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