

**Appendix S1. CONSORT checklist**

| Section/Topic                           | Item No | Checklist item                                                                                                                                                                              | Reported on page No |
|-----------------------------------------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| <b>Title and abstract</b>               |         |                                                                                                                                                                                             |                     |
|                                         | 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                   |
| <b>Introduction</b>                     |         |                                                                                                                                                                                             |                     |
| <b>Background and objectives</b>        | 2a      | Scientific background and explanation of rationale                                                                                                                                          | 3                   |
|                                         | 2b      | Specific objectives or hypotheses                                                                                                                                                           | 3                   |
| <b>Methods</b>                          |         |                                                                                                                                                                                             |                     |
| <b>Trial design</b>                     | 3a      | Description of trial design (such as parallel, factorial) including allocation ratio                                                                                                        | 4                   |
|                                         | 3b      | Important changes to methods after trial commencement (such as eligibility criteria), with reasons                                                                                          | N / A               |
| <b>Participants</b>                     | 4a      | Eligibility criteria for participants                                                                                                                                                       | 4                   |
|                                         | 4b      | Settings and locations where the data were collected                                                                                                                                        | 4                   |
| <b>Interventions</b>                    | 5       | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered                                                       | 5-6                 |
| <b>Outcomes</b>                         | 6a      | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed                                                                          | 6-7                 |
|                                         | 6b      | Any changes to trial outcomes after the trial commenced, with reasons                                                                                                                       | N / A               |
| <b>Sample size</b>                      | 7a      | How sample size was determined                                                                                                                                                              | 4                   |
|                                         | 7b      | When applicable, explanation of any interim analyses and stopping guidelines                                                                                                                | N / A               |
| <b>Randomization:</b>                   |         |                                                                                                                                                                                             |                     |
| <b>Sequence generation</b>              | 8a      | Method used to generate the random allocation sequence                                                                                                                                      | 4                   |
|                                         | 8b      | Type of randomization; details of any restriction (such as blocking and block size)                                                                                                         | 4                   |
| <b>Allocation concealment mechanism</b> | 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 | 4                   |
| <b>Implementation</b>                   | 10      | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions                                                                     | 4                   |
| <b>Blinding</b>                         | 11a     | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how                                                    | 5                   |

|                                                             |     |                                                                                                                                                   |                      |
|-------------------------------------------------------------|-----|---------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
|                                                             | 11b | If relevant, description of the similarity of interventions                                                                                       | 6                    |
| <b>Statistical methods</b>                                  | 12a | Statistical methods used to compare groups for primary and secondary outcomes                                                                     | 7                    |
|                                                             | 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses                                                                  | N / A                |
| <b>Results</b>                                              |     |                                                                                                                                                   |                      |
| <b>Participant flow (a diagram is strongly recommended)</b> | 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             |
| <b>Recruitment</b>                                          | 14a | Dates defining the periods of recruitment and follow-up                                                                                           | Figure 1             |
|                                                             | 14b | Why the trial ended or was stopped                                                                                                                | N / A                |
| <b>Baseline data</b>                                        | 15  | A table showing baseline demographic and clinical characteristics for each group                                                                  | Tables 1, 2, and 6   |
| <b>Numbers analyzed</b>                                     | 16  | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups           | Figure 1             |
| <b>Outcomes and estimation</b>                              | 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, 3, 5, and 6 |
|                                                             | 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended                                                       | N / A                |
| <b>Ancillary analyses</b>                                   | 18  | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory         | Table 4              |
| <b>Harms</b>                                                | 19  | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)                                             | N / A                |
| <b>Discussion</b>                                           |     |                                                                                                                                                   |                      |
| <b>Limitations</b>                                          | 20  | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses                                  | 12                   |
| <b>Generalizability</b>                                     | 21  | Generalizability (external validity, applicability) of the trial findings                                                                         | 12                   |
| <b>Interpretation</b>                                       | 22  | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence                                     | 11-12                |
| <b>Other information</b>                                    |     |                                                                                                                                                   |                      |
| <b>Registration</b>                                         | 23  | Registration number and name of trial registry                                                                                                    | 13                   |
| <b>Protocol</b>                                             | 24  | Where the full trial protocol can be accessed, if available                                                                                       | 13                   |
| <b>Funding</b>                                              | 25  | Sources of funding and other support (such as supply of drugs), role of funders                                                                   | 13                   |