



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

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>			
	1a	Identification as a randomised trial in the title	Title Page (Page 1)
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Abstract (Page 1)
<b>Introduction</b>			
Background and objectives	2a	Scientific background and explanation of rationale	Introduction, Paragraph 2 (Page 2)
	2b	Specific objectives or hypotheses	Introduction, Final Paragraph (Page 3)
<b>Methods</b>			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Methods, Study Design (Page 4)
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Not applicable (no changes made)
Participants	4a	Eligibility criteria for participants	Methods, Participants (Page 4)
	4b	Settings and locations where the data were collected	Methods, Study Design (Page 4)
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Methods, Anesthetic

			Techniques (Page 5-6)
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Methods, Outcomes (Page 6)
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Not applicable (no changes made)
Sample size	7a	How sample size was determined	Methods, Sample Size Calculation (Page 6)
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not applicable (no interim analyses)
Randomisation: Sequence generation	8a	Method used to generate the random allocation sequence	Methods, Randomizatio n (Page 5)
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Methods, Randomizatio n (Page 5)
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	Methods, Randomizatio n (Page 5)
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Methods, Randomizatio n (Page 5)
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Methods, Blinding (Page 6)
	11b	If relevant, description of the similarity of interventions	Not applicable (no placebo)

			used)
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Methods, Statistical Analysis (Page 7)
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Methods, Statistical Analysis (Page 7)
<b>Results</b>			
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	Results, Participant Flow (Page 8) and Fig. 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Results, Participant Flow (Page 8)
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Methods, Study Design (Page 4)
	14b	Why the trial ended or was stopped	Not applicable (trial completed as planned)
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Results, Baseline Characteristic s (Page 9) and 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, Statistical Analysis (Page 9)

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, Tables 2-4 (Page 10-12)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable (no binary primary outcomes)
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Results, Subgroup Analysis (Page 13)
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Results, Complications (Page 12) and Table 4
<b>Discussion</b>			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Discussion, Limitations (Page 15)
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Discussion, Generalisability (Page 15)
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Discussion, Interpretation (Page 16)
<b>Other information</b>			
Registration	23	Registration number and name of trial registry	Abstract (Page 1) and Methods, Trial Registration (Page 4)
Protocol	24	Where the full trial protocol can be accessed, if available	Not available

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Funding	25 Sources of funding and other support (such as supply of drugs), role of funders	Declaration of Interest (Page 17)
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Citation: Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. *BMC Medicine*. 2010;8:18. © 2010 Schulz et al. This is an Open Access article distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/2.0>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

\*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).