| 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                              | N/A, no randomisation              | /A, no randomisation due     |
| 1b                 |         | Structured summary of trial design, methods, results, and conclusions           | page 2, line 34-60                 | Abstract, Paragraph 1-4     |
| **Introduction**   |         |                                                                                  |                                    |                             |
| 2a                 |         | Scientific background and explanation of rationale                              | page 3, line 64-105                | Introduction, Paragraph     |
| 2b                 |         | Specific objectives or hypotheses                                               | page 4, line 106-113               | Introduction, Paragraph 5   |
| **Methods**        |         |                                                                                  |                                    |                             |
| 3a                 |         | Description of trial design (such as parallel, factorial) including allocation ratio | page 5, line 116-128              | Materials and Methods,      |
| 3b                 |         | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | N/A, no changes after trial | N/A, no changes after trial |
| 4a                 |         | Eligibility criteria for participants                                           | page 5, line 116-128              | Materials and Methods,      |
| 4b                 |         | Settings and locations where the data were collected                            | page 6, line 157-177               | Materials and Methods,      |
| 5                  |         | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | page 6, line 142-156              | Materials and Methods,      |
| 6a                 |         | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | page 6, 157-203                    | Materials and Methods,      |
| 6b                 |         | Any changes to trial outcomes after the trial commenced, with reasons           | N/A, no changes after trial        | A, no changes after trial   |
| 7a                 |         | How sample size was determined                                                  | N/A, as exploratory study          | N/A, as exploratory study   |
| 7b                 |         | When applicable, explanation of any interim analyses and stopping guidelines     | N/A, no interim analysis           | N/A, no interim analysis    |
| **Randomisation:** |         |                                                                                  |                                    |                             |
| 8a                 |         | Method used to generate the random allocation sequence                           | N/A, no randomisation              | N/A, no randomisation       |
| 8b                 |         | Type of randomisation; details of any restriction (such as blocking and block size) | N/A, no randomisation              | N/A, no 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 | N/A, no randomisation due to study design | N/A, no randomisation due to study design |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | N/A, no randomisation due to study design | N/A, no randomisation due to study design |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | N/A, no blinding due to study design | N/A, no blinding due to study design |
| | 11b | If relevant, description of the similarity of interventions | N/A, no blinding due to | N/A, no blinding due to |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes | page 8, line 204-208 | Materials and Methods, |
| | 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | N/A for current study | N/A for current study |
| Results | 13a | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome | page 5, line 116-128 | Materials and Methods, Study population, |
| | 13b | For each group, losses and exclusions after randomisation, together with reasons | N/A, no losses after | N/A, no losses after |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | page 5, line 116-141 | Materials and Methods, |
| | 14b | Why the trial ended or was stopped | N/A, trial was stopped by | N/A, trial was stopped by |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group | page 21, line 525-528 | Tables, Paragraph 1 |
| Numbers analysed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | page 5, line 116-128 | Materials and Methods, Study population, |
| 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 9, line 212-231 | Results, Paragraph 1-3 |
| | 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended | N/A, due to study design | N/A, due to study design |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory | N/A, due to study design | N/A, due to study design |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | N/A, no occurrence of | N/A, no occurrence of |
| Discussion | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | page 13, line 325-346 | Discussion, Paragraph 5 |
| Generalisability | 21 | Generalisability (external validity, applicability) of the trial findings | page 10, line 240-323 | Discussion, Paragraph 2-4 |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | page 14, line 347-353 | Conclusion, Paragraph 6 |
| Other information | 23 | Registration number and name of trial registry | N/A, no trial registration | N/A, no trial 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                                    | N/A, no randomisation               | N/A, no randomisation        |
| Authors *                | Contact details for the corresponding author                                 | page 1, line 15-23                  | Title page                   |
| Trial design             | Description of the trial design (e.g. parallel, cluster, non-inferiority)     | page 2, line 37-39                 | Abstract, Paragraph 1        |
| Methods                  |                                                                              |                                     |                              |
| Participants             | Eligibility criteria for participants and the settings where the data were collected | page 5, line 116-128               | Materials and Methods,       |
| Interventions            | Interventions intended for each group                                         | page 6, line 142-156               | Materials and Methods,       |
| Objective                | Specific objective or hypothesis                                              | page 4, line 106-113               | Introduction, Paragraph 5    |
| Outcome                  | Clearly defined primary outcome for this report                              | page 6, line 157-203               | Materials and Methods,       |
| Randomization            | How participants were allocated to interventions                              | N/A, no randomisation               | N/A, no randomisation        |
| Blinding (masking)       | Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment | N/A, no blindind due to            | N/A, no blindind due to      |
| Results                  |                                                                              |                                     |                              |
| Numbers randomized       | Number of participants randomized to each group                               | N/A, no randomisation               | N/A, no randomisation        |
| Recruitment              | Trial status                                                                  | page 5, line 116-128               | Materials and Methods,       |
| Numbers analysed         | Number of participants analysed in each group                                 | page 5, line 116-128               | Materials and Methods,       |
| Outcome                  | For the primary outcome, a result for each group and the estimated effect size and its precision | page 9, line 214-231               | Results, Paragraph 1-3       |
| Harms                    | Important adverse events or side effects                                      | page 9, line 214                   | Results, Paragraph 1         |

4-3
| Conclusions          | General interpretation of the results | page 14, line 348-353 | Conclusions, Paragraph 1 |
|----------------------|---------------------------------------|------------------------|--------------------------|
| Trial registration   | Registration number and name of trial register | N/A, no trial registration | N/A, no trial registration |
| Funding              | Source of funding                      | page 14, line 347-353  | Acknowledgments,          |

* 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;S(1):e20

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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.