CONSORT 2010 Checklist

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Scope: Consolidated Standards of Reporting Trials.

Reference: See `source/archetypes/consort-2010.yml` for canonical link and provenance.

Instructions

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

Title and Abstract

- ☐ **1a. Title:** Identification of the trial as randomised.
- ☐ **1b. Abstract:** Structured summary of trial design, methods, results, and conclusions.

Introduction

- ☐ **2a. Background:** Scientific background and explanation of rationale.
- ☐ **2b. Objectives:** Specific objectives or hypotheses.

Methods

- ☐ **3a. Trial design:** Description of trial design (e.g., parallel, factorial) including allocation ratio.
- ☐ **3b. Changes to trial design:** Important changes to methods after trial commencement (such as eligibility criteria), with reasons.
- ☐ **4a. Participants:** Eligibility criteria for participants.
- ☐ **4b. Study settings:** Settings and locations where the data were collected.
- ☐ **5. Interventions:** The interventions for each group with sufficient details to allow replication, including how and when they were actually administered.
- ☐ **6a. Outcomes:** Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed.
- ☐ **6b. Changes to outcomes:** Any changes to trial outcomes after the trial commenced, with reasons.
- ☐ **7a. Sample size:** How sample size was determined.
- ☐ **7b. Interim analyses and stopping guidelines:** When applicable, explanation of any interim analyses and stopping guidelines.

- ☐ **8a. Randomisation: sequence generation:** Method used to generate the random allocation sequence.
- ☐ **8b. Randomisation: type:** Type of randomisation; details of any restriction (e.g., blocking and block size).
- ☐ **9. Allocation concealment mechanism:** Mechanism used to implement the random allocation sequence (e.g., sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned.
- ☐ **10. Implementation:** Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions.
- ☐ **11a. Blinding:** If done, who was blinded after assignment to interventions (e.g., participants, care providers, those assessing outcomes) and how.
- ☐ **11b. Similarity of interventions:** If relevant, description of the similarity of interventions.
- ☐ **12a. Statistical methods:** Statistical methods used to compare groups for primary and secondary outcomes.
- ☐ **12b. Additional analyses:** Methods for additional analyses, such as subgroup analyses and adjusted analyses.

Results

- ☐ **13a. Participant flow (a diagram is strongly recommended):** For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome.
- ☐ **13b. Losses and exclusions:** For each group, losses and exclusions after randomisation, together with reasons.
- ☐ **14a. Recruitment:** Dates defining the periods of recruitment and follow-up.
- ☐ **14b. Reason for stopping:** Why the trial ended or was stopped.
- ☐ **15. Baseline data:** A table showing baseline demographic and clinical characteristics for each group.
- ☐ **16. Numbers analysed:** For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups.
- ☐ **17a. Outcomes and estimation:** For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval).
- ☐ **17b. Binary outcomes:** For binary outcomes, presentation of both absolute and relative effect sizes is recommended.
- ☐ **18. Ancillary analyses:** Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory.
- ☐ **19. Harms:** All important harms or unintended effects in each group.

Discussion

- ☐ **20. Limitations:** Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses.
- ☐ **21. Generalisability:** Generalisability (external validity, applicability) of the trial findings.
- ☐ **22. Interpretation:** Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence.

Other Information

- ☐ **23. Registration:** Registration number and name of trial registry.
- ☐ **24. Protocol:** Where the full trial protocol can be accessed, if available.
- ☐ **25. Funding:** Sources of funding and other support (such as supply of drugs), role of funders.

Notes

Reviewer notes

Provenance

- Source: See sidecar metadata in `source/archetypes/consort-2010.yml`
- Version: 2010
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