| 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 4                      | title                        |
|                               | 1b      | Structured summary of trial design, methods, results, and conclusions           | page 2/line 38–64                  | Abstract                     |
| Introduction                  | 2a      | Scientific background and explanation of rationale                              | page 3/line 74–108                 | 1–2                          |
|                               | 2b      | Specific objectives or hypotheses                                               | page 4/line 108–113                | 2                            |
| Methods                       | 3a      | Description of trial design (such as parallel, factorial) including allocation ratio | page 4/line 123–125                | methods/paragraph 1          |
|                               | 3b      | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | NA                                 | NA                           |
| Participants                  | 4a      | Eligibility criteria for participants                                          | page 4/line 119–125                | methods/paragraph 1          |
|                               | 4b      | Settings and locations where the data were collected                            | page 4/line 126                    | methods/paragraph 1          |
| Interventions                 | 5       | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | page 5/line 138–141                | methods/paragraph 3          |
| Outcomes                      | 6a      | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | page 5/line 140–154                | methods/paragraph 3          |
|                               | 6b      | Any changes to trial outcomes after the trial commenced, with reasons           | NA                                 | NA                           |
| Sample size                   | 7a      | How sample size was determined                                                  | NA                                 | NA                           |
|                               | 7b      | When applicable, explanation of any interim analyses and stopping guidelines     | NA                                 | NA                           |
| Randomisation                 | 8a      | Method used to generate the random allocation sequence                          | NA                                 | NA                           |
|                               | 8b      | Type of randomisation; details of any restriction (such as blocking and block size) | NA                                 | NA                           |
| 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 | NA                                 | NA                           |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | NA | NA |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | page 4/line 123 | methods/paragraph 1 |
| 11b | If relevant, description of the similarity of interventions | NA | NA |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes | page 5/line 166-177 | methods/paragraph 5 |
| 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | NA | NA |
| 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 | page 6/line 180-192 | results/paragraph 1 |
| 13b | For each group, losses and exclusions after randomisation, together with reasons | NA | NA |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | page 6/line 182-183 | results/paragraph 1 |
| 14b | Why the trial ended or was stopped | NA | NA |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group | NA | NA |
| Numbers analysed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | NA | NA |
| 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) | page 7/line 191-214 | results/paragraph 2-3 |
| 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended | NA | NA |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory | N/A | N/A |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | page 7/line 218-224 | results/paragraph 1 |
| Discussion | Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | page 9/line 302-306 | limitations/paragraph 1 |
| Generalisability | 21 | Generalisability (external validity, applicability) of the trial findings | page 10/line 310-315 | conclusions/paragraph 1 |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | page 7-9/line 228-298 | |
| Other information | Registration | 23 | Registration number and name of trial registry | page 4/line 118-119 | methods/paragraph 1 |
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/line4                         | title                               |
| Authors *       | Contact details for the corresponding author                                | page1/line6-12                      | Authors                             |
| Trial design    | Description of the trial design (e.g. parallel, cluster, non-inferiority)    | page1/line4                         | title                               |
| Methods         |                                                                              |                                     |                                     |
| Participants    | Eligibility criteria for participants and the settings where the data were collected | page2/line45                        | Abstract/paragraph2                 |
| Interventions   | Interventions intended for each group                                         | page2/line46-48                     | Abstract/paragraph2                 |
| Objective       | Specific objective or hypothesis                                             | page2/line41-44                     | Abstract/paragraph1                 |
| Outcome         | Clearly defined primary outcome for this report                             | page2/line49-52                     | Abstract/paragraph2                 |
| 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                             | N/A                                 | N/A                                 |
| Recruitment     | Trial status                                                                 | N/A                                 | N/A                                 |
| Numbers analysed | Number of participants analysed in each group                               | page2/line54                        | Abstract/paragraph3                 |
| Outcome         | For the primary outcome, a result for each group and the estimated effect size and its precision | page2/line58-60                     | Abstract/paragraph3                 |
| Harms           | Important adverse events or side effects                                     | N/A                                 | N/A                                 |
| Conclusions          | General interpretation of the results | page2/line61-63 | Abstract/paragraph4 |
|----------------------|----------------------------------------|-----------------|---------------------|
| Trial registration   | Registration number and name of trial register | page2/line64 | Abstract/paragraph5 |
| Funding              | Source of funding                       | NA              | NA                  |

* this item is specific to conference abstracts

From: Hopewell S, Clarke M, Moher D, et al. CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. PLoS Med. 2008;5(1):e20

Article information: https://dx.doi.org/10.21037/atm-21-3188

*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.