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| **Appendix S1. CONSORT checklist** | | | |
| **Section/Topic** | **Item No** | **Checklist item** | **Reported on page No** |
| **Title and abstract** | | | |
|  | 1a | Identification as a randomized trial in the title | 1 |
| 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) | 2 |
| **Introduction** | | | |
| **Background and objectives** | 2a | Scientific background and explanation of rationale | 3-5 |
| 2b | Specific objectives or hypotheses | 5 |
| **Methods** | | | |
| **Trial design** | 3a | Description of trial design (such as parallel, factorial) including allocation ratio | 5-6 |
| 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | N / A |
| **Participants** | 4a | Eligibility criteria for participants | 6 |
| 4b | Settings and locations where the data were collected | 5-6 |
| **Interventions** | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | 8-13 |
| **Outcomes** | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | 13-14 |
| 6b | Any changes to trial outcomes after the trial commenced, with reasons | N /A |
| **Sample size** | 7a | How sample size was determined | 6 |
| 7b | When applicable, explanation of any interim analyses and stopping guidelines | N / A |
| **Randomization:** |  |  |  |
| **Sequence generation** | 8a | Method used to generate the random allocation sequence | 6 |
| 8b | Type of randomization; details of any restriction (such as blocking and block size) | 6 |
| **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 | 6 |
| **Implementation** | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | 6 |
| **Blinding** | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | 7-8 |
| 11b | If relevant, description of the similarity of interventions | 11 |
| **Statistical methods** | 12a | Statistical methods used to compare groups for primary and secondary outcomes | 14 |
| 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | 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 analyzed for the primary outcome | Figure 1 |
| 13b | For each group, losses and exclusions after randomization, together with reasons | Figure 1 |
| **Recruitment** | 14a | Dates defining the periods of recruitment and follow-up | Figure 1 |
| 14b | Why the trial ended or was stopped | N / A |
| **Baseline data** | 15 | A table showing baseline demographic and clinical characteristics for each group | Tables 1 and 2 |
| **Numbers analyzed** | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | Figure 1 |
| **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) | Table 2, Table 3 |
| 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended | N / A |
| **Ancillary analyses** | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory | Table 4 |
| **Harms** | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | N / A |
| **Discussion** | | | |
| **Limitations** | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | 24-25 |
| **Generalizability** | 21 | Generalizability (external validity, applicability) of the trial findings | 24-25 |
| **Interpretation** | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | 21-25 |
| **Other information** | | |  |
| **Registration** | 23 | Registration number and name of trial registry | 26 |
| **Protocol** | 24 | Where the full trial protocol can be accessed, if available | 26 |
| **Funding** | 25 | Sources of funding and other support (such as supply of drugs), role of funders | 26 |