

CONSORT for N-of-1 Trials Checklist

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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