| Section/Topic         | Item No | Checklist item                                                                 | Reported on Page Number/Line Number | Reported on Section/Paragraph |
|-----------------------|---------|---------------------------------------------------------------------------------|-------------------------------------|-----------------------------|
| **Title and abstract**|         |                                                                                  |                                     |                             |
| 1a                    |         | Identification as a randomised trial in the title                                | Page 1/Line 3-6                     | title                       |
| 1b                    |         | Structured summary of trial design, methods, results, and conclusions (for specific guidance see Table 2) | Page 1-3/Line 32-67                | Abstract                    |
| **Introduction**      |         |                                                                                  |                                     |                             |
| Background and objectives | 2a    | Scientific background and explanation of rationale                              | Page 3-4/Line 74-113                | Introduction                |
|                       | 2b    | Specific objectives or hypotheses                                               | Page 4/Line 107-113                 | Introduction/P5             |
| **Methods**           |         |                                                                                  |                                     |                             |
| Trial design          | 3a    | Description of trial design (such as parallel, factorial) including allocation ratio | Page 4/Line 116-131                | Methods/P1                  |
|                       | 3b    | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | N/A                                  | No changes.                 |
| Participants          | 4a    | Eligibility criteria for participants                                           | Page 5/Line 135-143                 | Case selection              |
|                       | 4b    | Settings and locations where the data were collected                           | Page 4/Line 116-131                 | Methods/P1                  |
| Interventions         | 5     | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | Page 5-6/Line 147-164               | Treatment methods           |
| Outcomes              | 6a    | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | Page 6/Line 169-188                 | Primary endpoints and Secondary endpoints |
|                       | 6b    | Any changes to trial outcomes after the trial commenced, with reasons           | N/A                                  | No changes.                 |
| Sample size           | 7a    | How sample size was determined                                                  | Page 4/Line 119-124                 | Methods/P1                  |
|                       | 7b    | When applicable, explanation of any interim analyses and stopping guidelines     | N/A                                  | Not applicable.             |
| **Randomisation**     |         |                                                                                  |                                     |                             |
| Sequence generation   | 8a    | Method used to generate the random allocation sequence                          | N/A                                  | N/A                         |
|                       | 8b    | Type of randomisation; details of any restriction (such as blocking and block size) | Page 4/Line 116-131                 | Methods/P1                  |
| 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 | N/A                                  | No concealment mechanism.   |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | N/A | N/A |
|----------------|----|---------------------------------------------------------------------------------------------------------------------------------|------|------|
| Blinding       | 11a| If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | Page 4/Line 116-131 | Methods/P1 |
|                | 11b| If relevant, description of the similarity of interventions | Page 6/Line 159-164 | Treatment methods/P2 |
| Statistical methods | 12a| Statistical methods used to compare groups for primary and secondary outcomes | Page 7/Line 192-196 | Statistical methods |
|                | 12b| Methods for additional analyses, such as subgroup analyses and adjusted analyses | N/A | No additional analyses. |

**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 | Page 7/Line 199-208 | Results/P1 Figure 1 |
|                                                      | 13b| For each group, losses and exclusions after randomisation, together with reasons | N/A | No losses and exclusions. |
| Recruitment | 14a| Dates defining the periods of recruitment and follow-up | Page 7/Line 199-208 | Results/P1 |
|             | 14b| Why the trial ended or was stopped | Page 7/Line 199-208 | Results/P1 |
| Baseline data | 15| A table showing baseline demographic and clinical characteristics for each group | Page 7/Line 212-216 | Demographic of Patients |
| Numbers analysed | 16| For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | Page 7/Line 212-216 | Demographic of Patients |
| 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) | Page 7-8/Line 218-245 | Results/P2-4 |
|                                                      | 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 pre-specified from exploratory | N/A | No these data. |
| Harms | 19| All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | N/A | No harm was observed |

**Discussion**

| Limitations | 20| Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | Page 12/355-360 | Discussion/P12 |
| Generalisability | 21| Generalisability (external validity, applicability) of the trial findings | Page 8-12/Line 249-365 | Discussion/P1-13 |
| Interpretation | 22| Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | Page 12/Line 360-365 | Discussion/P13 |

**Other information**

| Registration | 23| Registration number and name of trial registry | Page 13/Line 391-393 | Registration |
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

*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.

Table 2 Items to include when reporting a randomized trial in a journal or conference abstract

| Item                  | Description                                                                 | Reported on Page Number/Line Number | Reported on Section/Paragraph |
|-----------------------|-----------------------------------------------------------------------------|-------------------------------------|------------------------------|
| Title                 | Identification of the study as randomized                                  | Page 1/Line 3-6                     | Abstract                     |
| Authors *             | Contact details for the corresponding author                              | Page 1/Line 16-20                   | Abstract                     |
| Trial design          | Description of the trial design (e.g. parallel, cluster, non-inferiority)  | Page 2/Line 45                      | Abstract                     |
| Methods               |                                                                             |                                     |                              |
| Participants          | Eligibility criteria for participants and the settings where the data were collected | Page 2/Line 46-52                  | Abstract                     |
| Interventions         | Interventions intended for each group                                       | Page 2/Line 46-52                   | Abstract                     |
| Objective             | Specific objective or hypothesis                                            | Page 2/Line 35-44                   | Abstract                     |
| Outcome               | Clearly defined primary outcome for this report                            | Page 2/Line 46-52                   | Abstract                     |
| Randomization         | How participants were allocated to interventions                            | Page 2/Line 46-52                   | Abstract                     |
| Blinding (masking)    | Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment | Page 2/Line 46-52                   | Abstract                     |
| Results               |                                                                             |                                     |                              |
| Numbers randomized    | Number of participants randomized to each group                             | Page 2/Line 54-62                   | Abstract                     |
| Recruitment           | Trial status                                                                | Page 2/Line 54                      | Abstract                     |
| Numbers analysed      | Number of participants analysed in each group                               | Page 2/Line 54-55                   | Abstract                     |
| Outcome               | For the primary outcome, a result for each group and the estimated effect size and its precision | Page 2/Line 54-62                   | Abstract                     |
| Harms                 | Important adverse events or side effects                                    | N/A                                 | Abstract                     |
| Conclusions | General interpretation of the results | Page 2/Line 63-66 | Abstract |
|-------------|--------------------------------------|-------------------|----------|
| Trial registration | Registration number and name of trial register | Page 2/Line 67 | Abstract |
| Funding | Source of funding | N/A | Stated in acknowledge |

* this item is specific to conference abstracts

From: Hopewell S, Clarke M, Moher D, et al. CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. PLoS Med. 2008;5(1):e20

Article information: https://dx.doi.org/10.21037/tp-21-243

*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.