



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	page 1
			1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	page 2
Introduction					
Background and objectives			2a	Scientific background and explanation of rationale	page 3-4
			2b	Specific objectives or hypotheses	page 4
Methods					
Trial design			3a	Description of trial design (such as parallel, factorial) including allocation ratio	page 4
			3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	page 4
Participants			4a	Eligibility criteria for participants	page 5
			4b	Settings and locations where the data were collected	page 5
Interventions			5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	page 5 + protocol paper
Outcomes			6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	page 7
			6b	Any changes to trial outcomes after the trial commenced, with reasons	no changes
Sample size			7a	How sample size was determined	protocol paper
			7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:					
Sequence generation			8a	Method used to generate the random allocation sequence	p. 4
			8b	Type of randomisation; details of any restriction (such as blocking and block size)	protocol paper
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	protocol paper
Implementation			10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	line 131-136
Blinding			11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	line 136-137

		assessing outcomes) and how	
Statistical methods	11b	If relevant, description of the similarity of interventions	NA
	12a	Statistical methods used to compare groups for primary and secondary outcomes	p. 8–9
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	p. 8–9
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 6 (diagram)
	13b	For each group, losses and exclusions after randomisation, together with reasons	page 6 (diagram)
Recruitment	14a	Dates defining the periods of recruitment and follow-up	page 4
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	page 9
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	page 14
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)	page 14
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	suppl. materials
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	line 426 –431
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	pages 15–16
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	pages 15–16
Other information			
Registration	23	Registration number and name of trial registry	line 147
Protocol	24	Where the full trial protocol can be accessed, if available	protocol published
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	page 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.