CONSORT for N-of-1 Trials

2015-04-29

# CONSORT for N-of-1 Trials Checklist

Scope: Preferred Reporting Items for N-of-1 trials.

Reference: See source/variants/consort-n-of-1.yml for canonical link and provenance.

## Instructions

* Use the boxes to confirm each reporting item.
* Add reviewer notes under each section as needed.

## Checklist Items

* **Title and abstract**
  + 1a. Identification as an N-of-1 trial in the title
  + 1b. Structured summary of trial design, methods, results, and conclusions
* **Introduction**
  + 2a. Scientific background and explanation of rationale
  + 2b. Specific objectives or hypotheses
* **Methods**
  + 3a. Description of trial design (including allocation ratio, if applicable)
  + 3b. Important changes to methods after trial commencement (such as eligibility criteria), with reasons
  + 4a. Eligibility criteria for participants
  + 4b. Settings and locations where the data were collected
  + 5. The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
  + 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
  + 7a. How sample size was determined
  + 7b. When applicable, explanation of any interim analyses and stopping guidelines
  + 8a. Method used to generate the random allocation sequence
  + 8b. Type of randomisation; details of any restriction (e.g., blocking and block size)
  + 9. Mechanism used to implement the random allocation sequence (e.g., central telephone; web-based), describing any steps taken to conceal the sequence until interventions were assigned
  + 10. Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions
  + 11a. If done, who was blinded after assignment to interventions (e.g., participants, care providers, those assessing outcomes) and how
  + 11b. If relevant, description of the similarity of interventions
  + 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
  + 14a. Dates defining the periods of recruitment and follow-up
  + 14b. Why the trial ended or was stopped
  + 15. A table showing baseline demographic and clinical characteristics for each group
  + 16. For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups
  + 17a. For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (e.g., 95% confidence interval)
  + 17b. For binary outcomes, presentation of both absolute and relative effect sizes is recommended
  + 18. Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory
  + 19. All important harms or unintended effects in each group
* **Discussion**
  + 20. Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
  + 21. Generalisability (external validity, applicability) of the trial findings
  + 22. Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence
* **Other information**
  + 23. Registration number and name of trial registry
  + 24. Where the full trial protocol can be accessed, if available
  + 25. Sources of funding and other support (e.g., supply of drugs), role of funders

### Notes

Reviewer notes