| 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                      | Title page                        |
| 1b                            | Structured summary of trial design, methods, results, and conclusions (for specific guidance see Table 2) | Page 2                             | Abstract                        |
| **Introduction**              |         |                                                                                |                                     |                              |
| **Background and objectives** | 2a      | Scientific background and explanation of rationale                           | Page 3/Line 59-67                  | Introduction                  |
| 2b                            | Specific objectives or hypotheses                      | Page 3/Line 68-73                  | Introduction                    |
| **Methods**                  |         |                                                                                |                                     |                              |
| Trial design                  | 3a      | Description of trial design (such as parallel, factorial) including allocation ratio | Page 4/Line 76                    | Methods                       |
| 3b                            | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | N/A                                 | Methods                         |
| Participants                  | 4a      | Eligibility criteria for participants                                        | Page 4/Line 81-85                  | Methods                       |
| 4b                            | Settings and locations where the data were collected  | Page 4/Line 76                    | Methods                         |
| Interventions                 | 5       | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | Page 4/Line 87-95                  | Methods                       |
| Outcomes                      | 6a      | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | Page 6/Line 120-127                | Methods                       |
| 6b                            | Any changes to trial outcomes after the trial commenced, with reasons | No                                  | Methods                         |
| Sample size                   | 7a      | How sample size was determined                                                 | No                                  | Methods                       |
| 7b                            | When applicable, explanation of any interim analyses and stopping guidelines | Page 5/Line 103-108                | Methods                         |
| Randomisation:                |         |                                                                                |                                     |                              |
| Sequence generation           | 8a      | Method used to generate the random allocation sequence                         | Page 5/Line 109                    | Methods                       |
| 8b                            | Type of randomisation; details of any restriction (such as blocking and block size) | Page 5/Line 109                    | Methods                         |
| Allocation concealment mechanism |         | 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 6/Line 109                    | Methods                       |
| Category          | Code | Description                                                                                          | Page/Line | Section       |
|-------------------|------|-------------------------------------------------------------------------------------------------------|-----------|---------------|
| Implementation    | 10   | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | 109-112   | Methods       |
| Blinding          | 11a  | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | 109-112   | Methods       |
|                   | 11b  | If relevant, description of the similarity of interventions                                             | No        | Methods       |
| Statistical methods| 12a  | Statistical methods used to compare groups for primary and secondary outcomes                          | 129-135   | Methods       |
|                   | 12b  | Methods for additional analyses, such as subgroup analyses and adjusted analyses                        | No        | Methods       |
| Results           | 13a  | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome | 138-144   | Results       |
|                   | 13b  | For each group, losses and exclusions after randomisation, together with reasons                       | 138-144   | Results       |
| Recruitment       | 14a  | Dates defining the periods of recruitment and follow-up                                               | 78-80     | Results       |
|                   | 14b  | Why the trial ended or was stopped                                                                    | No        | Results       |
| Baseline data     | 15   | A table showing baseline demographic and clinical characteristics for each group                      | 145-148   | Results       |
| Numbers analysed  | 16   | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | 138-144   | Results       |
| 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) | 7-10      | Results       |
|                   | 17b  | For binary outcomes, presentation of both absolute and relative effect sizes is recommended           | No        | Results       |
| Ancillary analyses| 18   | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory | No        | Results       |
| Harms             | 19   | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | No        | Results       |
| Discussion        | 20   | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | 271-278   | Discussion    |
| Generalisability  | 21   | Generalisability (external validity, applicability) of the trial findings                              | 279       | Discussion    |
| Interpretation    | 22   | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | 9-13      | Discussion    |
| Other information | 23   | Registration number and name of trial registry                                                         | 291-294   | Trial registration |
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                              | Title page                    |
| Authors *         | Contact details for the corresponding author                               | Page 1                              | Title page                    |
| Trial design      | Description of the trial design (e.g. parallel, cluster, non-inferiority)   | Page 2                              | abstract                      |
| Methods           |                                                                              |                                     |                               |
| Participants      | Eligibility criteria for participants and the settings where the data were collected | Page 4                              | Methods                       |
| Interventions     | Interventions intended for each group                                       | Page 4                              | Methods                       |
| Objective         | Specific objective or hypothesis                                            | Page 3                              | Methods                       |
| Outcome           | Clearly defined primary outcome for this report                            | Page 6                              | Methods                       |
| Randomization     | How participants were allocated to interventions                           | Page 5                              | Methods                       |
| Blinding (masking)| Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment | Page 5                              | Methods                       |
| Results           |                                                                              |                                     |                               |
| Numbers randomized| Number of participants randomized to each group                             | Page 6-7                            | Results                       |
| Recruitment       | Trial status                                                                | Page 6-7                            | Results                       |
| Numbers analysed  | Number of participants analysed in each group                               | Page 6-7                            | Results                       |
| Outcome           | For the primary outcome, a result for each group and the estimated effect size and its precision | Page 7-10                           | Results                       |
| Harms             | Important adverse events or side effects                                    | no                                  | Results                       |
| Conclusions | General interpretation of the results |
|-------------|-------------------------------------|
| Trial registration | Registration number and name of trial register |
| Funding | Source of funding |

* this item is specific to conference abstracts

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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.