



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

| Section/Topic             | Item No | Checklist item  | Reported in section  |
|---------------------------|---------|---|--|
| <b>Title and abstract</b> |         |   |  |
|                           | 1a      | Identification as a randomised trial in the title   | Title  |
|                           | 1b      | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)               | Abstract   |
| <b>Introduction</b>       |         |   |  |
| Background and objectives | 2a      | Scientific background and explanation of rationale  | Introduction   |
|                           | 2b      | Specific objectives or hypotheses   | Introduction   |
| <b>Methods</b>            |         |   |  |
| Trial design              | 3a      | Description of trial design (such as parallel, factorial) including allocation ratio  | Materials and Methods: Trial design                          |
|                           | 3b      | Important changes to methods after trial commencement (such as eligibility criteria), with reasons                                    | Materials and Methods; Table 1                               |
| Participants              | 4a      | Eligibility criteria for participants   | Materials and Methods: Recruitment of Practices and Patients |
|                           | 4b      | Settings and locations where the data were collected  | Materials and Methods: Recruitment of Practices and Patients |
| Interventions             | 5       | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | Materials and Methods: Interventions                         |
| Outcomes                  | 6a      | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed                    | Materials and Methods: Outcomes                              |
|                           | 6b      | Any changes to trial outcomes after the trial commenced, with reasons   | Materials and Methods; Table 1                               |

|  |     |   |  |
|--|-----|---|--|
| Sample size  | 7a  | How sample size was determined  | Materials and<br>Methods: Sample size                                    |
|  | 7b  | When applicable, explanation of any interim analyses and stopping guidelines  | N/A  |
| Randomisation:<br>Sequence<br>generation                   | 8a  | Method used to generate the random allocation sequence  | Materials and<br>Methods:<br>Randomisation and<br>allocation concealment |
|  | 8b  | Type of randomisation; details of any restriction (such as blocking and block size)   | Materials and<br>Methods:<br>Randomisation and<br>allocation concealment |
| Allocation<br>concealment<br>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 | Materials and<br>Methods:<br>Randomisation and<br>allocation concealment |
| Implementation   | 10  | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions   | Materials and<br>Methods:<br>Randomisation and<br>allocation concealment |
| Blinding   | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how  | Materials and<br>Methods: Blinding                                       |
|  | 11b | If relevant, description of the similarity of interventions   | Materials and<br>Methods: Interventions                                  |
| Statistical methods  | 12a | Statistical methods used to compare groups for primary and secondary outcomes   | Materials and<br>Methods: Analyses                                       |
|  | 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses  | Materials and<br>Methods: Analyses                                       |
| <b>Results</b>   |     |   |  |
| Participant flow (a<br>diagram is strongly<br>recommended) | 13a | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome  | Results  |
|  | 13b | For each group, losses and exclusions after randomisation, together with reasons  | Figure   |
| Recruitment  | 14a | Dates defining the periods of recruitment and follow-up   | Results  |

|                          |     |   |   |
|--------------------------|-----|---|---|
|                          | 14b | Why the trial ended or was stopped  | N/A   |
| Baseline data            | 15  | A table showing baseline demographic and clinical characteristics for each group  | Tables 2 and 3                                    |
| Numbers analysed         | 16  | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups           | Tables 4 to 7                                     |
| 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) | Tables 4 to 7                                     |
|                          | 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended   | Table 6   |
| 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   |
| <b>Discussion</b>        |     |   |   |
| Limitations              | 20  | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses                                  | Discussion: Strengths and Weaknesses of the Study |
| Generalisability         | 21  | Generalisability (external validity, applicability) of the trial findings   | Discussion  |
| Interpretation           | 22  | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence                                     | Discussion  |
| <b>Other information</b> |     |   |   |
| Registration             | 23  | Registration number and name of trial registry  | Abstract  |
| Protocol                 | 24  | Where the full trial protocol can be accessed, if available   | Protocol S1                                       |
| Funding                  | 25  | Sources of funding and other support (such as supply of drugs), role of funders   | Acknowledgements                                  |

\*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).