**CONSORT 2010 checklist of information to include when reporting a randomised trial**

| 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/Line1                         | Title/Paragraph1             |
| 1b                   | Structured summary of trial design, methods, results, and conclusions           | Page5/Line2-Page5/Line15            | Abstract/Paragraph2-4        |
| **Introduction**     |         |                                                                                  |                                     |                             |
| 2a                   | Scientific background and explanation of rationale                             | Page5/Line15-16                     | Introduction/Paragraph1      |
| 2b                   | Specific objectives or hypotheses                                              | Page7/Line15-19                     | Introduction/Paragraph1      |
| **Methods**          |         |                                                                                  |                                     |                             |
| Trial design         | 3a      | Description of trial design (such as parallel, factorial) including allocation ratio | Page9/Line6-Page9/Line11            | Methods/Paragraph1-2        |
|                      | 3b      | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | NA                                  | NA                          |
| Participants         | 4a      | Eligibility criteria for participants                                           | Page9/Line17-22                     | Methods/Paragraph2           |
|                      | 4b      | Settings and locations where the data were collected                            | Page12/Line9-12                     | CONSORT checklist/Paragraph1 |
| Interventions        | 5       | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | Page9/Line20-Page11/Line14          | Interventions and procedures/Paragraph2-4 |
| Outcomes             | 6a      | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | NA                                  | NA                          |
|                      | 6b      | Any changes to trial outcomes after the trial commenced, with reasons           | NA                                  | NA                          |
| Sample size          | 7a      | How sample size was determined                                                  | Page12/Line8-12                     | CONSORT checklist/Paragraph1 |
|                      | 7b      | When applicable, explanation of any interim analyses and stopping guidelines    | NA                                  | NA                          |
| Randomisation:       |         |                                                                                  |                                     |                             |
| Sequence generation  | 8a      | Method used to generate the random allocation sequence                           | Page9/Line6-Page9/Line10            | Methods/Paragraph2           |
|                      | 8b      | Type of randomisation; details of any restriction (such as blocking and block size) | Page9/Line6                          | Methods/Paragraph2           |
| 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 | Page9/Line7-Page9/Line10            | Methods/Paragraph2           |
| Implementation | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | Page6/Li ne12-13 | Study population/Parag raph1 |
|---------------|-----------------------------------------------------------------------------------------------------------------|------------------|-----------------------------|
| Blinding      | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | Page6/Li ne14    | Study population/Parag raph1 |
|               | If relevant, description of the similarity of interventions                                                      | NA               | NA                          |
| Statistical methods | Statistical methods used to compare groups for primary and secondary outcomes                                    | Page6/Li ne14    | Page6/Li ne14                |
|               | Methods for additional analyses, such as subgroup analyses and adjusted analyses                                  | NA               | NA                          |
| Results       | Participant flow (a diagram is strongly recommended)                                                              | Page14/Li ne16   | Results/Parag raph1          |
|               | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome | Page14/Li ne13-15| Results/Parag raph1          |
|               | For each group, losses and exclusions after randomisation, together with reasons                                      | NA               | NA                          |
| Recruitment   | Dates defining the periods of recruitment and follow-up                                                            | Page14/Li ne13   | Results/Parag raph1          |
|               | Why the trial ended or was stopped                                                                                  | NA               | NA                          |
| Baseline data | A table showing baseline demographic and clinical characteristics for each group                                     | Tabl e1          | Tabl e1                     |
| Numbers analysed | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | Page14/Li ne16-Page15/Li ne4 | Results/Parag raph1          |
| Outcomes and estimation | For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) | Page14/Li ne12-Page25/Li ne5 | Results/Parag raph1-12       |
|               | For binary outcomes, presentation of both absolute and relative effect sizes is recommended                          | NA               | NA                          |
| Ancillary analyses | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory | NA               | NA                          |
| Harms         | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)             | Page14/Li ne16   | Results/Parag raph12         |
| Discussion    | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses    | Page30/Li ne17   | Methods/Paragraph5           |
| Generalisability | Generalisability (external validity, applicability) of the trial findings                                          | Page28/Li ne5-21 | Page28/Li ne5-21             |
| Interpretation | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence        | Page27/Li ne7    |                              |
| Other information | Registration number and name of trial registry                                                                     | Page6/Li ne13    | Methods/Paragraph5           |
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                                    | Page 1/Line 4                      | Title                        |
| Authors *             | Contact details for the corresponding author                                | Page 1/Line 27                     | Corresponding author         |
| Trial design          | Description of the trial design (e.g. parallel, cluster, non-inferiority)    | NA                                  | NA                           |
| Methods               |                                                                            |                                     |                              |
| Participants          | Eligibility criteria for participants and the settings where the data were collected | NA                                  | N/A                          |
| Interventions         | Interventions intended for each group                                         | Page 2/Line 10-19                  | Abstract/Methods             |
| Objective             | Specific objective or hypothesis                                            | Page 2/Line 9-10                   | Abstract/Methods             |
| Outcome               | Clearly defined primary outcome for this report                             | Page 2/Line 8-19                   | Abstract/Methods             |
| Randomization         | How participants were allocated to interventions                            | Page 2/Line 9-10                   | Abstract/Methods             |
| Blinding (masking)    | Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment | NA                                  | N/A                          |
| Results               |                                                                            |                                     |                              |
| Numbers randomized    | Number of participants randomized to each group                              | Page 2/Line 10                     | Abstract/Methods             |
| Recruitment           | Trial status                                                                 | NA                                  | N/A                          |
| Numbers analysed      | Number of participants analysed in each group                                | NA                                  | N/A                          |
| Outcome               | For the primary outcome, a result for each group and the estimated effect size and its precision | Page 2/Line 20-30                  | Abstract/Results             |
| Harms                 | Important adverse events or side effects                                     | NA                                  | N/A                          |

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.
| Conclusions | General interpretation of the results | Page/Line 31-33 | Abstract/Conclusions |
|-------------|-------------------------------------|-----------------|----------------------|
| Trial registration | Registration number and name of trial register | NA | NA |
| 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-21-3888
*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.