



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

Section/Topic	Item No	Checklist item	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title and abstract				
	1a	Identification as a randomised trial in the title	Page 1/ Line3-4	manuscript title! paragraph 1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see Table 2)	Page 31 Line4-20	abstract/ paragraph 1
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Page 31 Line4-20	introduction/ paragraph 1-2
	2b	Specific objectives or hypotheses	Page2-4/ line 25-30, 1-6	introduction/ paragraph 2
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	page4,line 30-33	methods/ paragraph 1
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA	NA
Participants	4a	Eligibility criteria for participants	page 5, line3-5	methods! paragraph 1
	4b	Settings and locations where the data were collected	page 5, line 11-17	methods
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	page5-7,line 32 -34, 1-34, 1-11	methods/ paragraph 2
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	NA	NA
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA	NA
Sample size	7a	How sample size was determined	NA	NA
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA	NA
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence	NA	NA
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	NA	NA
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	NA	NA

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	NA	NA
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	NA	NA
	11b	If relevant, description of the similarity of interventions	NA	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	page8/line 1-3	methods/paragraph 12
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	NA	NA
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 8-9/line 32-33, 1-4	results/paragraph 4
	13b	For each group, losses and exclusions after randomisation, together with reasons	NA	NA
Recruitment	14a	Dates defining the periods of recruitment and follow-up	page 5/line1-2	methods/paragraph 1
	14b	Why the trial ended or was stopped	NA	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	page 8/line 7-13	results/paragraph 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	page8-9/line31-33,1-21	results/paragraph4-5
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)	NA	NA
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	page9/line 23-25	results/paragraph 6
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	page 8/line 20-28	results/paragraph 5-6
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	NA	NA
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	page 12/line 27-30	acknowledgment/ paragraph 1
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	page 9/line 31-34	discussion/paragraph 1
Other information				
Registration	23	Registration number and name of trial registry	NA	NA

Protocol	24	Where the full trial protocol can be accessed, if available	NA	NA
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	page 12/line 27-30	acknowledgment/ paragraph 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.

Table 2 Items to include when reporting a randomized trial in a journal or conference abstract

Item	Description	Reported on Page Number/Line Number	Reported on Section/Paragraph
Title	Identification of the study as randomized	page 5/line 1-2	methods/paragraph 1
Authors *	Contact details for the corresponding author	page 1/line 16-19	title page /paragraph 1
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	page 5-6/line 21-34,1-12	methods/paragraph 3-5
Methods			
Participants	Eligibility criteria for participants and the settings where the data were collected	page 5/line 4-11	methods/paragraph 1
Interventions	Interventions intended for each group	page 6/line 13-25, page 7/1-12	methods/paragraph 6,8
Objective	Specific objective or hypothesis	NA	NA
Outcome	Clearly defined primary outcome for this report	page 7/line 14-32	methods/paragraph 9-11
Randomization	How participants were allocated to interventions	page 5/line 1-2	methods/paragraph 1
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	NA	NA
Results			
Numbers randomized	Number of participants randomized to each group	page 8/line 7-13	results/paragraph 1
Recruitment	Trial status	NA	NA
Numbers analysed	Number of participants analysed in each group	page 12/line 27-30	results/paragraph 6
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	NA	NA
Harms	Important adverse events or side effects	page 8/line 20-28	results/paragraph 2-3

Conclusions	General interpretation of the results	page 12/line 17-23	discussion/paragraph 2
Trial registration	Registration number and name of trial register	NA	NA
Funding	Source of funding	page 12/line 27-30	acknowledgment/ paragraph 1

** this item is specific to conference abstracts*

From: Hopewell S, Clarke M, Moher D, et al. CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. PLoS Med. 2008;5(1):e20

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*As the checklist was provided upon initial submission, the page number/line number reported may be changed due to copyediting and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.