## 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                             | page 1/lines 1-2                    | cover page, title            |
|                               | 1b      | Structured summary of trial design, methods, results, and conclusions (for specific guidance see Table 2) | page 2/lines 17-44                  | Abstract                     |
| **Introduction**              |         |                                                                                  |                                      |                              |
| Background and objectives     | 2a      | Scientific background and explanation of rationale                             | page 3/lines 48-67                  | introduction paragraph 1-2   |
|                               | 2b      | Specific objectives or hypotheses                                               | page 3/lines 68-72                  | introduction paragraph 3     |
| **Methods**                   | 3a      | Description of trial design (such as parallel, factorial) including allocation ratio | pages 4/lines 72-88                 | mat&met: paragraphs 1-2      |
|                               | 3b      | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | page 4, lines 81-83                 | mat&met: paragraph 1         |
|                               |         |                                                                                  |                                      |                              |
| Participants                  | 4a      | Eligibility criteria for participants                                          | page 4/lines 76-81                  | mat&met: paragraph 1         |
|                               | 4b      | Settings and locations where the data were collected                           | page 4/lines 74-75                  | mat&met: 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/lines 124-136                | phys ter met: paragraph 1-2  |
| **Outcomes**                  | 6a      | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | page 6/lines 137-143                | phys ter meth: paragraph 3   |
|                               | 6b      | Any changes to trial outcomes after the trial commenced, with reasons          | page 7/lines 158-159                | statistical methods          |
| Sample size                   | 7a      | How sample size was determined                                                  | page 6/lines 145-146                | statistical methods          |
|                               | 7b      | When applicable, explanation of any interim analyses and stopping guidelines    | page 4/line 76                      | mat&met: paragraph 1         |
| Randomisation:                |         |                                                                                  |                                      |                              |
| Sequence generation           | 8a      | Method used to generate the random allocation sequence                          | page 4/lines 85-86                  | mat&met: paragraph 1         |
|                               | 8b      | Type of randomisation; details of any restriction (such as blocking and block size) | page 4/lines 87-88                  | mat&met: paragraph 2         |
| 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 4/lines 85-86                  | mat&met: paragraph 1         |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | page 4/lines 83-85 | mat&met: paragraph 2 |
|----------------|----|------------------------------------------------------------------|---------------------|----------------------|
| Blinding       | 11a| If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | page 11/lines 305-307 | discussion: paragraph 9 |
|                | 11b| If relevant, description of the similarity of interventions | pages 5-6/lines 124-132 | phys ter met: para 1-2 |
| Statistical methods | 12a| Statistical methods used to compare groups for primary and secondary outcomes | page 6/lines 145-159 | stat met: paragraph 1-2 |
|                | 12b| Methods for additional analyses, such as subgroup analyses and adjusted analyses | page 6, lines 145-151 | statistical methods |

**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 5/lines 87-90 | mat&met: paragraph 2 |
|                                                       | 13b| For each group, losses and exclusions after randomisation, together with reasons | page 4/lines 81-83 | mat&met: paragraph 1 |
| Recruitment                                           | 14a| Dates defining the periods of recruitment and follow-up | page 4/lines 74-75 | mat&met: paragraph 1 |
|                                                       | 14b| Why the trial ended or was stopped | page 4/line 76 | mat&met: paragraph 1 |
| Baseline data                                         | 15 | A table showing baseline demographic and clinical characteristics for each group | page 18 | 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 | page 4/lines 87-90 | mat&met: paragraph 2 |
| 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) | pages 9-10 lines 178-225 | results: para 3-7 |
|                                                       | 17b| For binary outcomes, presentation of both absolute and relative effect sizes is recommended | pages 8, lines 145-146 | statistical methods |
| Ancillary analyses                                    | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory | page 10, lines 206-212 | results: paragraph 5 |
| Harms                                                  | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | page 11/lines 226-228 | results: paragraph 8 |

**Discussion**

| Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | page 14, lines 289-313 | discussion: para 6-9 |
| Generalisability         | 21 | Generalisability (external validity, applicability) of the trial findings | page 13, lines 270-271 | discussion: paragraph 3 |
| Interpretation            | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | page 15, lines 325-331 | conclusion |

**Other information**

| Registration | 23 | Registration number and name of trial registry | page 1, lines 13-14 | cover page |
*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 1, lines 1-2                  | title                        |
| Authors *                   | Contact details for the corresponding author                                | page 1, lines 10-11                | cover page                   |
| **Trial design**            | Description of the trial design (e.g. parallel, cluster, non-inferiority)   | page 3, lines 68-72                | introduction: para 3         |
| **Methods**                 |                                                                            |                                    |                              |
| Participants                | Eligibility criteria for participants and the settings where the data were collected | page 5/lines 74-81                | mat&met: paragraph 1         |
| Interventions               | Interventions intended for each group                                        | page 5/lines 87-88                 | mat&met: paragraph 2         |
| Objective                   | Specific objective or hypothesis                                             | page 3/lines 67-71                 | introduction: paragraph 3    |
| Outcome                     | Clearly defined primary outcome for this report                              | page 10, lines 191-195             | results: paragraph 4         |
| Randomization               | How participants were allocated to interventions                              | page 5/lines 87-88                | mat&met: paragraph 2         |
| Blinding (masking)          | Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment | page 14, lines 305-307             | discussion: paragraph 9      |
| **Results**                 |                                                                            |                                    |                              |
| Numbers randomized          | Number of participants randomized to each group                              | page 4/lines 87-88                | mat&met: paragraph 2         |
| Recruitment                 | Trial status                                                                 | page 4, line 76                    | mat&met: paragraph 1         |
| Numbers analysed            | Number of participants analysed in each group                                | page 7, lines 137-140              | phys ter met: para 1         |
| Outcome                     | For the primary outcome, a result for each group and the estimated effect size and its precision | page 8, lines 191-205              | results: para 4              |
| Harms                       | Important adverse events or side effects                                      | page 11, lines 226-228             | results: paragraphs 8        |
| Conclusions               | General interpretation of the results | page 15, lines 325-331 | conclusion       |
|---------------------------|---------------------------------------|------------------------|------------------|
| Trial registration        | Registration number and name of trial register | page 1, lines 13-14     | cover page       |
| Funding                   | Source of funding                      | page 24/lines 477-479  | funding statement|

* 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/jtd-20-1668

*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.