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 line 2	Title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see Table 2)	Page 2 lines 26-44	Methods
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Page 3-4, lines 51-79	Introduction/P1-3
	2b	Specific objectives or hypotheses	Page 4, lines 78-81	Introduction/P3-4
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Page 4 and 5, lines 84-101	Methods/P1
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Page 4 and 5, lines 87-94	Methods/P1
Participants	4a	Eligibility criteria for participants	Page 4, lines 89-93	Methods/P1
	4b	Settings and locations where the data were collected	Page 4, lines 85-88	Methods/P1
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Page 5, lines 106-124	Methods/P2
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Page 6, lines 126-149	Methods/P3
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a	n/a
Sample size	7a	How sample size was determined	Page 7, lines 151-157	Methods/P4
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a	n/a
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence	Page 5, line 106	Methods/P2
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Page 5, line 106	Methods/P2
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	Page 5, line 106	Methods/P2

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Page 5, line 106	Methods/P2
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Page 5, line 123-124	Methods/P2
	11b	If relevant, description of the similarity of interventions	n/a	n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Page 7, lines 151-157	Methods/P4
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Page 7, lines 151-157	Methods/P2
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 7, lines 160-167	Results/P1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Page 7, lines 165-167	Results/P1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	P4, lines 85-88	Methods/P1
	14b	Why the trial ended or was stopped	n/a	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	n/a	Table1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	n/a	All tables
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)	All tables	All tables
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	All tables	All tables
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	All tables	All tables
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a	n/a
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Page 11, lines 262-270	Discussion/P6
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Page 11-12, lines 273-277	Discussion/P7
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Page 8-10, lines200-261	Discussion/P1-P5
Other information				
Registration	23	Registration number and name of trial registry	P5, line 102	Methods/P1

Protocol	24	Where the full trial protocol can be accessed, if available	n/a	n/a
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 12, line 280-281	Funding/P1

*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 1, line 2	Title
Authors *	Contact details for the corresponding author	page 1, lines 13-17	Author section
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	n/a	n/a
Methods			
Participants	Eligibility criteria for participants and the settings where the data were collected	Page 4-5, lines 85-101	Methods/P1
Interventions	Interventions intended for each group	Page 4, lines 106-124	Methods/P2
Objective	Specific objective or hypothesis	Page 4, lines 81-82	Introduction/P4
Outcome	Clearly defined primary outcome for this report	Page 6, lines 126-149	Methods/P3
Randomization	How participants were allocated to interventions	Page 5, line 106-110	Methods/P2
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	Page 5, line 123-124	Methods/P2
Results			
Numbers randomized	Number of participants randomized to each group	Page7, line 160-173	Results and all tables
Recruitment	Trial status	n/a	n/a
Numbers analysed	Number of participants analysed in each group	Page7, line 160-173	Results and all tables
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	Page7-8, line 171-191	All figures and tables
Harms	Important adverse events or side effects	n/a	n/a

Conclusions	General interpretation of the results	page 10-11, lines 273-277	Conclusion/P1
Trial registration	Registration number and name of trial register	P5, line 102	Methods/PI
Funding	Source of funding	Page 12, line 280-281	Funding/P1

** this item is specific to conference abstracts*

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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.