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	Page1/Line1-4	Title/Paragraph1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see Table 2)	Page3/Line33-51	Abstract/Paragraph1-3
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Page4-6/Line55-108	Introduction/Paragraph1-4
	2b	Specific objectives or hypotheses	Page6/Line109-112	Introduction/Paragraph5
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Page6/Line116-118	Study design/Paragraph1
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Page7/Line122-131	Study population/Paragraph1
Participants	4a	Eligibility criteria for participants	Page7/Line122-131	Study population/Paragraph1
	4b	Settings and locations where the data were collected		
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Page8-10/Line148-205	Treatment and management/Para1-3
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Page12/Line245-252	Endpoints/Paragraph1
	6b	Any changes to trial outcomes after the trial commenced, with reasons		
Sample size	7a	How sample size was determined	Page12/Line255-260	Sample size/Paragraph1
	7b	When applicable, explanation of any interim analyses and stopping guidelines		
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence	Page7/Line138-144	Randomization and blinding/Para1
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Page7/Line138-139	Randomization and blinding/Para1
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	Page7/Line139-141	Randomization and blinding/Para1

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Page7/Line139-143	Randomization and blinding/Para1
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Page7/Line141-142	Randomization and blinding/Para1
	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	Page13/Line266-276	Statistical analysis/Paragraph2-3
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Page13/Line269-270	Statistical analysis/Paragraph2
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	Figure1	Figure1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Page11/Line236-241	Withdrawal criteria/Paragraph1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page12/Line244-245	Endpoints/Paragraph1
	14b	Why the trial ended or was stopped	Page13/Line267-269	Statistical analysis/Paragraph2
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Tabel1	Table1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Page12-13/Line262-264	Statistical analysis/Paragraph1
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)	Page13/Line271-276	Statistical analysis/Paragraph2
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Page13/Line271-274	Statistical analysis/Paragraph2
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Page13/Line271-275	Statistical analysis/Paragraph3
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	Page10/Line207-214	Safety/Paragraph1
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Page14/Line288-289	Discussion/Paragraph1
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Page14/Line293-295	Discussion/Paragraph2
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Page14/Line301-306	Discussion/Paragraph3
Other information				
Registration	23	Registration number and name of trial registry	Page3/Line52	Abstract/Paragraph5

Protocol	24	Where the full trial protocol can be accessed, if available		
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page15/Line311-315	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	Page1/Line1-4	Title/Paragraph1
Authors *	Contact details for the corresponding author	Page1/Line13-17	Title/Paragraph9-12
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	Page6/Line116-118	Study design/Paragraph1
Methods			
Participants	Eligibility criteria for participants and the settings where the data were collected	Page7/Line122-131	Study population/Paragraph1
Interventions	Interventions intended for each group	Page8-10/Line162-204	Treatment and management /Paragraph2-3
Objective	Specific objective or hypothesis	Page6/Line109-111	Backgroud/Paragraph5
Outcome	Clearly defined primary outcome for this report	Page12/Line244-245	Endpoints/Paragraph1
Randomization	How participants were allocated to interventions	Page6/Line139-141	Randomization and blinding/Paragraph1
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	Page7/Line141-143	Randomization and blinding/Paragraph1
Results			
Numbers randomized	Number of participants randomized to each group	Page6/Line139-141	Randomization and blinding/Paragraph1
Recruitment	Trial status	Page13/Line279-280	Discussion/Paragraph1
Numbers analysed	Number of participants analysed in each group	Page13/Line266-276	Statistical analysis/Paragraph2-3
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	Page13-14/Line285-287	Discussion/Paragraph1
Harms	Important adverse events or side effects	Page10/Line207-214	Safety/Paragraph1

Conclusions	General interpretation of the results	Page6/Line116-118	
Trial registration	Registration number and name of trial register	Page6/Line116-118	
Funding	Source of funding	Page6/Line116-118	

** 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 copy editing and may not be referable in the published version. In this case, the section/paragraph may be used as an alternative reference.