## 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-Line3-5                       | Title Page/Paragraph1          |
| 1b                       | Structured summary of trial design, methods, results, and conclusions (for specific guidance see Table 2) | Page1-Line2-24-42                  | ABSTRACT/Paragraph1-           |
| **Introduction**         |         |                                                                                 |                                     |                              |
| 2a                       | Scientific background and explanation of rationale                            | Page2-Line48-67                    | Introduction/Paragraph1-2      |
| 2b                       | Specific objectives or hypotheses                                              | Page3-Line68-76                    | Introduction/Paragraph3        |
| **Methods**              |         |                                                                                 |                                     |                              |
| Trial design             | 3a      | Description of trial design (such as parallel, factorial) including allocation ratio | Page4-Line80, 94                   | Methods/Paragraph1, 4         |
|                          | 3b      | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | N/A                                | There are no important       |
| Participants             | 4a      | Eligibility criteria for participants                                           | Page4-Line87-89                    | Methods/Paragraph2            |
|                          | 4b      | Settings and locations where the data were collected                            | Page4-Line83-84                    | Methods/Paragraph1            |
| Interventions            | 5       | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | Page 4-Line 101-Page 7/Line 168    | Methods/Paragraph5-10         |
| Sample size              | 7a      | How sample size was determined                                                  | Page8-Line193-199                  | Methods/Paragraph15           |
|                          | 7b      | When applicable, explanation of any interim analyses and stopping guidelines    | N/A                                | There are no applicable       |
| Randomisation:           |         |                                                                                 |                                     |                              |
| Sequence generation      | 8a      | Method used to generate the random allocation sequence                           | Page4-Line 93-94                   | Methods/Paragraph4            |
|                          | 8b      | Type of randomisation; details of any restriction (such as blocking and block size) | Page4-Line 93-94                   | Methods/Paragraph4            |
| Allocation concealment   | 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 | Page4-Line 98-100                  | Methods/Paragraph4            |

*Note: The checklist is a guideline for reporting randomised trials and includes specific items to be included in the reporting of such trials. The report should include the items listed to ensure completeness and transparency in the reporting of trial results.*
| Section                  | Paragraph | Description                                                                                                                                                                                                 | Page | Line   | Method/Paragraph |
|--------------------------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|--------|------------------|
| Implementation           | 10        | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions                                                                                   |      |        | Methods/Paragraph4 |
| Blinding                 | 11a       | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how                                                                  |      |        | Methods/Paragraph4 |
|                          | 11b       | If relevant, description of the similarity of interventions                                                                                                                                                |      |        | Methods/Paragraph4 |
| Statistical methods      | 12a       | Statistical methods used to compare groups for primary and secondary outcomes                                                                                                                               |      |        | Methods/Paragraph15 |
|                          | 12b       | Methods for additional analyses, such as subgroup analyses and adjusted analyses                                                                                                                           |      |        | Methods/Paragraph15 |
| Results                  | 13a       | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome                                                              |      |        | Results/Paragraph1 |
|                          | 13b       | For each group, losses and exclusions after randomisation, together with reasons                                                                                                                           |      |        | Figure 4 |
| Recruitment              | 14a       | Dates defining the periods of recruitment and follow-up                                                                                                                                                |      |        | Methods/Paragraph1 |
|                          | 14b       | Why the trial ended or was stopped                                                                                                                                                                       |      |        | N/A |
| Baseline data            | 15        | A table showing baseline demographic and clinical characteristics for each group                                                                                                                        | Table|        | Table 1 |
| Numbers analysed         | 16        | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups                                                                  |      |        | Results/Paragraph1 |
| 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)                                                      |      |        | Results/Paragraph2-3 |
|                          | 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                                                                   |      |        | N/A |
| Harms                    | 19        | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)                                                                                                   |      |        | N/A |
| Discussion               | 20        | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses                                                                                         |      |        | Discussion/Paragraph7 |
| Generalisability         | 21        | Generalisability (external validity, applicability) of the trial findings                                                                                                                               |      |        | Discussion/Paragraph2 |
| Interpretation           | 22        | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence                                                                                           |      |        | Discussion/Paragraph2-6 |
| Other information        | 23        | Registration number and name of trial registry                                                                                                                                                    |      |        | Methods/Paragraph1 |
*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](http://www.consort-statement.org).

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/Line3-5                       | Title Page/Paragraph1        |
| Authors *                | Contact details for the corresponding author                                  | Page1/Line13-15                    | Title Page/Paragraph5        |
| Trial design             | Description of the trial design (e.g. parallel, cluster, non-inferiority)     | Page1/Line3-5                       | Title Page/Paragraph1        |
| Participants             | Eligibility criteria for participants and the settings where the data were collected | Page4/Line 83-84, 87-89            | Methods/Paragraph1, 2        |
| Interventions            | Interventions intended for each group                                          | Page 4/Line 101-Page 7/            | Methods/Paragraph5-10        |
| Objective                | Specific objective or hypothesis                                              | Page3/Line68-76                    | Introduction/Paragraph3     |
| Outcome                  | Clearly defined primary outcome for this report                              | Page7 /Line 183-184                | Methods/Paragraph3           |
| Randomization            | How participants were allocated to interventions                              | Page4 /Line 93-94, 98-100          | Methods/Paragraph4           |
| Blinding (masking)       | Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment | Page4 /Line 100                    | Methods/Paragraph4           |
| Results                  | Number of participants randomized to each group                               | Page8 /Line 209-Page9 /            | Results/Paragraph1           |
| Recruitment              | Trial status                                                                  | Page8 /Line 209-Page9 /            | Results/Paragraph1           |
| Numbers analysed         | Number of participants analysed in each group                                 | Page8 /Line 209-Page9 /            | Results/Paragraph1           |
| Outcome                  | For the primary outcome, a result for each group and the estimated effect size and its precision | Page9 /Line214-216                 | Results/Paragraph2           |
| Harms                    | Important adverse events or side effects                                      | N/A                                 | There are no important      |
| Conclusions   | General interpretation of the results | Page12 /Line 314-316 | Conclusions/Paragraph1 |
|---------------|----------------------------------------|-----------------------|------------------------|
| Trial registration | Registration number and name of trial register | Page4 /Line 84-85 | Methods/Paragraph1 |
| Funding       | Source of funding                       | N/A                   | There are no sources of |

*This item is specific to conference abstracts*

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*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.*