

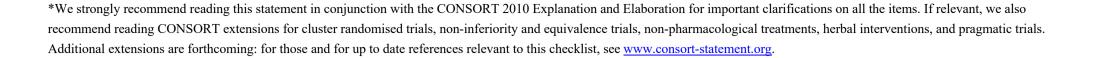
CONSORT 2010 checklist of information to include when reporting a randomised trial*

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)	1
Introduction			
Background and	2a	Scientific background and explanation of rationale	2-3
objectives	2b	Specific objectives or hypotheses	2-3
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	3
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	none
Participants	4a	Eligibility criteria for participants	3
	4b	Settings and locations where the data were collected	3
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	3
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	4
	6b	Any changes to trial outcomes after the trial commenced, with reasons	none
Sample size	7a	How sample size was determined	3, 5
·	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence	8a	Method used to generate the random allocation sequence	3
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	3
Allocation	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers),	Not applied,
concealment mechanism		describing any steps taken to conceal the sequence until interventions were assigned	see p. 4
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	4, Author contribution's
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	Not applied,

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		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	see p. 4 n/a
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	5
Statistical methods			5
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	<u> </u>
Results			
Participant flow (a	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and	5, CONSORT
diagram is strongly		were analysed for the primary outcome	flow diagram
recommended)			in
			Supplement 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	ditto
Recruitment	14a	Dates defining the periods of recruitment and follow-up	3
	14b	Why the trial ended or was stopped	3
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was	3, Table 1,
		by original assigned groups	Supplement 1
Outcomes and	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its	Tables 1-3
estimation		precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Table 1
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Not applied
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	None
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	8 – 11
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	8 – 11
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	8 – 11
•		interpretation conditions with receite, balancing benefite and narme, and conditioning earler relevant evidence	
Other information	00		A1 () 0
Registration	23	Registration number and name of trial registry	Abstract, 3
Protocol	24	Where the full trial protocol can be accessed, if available	See #23
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	13,
			Declarations

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