

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	5, 6
	2b	Specific objectives or hypotheses	6
Methods Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7, 8
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	No changes
	4a	Eligibility criteria for participants	7
	4b	Settings and locations where the data were collected	7, 8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8, 9
	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9
Sample size	6b	Any changes to trial outcomes after the trial commenced, with reasons	9, 11, 12
	7a	How sample size was determined	9
Randomisation: Sequence	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not applicable
	8a	Method used to generate the random allocation sequence	8
Allocation concealment mechanism	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8
	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	8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	8

	assessing outcomes) and how	
	If relevant, description of the similarity of interventions	Not relevant
11b	Statistical methods used to compare groups for primary and secondary outcomes	9, 10
12a	Statistical methods used to compare groups for primary and secondary outcomes	9, 10
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	9, 10
Results		
13a	Participant flow (a diagram is strongly recommended)	11
13b	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	11
14a	For each group, losses and exclusions after randomisation, together with reasons	7
14b	Dates defining the periods of recruitment and follow-up	11
15	Why the trial ended or was stopped	11, Table
16	A table showing baseline demographic and clinical characteristics for each group	11
17a	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	11, 12, Figs. 1-3, Suppl. Table, Suppl. Figure
17b	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	11, 12
18	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	11, 12
19	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	12
20	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion		
20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	13, 14
21	Generalisability (external validity, applicability) of the trial findings	14, 15
22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	15, 16
Other information		
23	Registration number and name of trial registry	2
24	Where the full trial protocol can be accessed, if available	18
25	Sources of funding and other support (such as supply of drugs), role of funders	18

*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.