) |  |
| Introduction | Most of the times, introduction has three paragraphs. The first is the background, the second is the rationale, and the third is the hypothesis and objective. |
| Background and objectives | 2a | Scientific background and explanation of rationale |  |
| 2b | Specific objectives or hypotheses |  |
| Methods | Study design, research location and duration, ethical approval, online registration should be placed in the first paragraph.Clearly defined inclusion and exclusion criteria of the study participant selection should be provided.Intervention method should be described in detail to allow the replication by other persons not involved in the present study.Every outcome reported as the results of the clinical trial should be explained in the methods section. The definitions and methods to measure these outcomes should be explained. |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio |  |
| 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons |  |
| Participants | 4a | Eligibility criteria for participants |  |
| 4b | Settings and locations where the data were collected |  |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered |  |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed |  |
| 6b | Any changes to trial outcomes after the trial commenced, with reasons |  |
| Sample size | 7a | How sample size was determined |  |
| 7b | When applicable, explanation of any interim analyses and stopping guidelines |  |
| Randomisation: |  |  |  |
|  Sequence generation | 8a | Method used to generate the random allocation sequence |  |
| 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 | CONSORT flow diagram should be placed in the first paragraph.Baseline characteristic comparisons should be the first Table presented.Number of participants finally analyzed should be mentioned together with the outcome presentations.  |
| 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 |  |
| 13b | For each group, losses and exclusions after randomisation, together with reasons |  |
| 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 |  |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) |  |
| Discussion | Limitations of the study should be discussed in the last paragraph, before the paragraph for conclusions.  |
| 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 |  | Some journals not only require an online registration but also ask to register the clinical trial before the patient enrollment (prospective registration).Some journals also require the trial registered in the specified trial registry. |
| Registration | 23 | Registration number and name of trial registry |  |
| 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 |  |