| 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 1-2 Line 30-46                | Abstract                     |
| 1b                    |         | Structured summary of trial design, methods, results, and conclusions         | Page 1 Line 27-29                 | Abstract                     |
| **Introduction**      |         |                                                                               |                                    |                              |
| Background and        | 2a      | Scientific background and explanation of rationale                           | Page 2 Line 54-64                 | Introduction 1               |
| objectives            | 2b      | Specific objectives or hypotheses                                             | Page 2-3 Line 65-91               | Introduction 2               |
| **Methods**           |         |                                                                               |                                    |                              |
| Trial design          | 3a      | Description of trial design (such as parallel, factorial) including allocation ratio | Page 3-4 Line 97-108              | Methods 1                     |
|                       | 3b      | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | N/A                                | N/A                          |
| Participants          | 4a      | Eligibility criteria for participants                                         | Page 4 Line 110-118               | Methods 2                     |
|                       | 4b      | Settings and locations where the data were collected                          | Page 7 Line 219-237               | Methods 4                     |
| Interventions         | 5       | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | Page 4-7 Line 119-217             | Methods 3                     |
| Outcomes              | 6a      | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | Page 4-7 Line 119-217             | Methods 3                     |
|                       | 6b      | Any changes to trial outcomes after the trial commenced, with reasons        | N/A                                | N/A                          |
| Sample size           | 7a      | How sample size was determined                                                | Page 3-4 Line 97-108              | Methods 1                     |
|                       | 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                        | Page 3-4 Line 97-108              | Methods 1                     |
|                       | 8b      | Type of randomisation; details of any restriction (such as blocking and block size) | Page 3-4 Line 97-108              | Methods 1                     |
| Allocation concealment| 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 | Page 3-4 Line 97-108              | Methods 1                     |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | Page 3-4 Line 97-108 | Methods 1 |
|----------------|----|------------------------------------------------------------------------------------------------------------------------------------|----------------------|--------|
| Blinding       | 11a| If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | Page 3-4 Line 97-108 | Methods 1 |
|                | 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                                                      | Page 8 Line 239-245 | Methods 5 |
|                | 12b| Methods for additional analyses, such as subgroup analyses and adjusted analyses                                                    | N/A                  | N/A    |

**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 8 Line 249-262 | Results 1-3 |
|------------------------------------------------------|----|-------------------------------------------------------------------------------------------------------------------------------------|-------------------|----------|
|                                                      | 13b| For each group, losses and exclusions after randomisation, together with reasons                                                   | Page 8 Line 249-262 | Results 1-3 |
| Recruitment                                           | 14a| Dates defining the periods of recruitment and follow-up                                                                           | N/A                | N/A      |
|                                                      | 14b| Why the trial ended or was stopped                                                                                               | N/A                | N/A      |
| Baseline data                                         | 15 | A table showing baseline demographic and clinical characteristics for each group                                                  | N/A                | N/A      |
| Numbers analysed                                      | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | N/A                | N/A      |
| 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 8 Line 249-262 | Results 1-3 |
|                                                      | 17b| For binary outcomes, presentation of both absolute and relative effect sizes is recommended                                         | Page 8 Line 249-262 | Results 1-3 |
| Ancillary analyses                                    | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory | N/A                | N/A      |
| Harms                                                 | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)                             | N/A                | N/A      |

**Discussion**

| Limitations                                           | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses                    | Page 10 Line 323-331 | Discussion 4 |
| Generalisability                                      | 21 | Generalisability (external validity, applicability) of the trial findings                                                   | Page 9-10 Line 280-308 | Discussion 2 |
| Interpretation                                         | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence                   | Page 8-9 Line 269-279 | Discussion 1 |

**Other information**

| Registration                                           | 23 | Registration number and name of trial registry                                                                               | N/A                | N/A      |
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 3-4 | Title |
| Authors * | Contact details for the corresponding author | Page 1 Line 11-12 | Authors |
| Trial design | Description of the trial design (e.g. parallel, cluster, non-inferiority) | Page 1-2 Line 30-35 | Abstract |

**Methods**

| Item | Description | Reported on Page Number/Line Number | Reported on Section/Paragraph |
|------|-------------|-----------------------------------|-----------------------------|
| Participants | Eligibility criteria for participants and the settings where the data were collected | Page 3-4 Line 97-118 | Methods 1-2 |
| Interventions | Interventions intended for each group | Page 4-7 Line 119-217 | Methods 3 |
| Objective | Specific objective or hypothesis | Page 7 Line 219-237 | Methods 4 |
| Outcome | Clearly defined primary outcome for this report | Page 7 Line 219-237 | Methods 4 |
| Randomization | How participants were allocated to interventions | Page 3-4 Line 97-108 | Methods 1 |
| Blinding (masking) | Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment | Page 3-4 Line 97-108 | Methods 1 |

**Results**

| Item | Description | Reported on Page Number/Line Number | Reported on Section/Paragraph |
|------|-------------|-----------------------------------|-----------------------------|
| Numbers randomized | Number of participants randomized to each group | Page 8 Line 249-262 | Results 1-3 |
| Recruitment | Trial status | Page 8 Line 249-262 | Results 1-3 |
| Numbers analysed | Number of participants analysed in each group | Page 9 Line 280-289 | Discussion 2 |
| Outcome | For the primary outcome, a result for each group and the estimated effect size and its precision | Page 9 Line 280-289 | Discussion 2 |
| Harms | Important adverse events or side effects | N/A | N/A |

"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."
| Conclusions                      | General interpretation of the results | Page 10 Line 319-331 | Discussion 4 |
|----------------------------------|----------------------------------------|-----------------------|--------------|
| Trial registration               | Registration number and name of trial register | N/A                   | N/A          |
| Funding                          | Source of funding                       | N/A                   | N/A          |

* 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

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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.