—

2023-10-20

CONSORT for Dose-finding Trials Checklist

Scope: Preferred Reporting Items for early phase dose-finding trials.

Reference: See `source/variants/consort-dose-finding.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 a dose-finding 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