# CONSORT 2010 Checklist

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
* License: CC BY 4.0