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

| Section/Topic | Item No | Checklist item | Reported on page No |
|---|---|---|---|
| **Title and abstract** | | | |
| | 1a | Identification as a randomised trial in the title | p1 |
| | 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) | p4 |
| **Introduction** | | | |
| Background and objectives | 2a | Scientific background and explanation of rationale | p4 |
| | 2b | Specific objectives or hypotheses | p4 |
| **Methods** | | | |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio | p5 |
| | 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | Not applicable |
| Participants | 4a | Eligibility criteria for papers | p5 |
| | 4b | Settings and locations where the data were collected | p8 |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | p5-6 |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | p6-7 |
| | 6b | Any changes to trial outcomes after the trial commenced, with reasons | p8 |
| Sample size | 7a | How sample size was determined | p7 |
| | 7b | When applicable, explanation of any interim analyses and stopping guidelines | Not applicable |
| Randomisation: | | | |
| Sequence generation | 8a | Method used to generate the random allocation sequence | p5 |
| | 8b | Type of randomisation; details of any restriction (such as blocking and block size) | p5 |
| 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 | p6 |
| Implementation | 10 | Who generated the random allocation sequence, who identified papers, and who assigned papers to interventions | p6 |
| Blinding | 11a | If done, who was blinded after assignment to interventions and how | p6 |

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| | 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 | p9 |
| | 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | p9-10 |
| **Results** | | | |
| Participant flow (a diagram is strongly recommended) | 13a | For each group, the numbers of papers which were randomly assigned, received the intended intervention, and were analysed for the primary outcome | p10; p18 Flowchart (Figure 1) |
| | 13b | For each group, losses and exclusions after randomisation, together with reasons | p10; p18 Flowchart (Figure 1 |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | p5 |
| | 14b | Why the trial ended or was stopped | Not applicable |
| Baseline data | 15 | A table showing baseline characteristics for each group | p17 |
| Numbers analysed | 16 | For each group, number of papers (denominator) included in each analysis and whether the analysis was by original assigned groups | p17 |
| 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) | p20-24 |
| | 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 | p25-26 |
| 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 | p14 |
| Generalisability | 21 | Generalisability (external validity, applicability) of the trial findings | p13 |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | p13-14 |
| **Other information** | | | |
| Registration | 23 | Registration number and name of trial registry | Not applicable |
| Protocol | 24 | Where the full trial protocol can be accessed, if available | p5 |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders | p15 |

*We modified the CONSORT checklist (amendments in red) to apply to our RCT in publishing where manuscripts were randomised to the intervention and control groups.