# CONSORT checklist

**CONSORT 2010 checklist of information to include when reporting a randomised trial\***

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| **Section/Topic** | **Item No** | **Checklist item** | **Reported on page No** |
| **Title and abstract** |
|  | 1a | Identification as a randomised trial in the title | Title page |
| 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) | Abstract |
| **Introduction** |
| Background and objectives | 2a | Scientific background and explanation of rationale | Paragraphs 1-3 |
| 2b | Specific objectives or hypotheses | Paragraph 3; Table 1 |
| **Methods** |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio | Study Design, paragraphs 1-3 |
| 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | Text S1; Text S3; Figure S3 |
| Participants | 4a | Eligibility criteria for participants | Study Design, paragraph 4; Figure 3, Figure 4; Table 2; Figure S1; Figure S2; |
| 4b | Settings and locations where the data were collected | Study Setting, paragraph 1-3; Study Design, paragraph 1 |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | Study Design, paragraph 2-3; Study Vaccines and Vaccination Schedule; |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | Study Design, paragraph 2; Disease Surveillance and Case Definitions; Immunogenicity assessment;  |
| 6b | Any changes to trial outcomes after the trial commenced, with reasons | Ethics Statement; Statistical analysis; Text S3 |
| Sample size | 7a | How sample size was determined | Statistical Analysis Primary Outcome, First secondary outcome, paragraph 2-3 |
| 7b | When applicable, explanation of any interim analyses and stopping guidelines | Statistical Analysis, paragraphs 3-4; Table 1 |
| Randomisation: |  |  |  |
|  Sequence generation | 8a | Method used to generate the random allocation sequence | Study Design Paragraph 3-4 |
| 8b | Type of randomisation; details of any restriction (such as blocking and block size) | Study Design Paragraph 3-4 |
|  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 | Study Design Paragraph 3-4 |
|  Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | Study Design, paragraph 3-4 |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | Study Design, paragraph 3-4 |
| 11b | If relevant, description of the similarity of interventions | Study Design, paragraph 3-4 |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes | Statistical Analysis Primary Outcome, First secondary outcome paragraphs |
| 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | Statistical Analysis, Other secondary outcomes |
| **Results** |
| Participant flow (a diagram is strongly recommended) | 13a | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome | Fig. 3, 4, Fig. S1, S2 |
| 13b | For each group, losses and exclusions after randomisation, together with reasons | Fig. 3, 4, Fig. S1, S2 |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | Study Design, paragraph 2; Trial Profile paragraph 1, Tables 3, Fig S3 |
| 14b | Why the trial ended or was stopped | N/A |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group | Table 2; Table 3 |
| Numbers analysed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | Fig. 2; Fig. S2, S3 |
| Outcomes and estimation | 17a | For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) | Tables 3, 4; Tables S6 to S7 |
| 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended | N/A |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory | Disease Reporting and Vaccine Efficacy, Paragraph 1-3 |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | Serious Adverse Events, MortalityTables 6 and S8 |
| **Discussion** |
| Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | Paragraphs 2, 4, 8 |
| Generalisability | 21 | Generalisability (external validity, applicability) of the trial findings | Paragraphs 2, 3, 6, 7, 8, 10 |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | Paragraphs 1 to 10 |
| **Other information** |  |
| Registration | 23 | Registration number and name of trial registry | Abstract, Study Design, paragraph 1 |
| Protocol | 24 | Where the full trial protocol can be accessed, if available | Ethics Statement; Study Design, paragraph 1 |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders | Abstract, Study Oversight |

\*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.