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			
	١a	Identification as a randomised trial in the title	
	١b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
Introduction			
Background and objectives	٢a	Scientific background and explanation of rationale	
	٢b	Specific objectives or hypotheses	
Methods			
Trial design	٣a	Description of trial design (such as parallel, factorial) including allocation ratio	
	٣b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	٤a	Eligibility criteria for participants	
	٤b	Settings and locations where the data were collected	
Interventions	٥	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	٦a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	٦b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	٧a	How sample size was determined	
	٧b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	٨a	Method used to generate the random allocation sequence	
	٨b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	٩	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	
Implementation	١٠	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	

Blinding	١١a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
	١١b	If relevant, description of the similarity of interventions	
Statistical methods	١٢a	Statistical methods used to compare groups for primary and secondary outcomes	
	١٢b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	١٣a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
	١٣b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	١٤a	Dates defining the periods of recruitment and follow-up	
	١٤b	Why the trial ended or was stopped	
Baseline data	١٥	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	١٦	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	١٧a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as ٩٥٪ confidence interval)	
	١٧b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	١٨	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	١٩	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	٢٠	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	٢١	Generalisability (external validity, applicability) of the trial findings	
Interpretation	٢٢	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	٢٣	Registration number and name of trial registry	
Protocol	٢٤	Where the full trial protocol can be accessed, if available	
Funding	٢٥	Sources of funding and other support (such as supply of drugs), role of funders	

Citation: Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT ٢٠١٠ Statement: updated guidelines for reporting parallel group randomised trials. BMC Medicine. ٢٠١٠;٨:١٨.

*We strongly recommend reading this statement in conjunction with the CONSORT ٢٠١٠ 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.