| 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                                                                                                                                                    | Page1/Line 1-2                     | Title/Paragraph1             |
| 1b            | Structured summary of trial design, methods, results, and conclusions (for specific guidance see Table 2)                                                                                       | Page1/Line 17-37                  | Abstract/Paragraph1-2        |
| Introduction  |         |                                                                                                                                                                                                               |                                   |                             |
| 2a            | Scientific background and explanation of rationale                                                                                                                                                    | Page2/Line 41-65                  | Introduction/Paragraph2-65   |
| 2b            | Specific objectives or hypotheses                                                                                                                                                                    | Page2/Line 66-69                  | Introduction/Paragraph2-65   |
| Methods       |         |                                                                                                                                                                                                               |                                   |                             |
| Trial design  | 3a      | Description of trial design (such as parallel, factorial) including allocation ratio                                                                                                                                               | Page4/Line 127-129                | Methods/Paragraph4          |
| 3b            | Important changes to methods after trial commencement (such as eligibility criteria), with reasons                                                                                                      | N/A                               | N/A                          |
| Participants  | 4a      | Eligibility criteria for participants                                                                                                                                                                                 | Page3/Line 73-79                  | Methods/Paragraph3          |
| 4b            | Settings and locations where the data were collected                                                                                                                                                       | Page3/Line 80-84                  | Methods/Paragraph3          |
| Interventions | 5       | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered                                                                       | Page5/Line 100-122                | Methods/Paragraph5-8        |
| 6a            | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed                                                                                     | Page6-7/Line 193,196, 200-207     | Methods/Record indicators and evaluation |
| 6b            | Any changes to trial outcomes after the trial commenced, with reasons                                                                                                                                     | No                                | No                           |
| Sample size   | 7a      | How sample size was determined                                                                                                                                                                                     | No                                | No                           |
| 7b            | When applicable, explanation of any interim analyses and stopping guidelines                                                                                                                                  | No                                | No                           |
| Randomisation:|         |                                                                                                                                                                                                               |                                   |                             |
| Sequence generation | 8a | Method used to generate the random allocation sequence                                                                                                                                                  | Page4-5/Line 129-136              | Methods/Paragraph3          |
| 8b            | Type of randomisation; details of any restriction (such as blocking and block size)                                                                                                                        | Page3/Line 85-92                  | Methods/Paragraph3          |
| 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 | Page3/Line 85-92                  | Methods/Paragraph3          |
Implementation 10 Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions |
Blinding 11a If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how |
11b If relevant, description of the similarity of interventions |
Statistical methods 12a Statistical methods used to compare groups for primary and secondary outcomes |
12b Methods for additional analyses, such as subgroup analyses and adjusted 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 |
13b For each group, losses and exclusions after randomisation, together with reasons |
Recruitment 14a Dates defining the periods of recruitment and follow-up |
14b Why the trial ended or was stopped |
Baseline data 15 A table showing baseline demographic and clinical characteristics for each group |
Numbers analysed 16 For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups |
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) |
17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended |
Ancillary analyses 18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory |
Harms 19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) |

Discussion

Limitations 20 Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses |
Generalisability 21 Generalisability (external validity, applicability) of the trial findings |
Interpretation 22 Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence |

Other information

Registration 23 Registration number and name of trial registry
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                                    | Page1/Line 3-4                      | Abstract/ Paragraph2         |
| Authors *           | Contact details for the corresponding author                                | Page1/Line 24-28                    | Abstract/ Paragraph6         |
| Trial design        | Description of the trial design (e.g. parallel, cluster, non-inferiority)    | Page2/Line 44-50                    | Abstract/Paragraph12         |
| **Methods**         |                                                                             |                                     |                              |
| Participants        | Eligibility criteria for participants and the settings where the data were collected | Page2/Line 44-50                    | Abstract/Paragraph12         |
| Interventions       | Interventions intended for each group                                        | Page2/Line 47-50                    | Abstract/Paragraph12         |
| Objective           | Specific objective or hypothesis                                             | Page2/Line 50-53                    | Abstract/Paragraph12         |
| Outcome             | Clearly defined primary outcome for this report                             | Page2/Line 50-53                    | Abstract/Paragraph12         |
| Randomization       | How participants were allocated to interventions                             | N/A                                 | N/A                          |
| Blinding (masking)  | Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment | N/A                                 | N/A                          |
| **Results**         |                                                                             |                                     |                              |
| Numbers randomized  | Number of participants randomized to each group                              | Page2/Line 44-47                    | Abstract/Paragraph12         |
| Recruitment         | Trial status                                                                 | Page2/Line 55-60                    | Abstract/Paragraph13         |
| Numbers analysed    | Number of participants analysed in each group                                | Page2/Line 46-47                    | Abstract/Paragraph12         |
| Outcome             | For the primary outcome, a result for each group and the estimated effect size and its precision | Page2/Line 54-60                    | Abstract/Paragraph13         |
| Harms               | Important adverse events or side effects                                      | N/A                                 | N/A                          |
| Conclusions | General interpretation of the results | Page11/Line318-321 | Conclusions/Paragraph1 |
|-------------|--------------------------------------|---------------------|------------------------|
| Trial registration | Registration number and name of trial register | Page3/Line77 | Registered ID |
| Funding | Source of funding | No | No |

*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.*