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 1	Title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see Table 2)	Page 2/Line 35-65	abstract/Paragraph1-4
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Page3/Line74-88	Introduction/Paragraph1
	2b	Specific objectives or hypotheses	Page 4/ Line 100-108	Introduction/Paragraph1
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Page 4/Line 113-page5/line131	methods/Paragraph1
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/ A	N/A
Participants	4a	Eligibility criteria for participants	Page 4/ Line 113-114	methods/Paragraph1
	4b	Settings and locations where the data were collected	Page 4/ Line113-116	methods/Paragraph1
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Page 5/Line 136-142	Study methods/Paragraph1
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Page 7/Line 198-page8/232	Observation indexes/Paragraph1
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/ A	N/A
Sample size	7a	How sample size was determined	N/ A	N/ A
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/ A	N/A
Randomisation:				
Sequence	8a	Method used to generate the random allocation sequence	Page 4/ Line113-116	methods/Paragraph1

generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	N/A	N/A
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	N/A	N/A
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	N/ A	N/ A
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	N/ A	N/ A
	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 8/Line 234-241	Statistical methods/Paragraph1
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	N/ A	N/ A
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 15/Line 515-516	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	N/ A	N/ A
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page 8, Line 266	Results/paragraph1
	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	Page 15, Line 476-478	Table 1
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	N/ A
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 8/Line 244-page9/line298	Results/paragraph1-4
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/ A	N/ A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/ A	N/ A
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/Line 358-page12/line369	Limitations/paragraph1

Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Page 9Line272-page11/line354	**Discussion**/paragraph1
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Page 9/Line272-page11/line354	**Discussion**/paragraph1
Other information				
Registration	23	Registration number and name of trial registry	Page 2/Line65	Abstract/Paragraph 5
Protocol	24	Where the full trial protocol can be accessed, if available	Page 13/line 426	Footnote/Paragraph 1
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page13/Line394-395	Funding/paragraph1

*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 1	Title
Authors *	Contact details for the corresponding author	Page 1/ Line 5-6	Authors
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	Page 2/ Line 35-64	Abstract/paragraph1-4
Methods			
Participants	Eligibility criteria for participants and the settings where the data were collected	Page 2/ Line 41	Abstract/paragraph2
Interventions	Interventions intended for each group	Page 2/Line 44-47	Abstract/paragraph 2
Objective	Specific objective or hypothesis	N/ A	N/ A
Outcome	Clearly defined primary outcome for this report	Page 2/Line 48-59	Abstract/paragraph 3
Randomization	How participants were allocated to interventions	Page 2/ Line 42	Abstract/paragraph2
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	N/ A	N/ A
Results			
Numbers randomized	Number of participants randomized to each group	Page 4/ Line 113-114	methods/Paragraph1
Recruitment	Trial status	N/ A	N/ A
Numbers analysed	Number of participants analysed in each group	Page 8/Line 244-page9/line298	Results/paragraph1-4
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	Page 8/Line 244-page9/line298	Results/paragraph1-4
Harms	Important adverse events or side effects	N/ A	N/ A

Conclusions	General interpretation of the results	Page 12/ Line 373-390	Conclusions/Paragraph1
Trial registration	Registration number and name of trial register	Page 13/Line403	**Footnote**/paragraph2
Funding	Source of funding	Page13/Line394-395	Funding/paragraph1

** 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.