## 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 | 1, 2 | Title |
| Abstract† | 1b | Specify a crossover design and report all information outlined in *table 2* | 4, 62 | Abstract |
| **Introduction** | | | | |
| Background‡ | 2a | Scientific background and explanation of rationale | 6, 93 | Introduction |
| Objectives‡ | 2b | Specific objectives or hypotheses | 7, 120 | Introduction |
| **Methods** | | | | |
| 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 | 7, 134 | Methods |
| Change from protocol‡ | 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | n/a | n/a |
| Participants‡ | 4a | Eligibility criteria for participants | 8, 141 | Methods |
| Settings and location‡ | 4b | Settings and locations where the data were collected | 8, 142 | Methods |
| Interventions† | 5 | The interventions with sufficient details to allow replication, including how and when they were actually administered | 8, 157 | Methods |
| Outcomes‡ | 6a | Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed | 9, 172 | Methods |
| Changes to outcomes‡ | 6b | Any changes to trial outcomes after the trial commenced, with reasons | n/a | n/a |
| Sample size† | 7a | How sample size was determined, accounting for within participant variability | 10, 187 | Methods |
| Interim analyses and stopping guidelines‡ | 7b | When applicable, explanation of any interim analyses and stopping guidelines | n/a | n/a |

| | | | | |
|---|---|---|---|---|
| Randomisation: | | | | |
| Sequence generation‡ | 8a | Method used to generate the random allocation sequence | 8, 157 | Methods |
| Sequence generation‡ | 8b | Type of randomisation; details of any restriction (such as blocking and block size) | 8, 157 | Methods |
| 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 | 8, 158 | Methods |
| Implementation† | 10 | Who generated the random allocation sequence,§ who enrolled participants, and who assigned participants to the sequence of interventions | 8, 157 | Methods |
| Blinding‡ | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | 9, 162 | Methods |
| Similarity of interventions‡ | 11b | If relevant, description of the similarity of interventions | n/a | n/a |
| 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) | 10, 192 | Methods |
| Additional analyses‡ | 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | 10, 192 | Methods |
| **Results** | | | | |
| 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 | 23, 426 | Figure 2 |
| Losses and exclusions† | 13b | No of participants excluded at each stage, with reasons, separately for each sequence and period | 11, 222 | Results |
| Recruitment‡ | 14a | Dates defining the periods of recruitment and follow-up | 8, 143 | Results |
| Trial end‡ | 14b | Why the trial ended or was stopped | n/a | n/a |
| Baseline data† | 15 | A table showing baseline demographic and clinical characteristics by sequence and period | 27, 451 | Table 1 |

| | | | | |
|---|---|---|---|---|
| Numbers analysed† | 16 | Number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | 23, 426 | Figure 2 |
| 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 | 10, 201 | Results |
| Binary outcomes‡ | 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended | n/a | n/a |
| Ancillary analyses‡ | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory | | supplementary Appendix |
| Harms† | 19 | Describe all important harms or untended effects in a way that accounts for the design (for specific guidance, see CONSORT for harms32) | 11, 210 | Results |
| **Discussion** | | | | |
| Limitations† | 20 | Trial limitations, addressing sources of potential bias, imprecision, and if relevant, multiplicity of analyses. Consider potential carry over effects | 15, 298 | Discussion |
| Generalisability‡ | 21 | Generalisability (external validity, applicability) of the trial findings | 15, 311 | Discussion |
| Interpretation‡ | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | 16, 321 | Discussion |
| **Other information** | | | | |
| Registration‡ | 23 | Registration number and name of trial registry | 7, 132 | Methods |
| Protocol‡ | 24 | Where the full trial protocol can be accessed, if available | 7, 132 | Methods |
| Funding‡ | 25 | Sources of funding and other support (such as supply of drugs), role of funders | 17, 329 | Footnote |

† 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.

## Table 2 Information to include in abstract of report of randomised crossover trial: extension of CONSORT for abstracts checklist35

| Item | Description | Reported on Page Number/Line Number | Reported on Section/Paragraph |
|---|---|---|---|
| Title* | Identification of study as a randomised crossover trial | 4, 62 | Title |
| Trial design* | Description of the trial design (crossover trial and number of periods) | 4, 71 | Abstract |
| **Methods** | | | |
| Participants† | Eligibility criteria for participants and the settings where the data were collected | 4, 73 | Abstract |
| Interventions* | Interventions intended for all participants | 4, 75 | Abstract |
| Objective† | Specific objective or hypothesis | 4, 66 | Abstract |
| Outcome† | Clearly defined primary outcome for this report | 4, 77 | Abstract |
| Randomisation* | How participants were allocated to sequences | 4, 75 | Abstract |
| Blinding (masking)* | Whether or not participants, care givers, and those assessing the outcomes were blinded to intervention | 4, 71 | Abstract |
| **Results** | | | |
| Numbers randomised* | Number of participants randomised to each sequence | 4, 79 | Abstract |
| Recruitment† | Trial status‡ | n/a | n/a |
| Numbers analysed* | Number of participants analysed | 4, 79 | Abstract |
| Outcome* | For the primary outcome, the estimated effect size and its precision based on within participant comparisons | 4, 79 | Abstract |
| Harms† | Important adverse events or side effects | 4, 82 | Abstract |
| Conclusions† | General interpretation of the results | 4, 83 | Abstract |
| Trial registration† | Registration number and name of trial register | 4, 89 | Abstract |
| Funding† | Source of funding | 17, 329 | Footnote |

* Modified original CONSORT item.

† Unmodified CONSORT item.

‡ This is applicable to conference abstracts.

From: Dwan K, Li T, Altman DG, Elbourne D. CONSORT 2010 statement: extension to randomised crossover trials. BMJ. 2019

Article information: https://dx.doi.org/10.21037/ajo-23-15
*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.