| 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 3                      | Title                         |
|                    | 1b      | Structured summary of trial design, methods, results, and conclusions (for specific guidance see Table 2)                                                                                              | Page 3/Line 49-73                 | Abstract                      |
| Introduction       | 2a      | Scientific background and explanation of rationale                                                                                                                                                | Page 4-5/Line 75-110              | Introduction                  |
|                    | 2b      | Specific objectives or hypotheses                                                                                                                                                                   | Page 5/Line 110-116              |                               |
| Methods            | 3a      | Description of trial design (such as parallel, factorial) including allocation ratio                                                                                                                    | Page 6/Line 120-121              | Methods/ Patients             |
|                    | 3b      | Important changes to methods after trial commencement (such as eligibility criteria), with reasons                                                                                                   |                                    |                               |
| Participants       | 4a      | Eligibility criteria for participants                                                                                                                                                            | Page 6/Line 123-24               | Methods/ Patients             |
|                    | 4b      | Settings and locations where the data were collected                                                                                                                                             | Page 6/Line 123                  |                               |
| Interventions      | 5       | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered                                                                  | Page 6/Line 124-127, 7-8/Line 161-188 | Methods                     |
| Outcomes           | 6a      | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed                                                                                 | Page 7/Line 145-153              | Methods/Clinical outcomes     |
|                    | 6b      | Any changes to trial outcomes after the trial commenced, with reasons                                                                                                                            |                                    |                               |
| Sample size        | 7a      | How sample size was determined                                                                                                                                                                  | Page 7 Line 154-160              | Methods/Sample size           |
| Randomisation:     | 7b      | When applicable, explanation of any interim analyses and stopping guidelines                                                                                                                         |                                    |                               |
| Sequence generation| 8a      | Method used to generate the random allocation sequence                                                                                                                                           | Page 6/Line 127-132              | Methods/ Patients             |
|                    | 8b      | Type of randomisation; details of any restriction (such as blocking and block size)                                                                                                              |                                    |                               |
| 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 6/Line 127-132              | Methods/ Patients enrollment and study design |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | Page 6/ Line 127-132 | Methods/ Patients enrollment and study |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | Page 6/Line 133 | Methods/ Patients enrollment and study |
| | 11b | If relevant, description of the similarity of interventions | not applicable |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes | Page 8-9/Line 194-207 | Methods/ Statistical |
| | 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | Page 9/Line 190-193 | Methods/ Statistical |
| 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 8-9/ Line 209-222 | Results Figure 1 |
| | | 13b | For each group, losses and exclusions after randomisation, together with reasons | Page 8-9/ Line 209-222 | Results |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | Page 9/Line 209-211 | Results |
| | 14b | Why the trial ended or was stopped | not applicable |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group | Page 21 | Table 2 |
| Numbers analysed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | Page 10-12/ Line 235-266; Page 23 | Results/Paragraph 2-4 |
| 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) | not applicable |
| | 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended | not applicable |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory | not applicable |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | not applicable |
| Discussion | Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | Page 14/Line 321-328 | Discussion/ Strenghts and |
| Generalisability | 21 | Generalisability (external validity, applicability) of the trial findings | Page 12 Line 277-284 | Discussion |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | Page 12-13/Line 279-310 | Discussion |
| Other information | Registration | 23 | Registration number and name of trial registry | Page 4/ Line 75-76 | Abstract |
*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                                    | Page 3 Line 59                      | Abstract                     |
| **Authors * **            | Contact details for the corresponding author                                  | not applicable                      |                              |
| **Trial design**          | Description of the trial design (e.g. parallel, cluster, non-inferiority)    | not applicable                      |                              |
| **Methods**               |                                                                              |                                     |                              |
| Participants              | Eligibility criteria for participants and the settings where the data were collected | Page 3/ Line 60-61                  | Abstract                     |
| Interventions             | Interventions intended for each group                                         | Page 3/ Line 61-64                  | Abstract                     |
| Objective                 | Specific objective or hypothesis                                              | Page 3/ Line 61-64                  | Abstract                     |
| Outcome                   | Clearly defined primary outcome for this report                              | Page 3/ Line 61-62                  | Abstract                     |
| Randomization             | How participants were allocated to interventions                              | Page 3/ Line 59                     | Abstract                     |
| Blinding (masking)        | Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment | not applicable                      |                              |
| **Results**               |                                                                              |                                     |                              |
| Numbers randomized        | Number of participants randomized to each group                              | Page 3/ Line 59-60                  | Abstract                     |
| Recruitment               | Trial status                                                                  | not applicable                      |                              |
| Numbers analysed          | Number of participants analysed in each group                                 | Page 3/ Line 61-62                  | Abstract                     |
| Outcome                   | For the primary outcome, a result for each group and the estimated effect size and its precision | Page 3/ Line 65-68                  | Abstract                     |
| Harms                     | Important adverse events or side effects                                      | not applicable                      |                              |
| Conclusions | General interpretation of the results | Page 3/ Line 71-72 | Abstract |
|------------|--------------------------------------|-------------------|-----------|
| Trial registration | Registration number and name of trial register | Page 4/ Line 75-76 | Abstract |
| Funding | Source of funding | not applicable |

* 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

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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.