### 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                             | N/A: as this was a pre-randomised trial study                                    | NA                                 |
| 1b                  | Structured summary of trial design, methods, results, and conclusions (for specific guidance see Table 2) | Page 3-4/Line 65-89                 | Abstract/Para 1-Para 4            |
| **Introduction**    |         |                                                                                 |                                     |                              |
| 2a                  | Scientific background and explanation of rationale                           | Page 5-6/Line 103-143               | Introduction/Para 1-Para 5       |
| 2b                  | Specific objectives or hypotheses                                            | Page 6/Line 139-143                 | Introduction/Para 5             |
| **Methods**         |         |                                                                                 |                                     |                              |
| 3a                  | Description of trial design (such as parallel, factorial) including allocation ratio | Page 7-9/Line 146-213               | Methods/Para 1-11               |
| 3b                  | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | NA                                  | NA                               |
| **Participants**    | 4a      | Eligibility criteria for participants                                         | Page 7/Line 156-157                 | Methods/Para 3                |
| 4b                  | Settings and locations where the data were collected                          | Page 7/Line 161-167                 | Methods/Para 4                  |
| **Interventions**   | 5       | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | Page 8/Line 168-173                 | Methods/Para 5                |
| **Outcomes**        | 6a      | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | Page 7/Line 147-150                 | Methods/Para 1                |
| 6b                  | Any changes to trial outcomes after the trial commenced, with reasons         | NA                                  | NA                               |
| **Sample size**     | 7a      | How sample size was determined                                                  | Page 7/Line 147-150                 | Methods/Para 1                |
| 7b                  | When applicable, explanation of any interim analyses and stopping guidelines   | NA                                  | NA                               |
| **Randomisation:**  |         |                                                                                 |                                     |                              |
| 8a                  | Method used to generate the random allocation sequence                         | Page 7/Line 163-165                 | Methods/Para 4                  |
| 8b                  | Type of randomisation; details of any restriction (such as blocking and block size) | Page 7/Line 163-165                 | Methods/Para 4                  |
| **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 | Page 7/Line 163-165                 | Methods/Para 4                |
| Implementation       | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | Page7/Line163-165 | Methods/Para4 |
|----------------------|----|--------------------------------------------------------------------------------------------------|------------------|---------------|
| Blinding             | 11a| If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | Page7/Line165    | Methods/Para4 |
|                      | 11b| If relevant, description of the similarity of interventions | Page8/Line168-173 | Methods/Para5 |
| Statistical methods  | 12a| Statistical methods used to compare groups for primary and secondary outcomes | Page8-9/Line187-192 | Methods/Para8 |
|                      | 12b| Methods for additional analyses, such as subgroup analyses and adjusted analyses | Page8-9/Line187-192 | Methods/Para8 |

**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 | NA: This has been previously reported as | NA |
|------------------------------------------------------|----|---------------------------------------------------------------------------------------------------------------------------------|------------------|-------|
|                                                      | 13b| For each group, losses and exclusions after randomisation, together with reasons | NA: This has been | NA |
| Recruitment                                          | 14a| Dates defining the periods of recruitment and follow-up | Page7/Line151    | Methods/Para2 |
|                                                      | 14b| Why the trial ended or was stopped | NA: not stopped | NA |
| Baseline data                                        | 15 | A table showing baseline demographic and clinical characteristics for each group | NA: This has been | 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: This has been previously reported as | 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) | Table 2 and 3    | Table 2 and 3 |
|                                                      | 17b| For binary outcomes, presentation of both absolute and relative effect sizes is recommended | Table 2          | Table 2 |
| Ancillary analyses                                   | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory | Figure 1.2, Table 2, 3 | Figure 1.2, Table 2, 3 |
| Harms                                               | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | NA               | NA |

**Discussion**

| Limitations                                          | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | Page14-15/Line312-321 | Discussion/Para11 |
| Generalisability                                    | 21 | Generalisability (external validity, applicability) of the trial findings | Page11/Line246-249 | Discussion/Para11 |
| Interpretation                                       | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | Page11-14/Line246-321 | Discussion/Para1-11 |

**Other information**

| Registration                                         | 23 | Registration number and name of trial registry | Page2/Line53-55 | Acknowledgements |
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                                    | N/A: as this was a                | NA                          |
| Authors *                 | Contact details for the corresponding author                                | Page2/Line34-43                   | Title Page                  |
| Trial design              | Description of the trial design (e.g., parallel, cluster, non-inferiority)   | Page7/Line147-150                 | Methods/Para1               |
| Methods                   |                                                                              |                                    |                             |
| Participants              | Eligibility criteria for participants and the settings where the data were collected | Page7/Line161-165 | Methods/Para4               |
| Interventions             | Interventions intended for each group                                         | Page7-9/Line146-213               | Methods/Para1-11            |
| Objective                 | Specific objective or hypothesis                                              | Page6/Line139-143                 | Introduction/Para5          |
| Outcome                   | Clearly defined primary outcome for this report                              | Page6/Line139-143                 | Introduction/Para5          |
| Randomization             | How participants were allocated to interventions                              | Page7-9/Line146-213               | Methods/Para1-11            |
| Blinding (masking)        | Whether or not participants, caregivers, and those assessing the outcomes were blinded to group assignment | Page7-9/Line146-213               | Methods/Para1-11            |
| Results                   |                                                                              |                                    |                             |
| Numbers randomized        | Number of participants randomized to each group                               | NA: previously reported,           | NA                          |
| Recruitment               | Trial status                                                                  | Page7/Line151-155                 | Methods/Para2               |
| Numbers analysed          | Number of participants analysed in each group                                 | Page7/Line147-150                 | Methods/Para1               |
| Outcome                   | For the primary outcome, a result for each group and the estimated effect size and its precision | Page10-11/Line215-244             | Results                     |
| Harms                     | Important adverse events or side effects                                      | Page7/Line147-150                 | Methods/Para1               |
| Conclusions | General interpretation of the results | Page15/Line324-334 | Conclusions |
|-------------|--------------------------------------|--------------------|-------------|
| Trial registration | Registration number and name of trial register | Page2/Line53-55 | Acknowledgements |
| Funding | Source of funding | Page2/Line53-55 | Acknowledgements |

* 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: http://dx.doi.org/10.21037/atm-20-2048

*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.