

**Table 1 CONSORT checklist of information to include when reporting randomised crossover trials**

| Section/topic                             | Item No | Description  | Reported on Page Number/Line Number | Reported on Section/Paragraph |
|---|---------|--|-------------------------------------|-------------------------------|
| Title†                                    | 1a      | Identification as a randomised crossover trial in the title  |                                     |                               |
| Abstract†                                 | 1b      | Specify a crossover design and report all information outlined in <i>table 2</i>   |                                     |                               |
| <b>Introduction</b>                       |         |  |                                     |                               |
| Background‡                               | 2a      | Scientific background and explanation of rationale   |                                     |                               |
| Objectives‡                               | 2b      | Specific objectives or hypotheses  |                                     |                               |
| <b>Methods</b>                            |         |  |                                     |                               |
| Trial design†                             | 3a      | Rationale for a crossover design. Description of the design features including allocation ratio, especially the number and duration of periods, duration of washout period, and consideration of carry over effect |                                     |                               |
| Change from protocol‡                     | 3b      | Important changes to methods after trial commencement (such as eligibility criteria), with reasons   |                                     |                               |
| Participants‡                             | 4a      | Eligibility criteria for participants  |                                     |                               |
| Settings and location‡                    | 4b      | Settings and locations where the data were collected   |                                     |                               |
| Interventions†                            | 5       | The interventions with sufficient details to allow replication, including how and when they were actually administered   |                                     |                               |
| Outcomes‡                                 | 6a      | Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed  |                                     |                               |
| Changes to outcomes‡                      | 6b      | Any changes to trial outcomes after the trial commenced, with reasons  |                                     |                               |
| Sample size†                              | 7a      | How sample size was determined, accounting for within participant variability  |                                     |                               |
| Interim analyses and stopping guidelines‡ | 7b      | When applicable, explanation of any interim analyses and stopping guidelines   |                                     |                               |

|   |     |  |  |
|---|-----|--|--|
| Randomisation:  |     |  |  |
| Sequence generation‡                                  | 8a  | Method used to generate the random allocation sequence   |  |
| Sequence generation‡                                  | 8b  | Type of randomisation; details of any restriction (such as blocking and block size)  |  |
| 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 |  |
| Implementation†                                       | 10  | Who generated the random allocation sequence,§ who enrolled participants, and who assigned participants to the sequence of interventions   |  |
| Blinding‡   | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how   |  |
| Similarity of interventions‡                          | 11b | If relevant, description of the similarity of interventions  |  |
| Statistical methods†                                  | 12a | Statistical methods used to compare groups for primary and secondary outcomes which are appropriate for crossover design (that is, based on within participant comparison)                   |  |
| Additional analyses‡                                  | 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses   |  |
| <b>Results</b>  |     |  |  |
| Participant flow (a diagram is strongly recommended)† | 13a | The numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome, separately for each sequence and period                      |  |
| Losses and exclusions†                                | 13b | No of participants excluded at each stage, with reasons, separately for each sequence and period   |  |
| Recruitment‡  | 14a | Dates defining the periods of recruitment and follow-up  |  |
| Trial end‡  | 14b | Why the trial ended or was stopped   |  |
| Baseline data†  | 15  | A table showing baseline demographic and clinical characteristics by sequence and period   |  |

|                          |     |   |  |  |
|--------------------------|-----|---|--|--|
| Numbers analysed†        | 16  | Number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups   |  |  |
| Outcomes and estimation† | 17a | For each primary and secondary outcome, results including estimated effect size and its precision (such as 95% confidence interval) should be based on within participant comparisons.¶ In addition, results for each intervention in each period are recommended |  |  |
| Binary outcomes‡         | 17b | 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 prespecified from exploratory  |  |  |
| Harms†                   | 19  | Describe all important harms or untended effects in a way that accounts for the design (for specific guidance, see CONSORT for harms <sup>32</sup> )  |  |  |
| <b>Discussion</b>        |     |   |  |  |
| Limitations†             | 20  | Trial limitations, addressing sources of potential bias, imprecision, and if relevant, multiplicity of analyses. Consider potential carry over effects  |  |  |
| 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   |  |  |
| <b>Other information</b> |     |   |  |  |
| Registration‡            | 23  | Registration number and name of trial registry  |  |  |
| Protocol‡                | 24  | Where the full trial protocol can be accessed, if available   |  |  |
| Funding‡                 | 25  | Sources of funding and other support (such as supply of drugs), role of funders   |  |  |

† Modified original CONSORT item.

‡ Unmodified CONSORT item.

§ Random sequence here refers to a list of random orders, typically generated through a computer program. This should not be confused with the sequence of interventions in a randomised crossover trial, for example receiving intervention A before B for an individual trial participant.

¶ A within participant comparison takes into account the correlation between measurements for each participant because they act as their own control, therefore measurements are not independent.

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\*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.