

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| SUBMISSION COMPLIANCE CHECKLIST: RANDOMISED TRIALS  DOCUMENT VERSION 14 AUGUST 2020  Ensure your manuscript complies with author guidelines by completing this SUBMISSION COMPLIANCE CHECKLIST, ensure to report the corresponding page number. Submit the completed form on the journal website during the manuscript submission process (Step 4). | | | | | |
| Was a statistician involved in this study? | | | Yes | No | N/A |
| Consultation only? | | | Yes | No | N/A |
| Was a statistician involved in data management? | | | Yes | No | N/A |
| Statistician’s name: | | |  | | |
| Statistician’s affiliated institution: | | |  | | |
| Statistician’s qualifications: | | |  | | |
| COMPLIANCE CRITERIA | | | | | COMPULSARY SECTION TO COMPLETE |
| SECTION/TOPIC | # | CHECKLIST ITEM | | | REPORTED ON PAGE # |
| *TITLE* |  |  | | |  |
| Title | 1 | Identification as a randomised trial in the title. | | |  |
| *ABSTRACT* |  |  | | |  |
| Structured summary | 2 | Structured summary of trial design, methods, results, and conclusions. | | |  |
| *INTRODUCTION* |  |  | | |  |
| Background | 3 | Scientific background and explanation of rationale. | | |  |
| Objectives | 4 | Specific objectives or hypotheses. | | |  |
| *METHODS* |  |  | | |  |
| Trial design | 5 | (a) Description of trial design (such as parallel, factorial) including allocation ratio. | | |  |
| (b) Important changes to methods after trial commencement (such as eligibility criteria), with reasons. | | |  |
| Participants | 4 | (a) Eligibility criteria for participants. | | |  |
| (b) Settings and locations where the data were collected | | |  |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered. | | |  |
| Outcomes | 6 | (a) Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed. | | |  |
| (b) Any changes to trial outcomes after the trial commenced, with reasons. | | |  |
| Sample size | 7 | (a) How sample size was determined. | | |  |
| (b) When applicable, explanation of any interim analyses and stopping guidelines. | | |  |
| Randomisation: Sequence generation | 8 | (a) Method used to generate the random allocation sequence. | | |  |
| (b) Type of randomisation; details of any restriction (such as blocking and block size). | | |  |
| Randomisation: Allocation concealment mechanism | 9 | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned. | | |  |
| Randomisation: Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions. | | |  |
| Blinding | 11 | (a) If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how. | | |  |
| (b) If relevant, description of the similarity of interventions. | | |  |
| Statistical methods | 12 | Statistical methods used to compare groups for primary and secondary outcomes. | | |  |
| Methods for additional analyses, such as subgroup analyses and adjusted analyses. | | |  |
| *RESULTS* |  |  | | |  |
| Participant flow (a diagram is strongly recommended) | 13 | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome. | | |  |
| For each group, losses and exclusions after randomisation, together with reasons. | | |  |
| Recruitment | 14 | Dates defining the periods of recruitment and follow-up. | | |  |
| Why the trial ended or was stopped. | | |  |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group. | | |  |
| Numbers analysed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups. | | |  |
| Outcomes and estimation | 17 | (a) For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval). | | |  |
| (b) For binary outcomes, presentation of both absolute and relative effect sizes is recommended. | | |  |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory. | | |  |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms). | | |  |
| *DISCUSSION* |  |  | | |  |
| Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses. | | |  |
| Generalisability | 21 | Generalisability (external validity, applicability) of the trial findings. | | |  |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence. | | |  |
| Ethics: Registration | 23 | Registration number and name of trial registry. This will be essential as from January 2021 and RCT’s will not be accepted unless registered. | | |  |
| Ethics: Protocol | 24 | Where the full trial protocol can be accessed, if available. | | |  |
| *ACKNOWLEDGEMENT* |  |  | | |  |
| Acknowledgements | 22 | The acknowledgement section follows the conclusions section and addresses formal, required statements of gratitude and required disclosures. It includes listing those who contributed to the work but did not meet authorship criteria, with the corresponding description of the contribution. | | |  |
| Competing interests | 23 | This section should list specific competing interests associated with any of the authors, potential sources of influence or perceived influence on the study conduct and conclusions; how these were managed. | | |  |
| Author contributions | 24 | All authors must meet the criteria for authorship as outlined in the [authorship](https://aosis.co.za/policies#authorship) policy and [author contribution](https://aosis.co.za/policies#author_contributions_affiliations) statement policies. | | |  |
| Funding | 25 | Sources and role of funding (e.g. such as supply of drugs) and other support; role of funders in data collection, interpretation, and reporting. | | |  |
| Data availability statement | 26 | Guide readers where the data associated with a paper is available, and under what conditions the data can be accessed. | | |  |
| Disclaimer | 27 | A statement that the views expressed in the submitted article are his or her own and not an official position of the institution or funder. | | |  |
| **Note:** \*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org. | | | | | |