

# 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	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction Background and objectives	2a	Scientific background and explanation of rationale	4
	2b	Specific objectives or hypotheses	5
Methods Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5
Participants	4a	Eligibility criteria for participants	5
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6
Sample size	6b	Any changes to trial outcomes after the trial commenced, with reasons	0
	7a	How sample size was determined	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	0
Randomisation: Sequence generation	8a	Method used to generate the random allocation sequence	5
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	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	5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	5

	assessing outcomes) and how		
	If relevant, description of the similarity of interventions	11b	0
Statistical methods	Statistical methods used to compare groups for primary and secondary outcomes	12a	7 and 8
	Methods for additional analyses, such as subgroup analyses and adjusted analyses	12b	
<b>Results</b>			
Participant flow (a diagram is strongly recommended)	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	13a	8
Recruitment	For each group, losses and exclusions after randomisation, together with reasons	13b	5
	Dates defining the periods of recruitment and follow-up	14a	5
	Why the trial ended or was stopped	14b	0
Baseline data	A table showing baseline demographic and clinical characteristics for each group	15	Attached Table 1
Numbers analysed	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	16	Attached in table 1
Outcomes and estimation	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	17a	0
	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	17b	0
Ancillary analyses	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	18	Attached tables 2,3,6,8 &10
Harms	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	19	5
<b>Discussion</b>			
Limitations	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	20	0
Generalisability	Generalisability (external validity, applicability) of the trial findings	21	0
Interpretation	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	22	9-12
<b>Other information</b>			
Registration	Registration number and name of trial registry	23	2
Protocol	Where the full trial protocol can be accessed, if available	24	19
Funding	Sources of funding and other support (such as supply of drugs), role of funders	25	1

\*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).