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 3 / Line 95	Introduction
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see Table 2)	Page 2 / Line 35-56	Abstract
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Page 2-3 / Line 63-96	Introduction
	2b	Specific objectives or hypotheses	Page 3 / Line 89-93	Introduction
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Page 6 / Line 184-188	Results, Figure 1
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	No important changes	
Participants	4a	Eligibility criteria for participants	Page 4 / Line 105-118	Methods
	4b	Settings and locations where the data were collected	Page 6 / Line 174-175	Methods
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Page 4 / Line 125-146 Page 6 / Line 186-187	Methods
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Page 5 / Line 161-173	Methods
	6b	Any changes to trial outcomes after the trial commenced, with reasons	No changes	
Sample size	7a	How sample size was determined	Page 4 / Line 119-123	Methods
	7b	When applicable, explanation of any interim analyses and stopping guidelines	None	
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence	Page 4 / Line 127-128	Methods
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Page 4 / Line 127-128	Methods
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 4 / Line 128-130	Methods

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Page 4 / Line 129-132	Methods
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Page 4 / Line 129-130	Methods
	11b	If relevant, description of the similarity of interventions	Page 4 / Line 132-133	Methods
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Page 6 / Line 175-182	Methods
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Page 6 / Line 175-182	Methods
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 6 / Line 186-192	Results, Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Page 6 / Line 186-192	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page 6 / Line 186	Results
	14b	Why the trial ended or was stopped	Page 6 / Line 192-194	Results
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 2	Table 2
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Table 2	Table 2
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)	Page 7 / Line 213-215	Results
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	None	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Page 7 / Line 207-212	Results
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	Page 9 / Line 280-285	Discussion
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Page 9 / Line 276-279	Discussion
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Page 9 / Line 277-280	Discussion
Other information				
Registration	23	Registration number and name of trial registry	None	

Protocol	24	Where the full trial protocol can be accessed, if available	None	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page 9 / Line 297-300	Acknowdgement

*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 3	Title
Authors *	Contact details for the corresponding author	Page 1 / Line 28-30	Title
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	Figure 1	Figure 1
Methods			
Participants	Eligibility criteria for participants and the settings where the data were collected	Page 4 / Line 105-118	Methods
Interventions	Interventions intended for each group	Page 4-5 / Line 125-146	Methods
Objective	Specific objective or hypothesis	Page 5-6 / Line 169-173	Methods
Outcome	Clearly defined primary outcome for this report	Page 5 / Line 163-165	Methods
Randomization	How participants were allocated to interventions	Page 4 / Line 127-133	Methods
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	Page 4 / Line 127-133	Methods
Results			
Numbers randomized	Number of participants randomized to each group	Page 6 / Line 186-192	Results
Recruitment	Trial status	Page 6 / Line 186-192	Results
Numbers analysed	Number of participants analysed in each group	Page 6 / Line 190-192	Results
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	Page 6 / Line 196-198	Results
Harms	Important adverse events or side effects	None	

Conclusions	General interpretation of the results	Page 9 / Line 290-293	Conclusions
Trial registration	Registration number and name of trial register	None	
Funding	Source of funding	Page 9 / Line 297-300	Acknowdgement

* *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.