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| **Section** | **Item no** | **Checklist item** | **Extension** | **Tagged section** | **Page no** |
| **Title and abstract** |  |  |  |  |  |
| Randomised trial | 1a | Identification as a randomised trial in the title |  |  |  |
| Structured summary | 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) |  |  |  |
| **Introduction** |  |  |  |  |  |
| Background/rationale | 2a | Scientific background and explanation of rationale |  |  |  |
| Objectives/hypotheses | 2b | Specific objectives or hypotheses |  |  |  |
| **Methods** |  |  |  |  |  |
| Description trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio |  |  |  |
| Changes to methods | 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons |  |  |  |
| Participants | 4a | Eligibility criteria for participants |  |  |  |
| Settings/locations data | 4b | Settings and locations where the data were collected |  |  |  |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered |  |  |  |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed |  |  |  |
| Changes to outcomes | 6b | Any changes to trial outcomes after the trial commenced, with reasons |  |  |  |
| Sample size | 7a | How sample size was determined |  |  |  |
| Interim analyses | 7b | When applicable, explanation of any interim analyses and stopping guidelines |  |  |  |
| Randomisation:Sequence generation | 8a | Method used to generate the random allocation sequence |  |  |  |
| Type of randomisation | 8b | Type of randomisation; details of any restriction (such as blocking and block size) |  |  |  |
| 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 |  |  |  |
| Randomisation: 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 |  |  |  |
| Similarity of interventions | 11b | If relevant, description of the similarity of interventions |  |  |  |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes |  |  |  |
| Methods for additional analyses | 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 |  |  |  |
| Losses and exclusions | 13b | For each group, losses and exclusions after randomisation, together with reasons |  |  |  |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up |  |  |  |
| Reason end/stop | 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) |  |  |  |
| Absolute/relative effect sizes | 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 |  |  |  |
| 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 |  |  |  |