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	Page3/Line 65-66;	Titile
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see Table 2)	Page3,4/Line 68-97;	abstract
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Page5,6Line 112-141;	introduction para2,3,4
	2b	Specific objectives or hypotheses	page7Line 142-147	introduction para5
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	page8,LINE177,	Methods para4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	No	No
Participants	4a	Eligibility criteria for participants	page7.8 /line 160-172	Methods para3
	4b	Settings and locations where the data were collected	page9line 191-206	Methods para5.6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	page9line 191-206	Methods para5.6
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	page9line 201-204	Methods para6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	No	No
Sample size	7a	How sample size was determined	page17 line377-392	Discussion para5
	7b	When applicable, explanation of any interim analyses and stopping guidelines	No	No
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence	page8line 182-184	Methods para4
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	page8line 182-184	Methods para4
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	page8line 182-184	Methods para4

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	page9 line188-189	Methods para4
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	page 9 line204-206	Methods para6
	11b	If relevant, description of the similarity of interventions	No	NO
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	page11 page246-259	Methods para11
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	page11 page246-259	Methods para11
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	Fig1	FIG1
	13b	For each group, losses and exclusions after randomisation, together with reasons	page12 line262-271	Results para1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	page13 line273-294	Results para2
	14b	Why the trial ended or was stopped	no	no
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table1	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 line262-271	Results para1
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)	Table2	table2
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	page13 line273-294	Results para2
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NO	no
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	no	no
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	page17 line371-392	Discussion para5
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	page18 line 394-404	conclusion
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	page16 linw 360-370	discussion para4
Other information				
Registration	23	Registration number and name of trial registry	Page4line94-96	abstract para5

Protocol	24	Where the full trial protocol can be accessed, if available	Fig1	FIG1
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	page2line48-51	Funding

*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	Page3/Line 65-66;	Titile
Authors *	Contact details for the corresponding author	Page1/Line 20-32	Title page
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	page3/Line 56-63	abstract/para2
Methods			
Participants	Eligibility criteria for participants and the settings where the data were collected	page7.8 /line 160-172	Methods para3
Interventions	Interventions intended for each group	page9line 191-206	Methods para5.6
Objective	Specific objective or hypothesis	page7Line 142-147	introduction para5
Outcome	Clearly defined primary outcome for this report	Table2	Table2
Randomization	How participants were allocated to interventions	page8line 182-184	Methods para4
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	page 9 line204-206	Methods para6
Results			
Numbers randomized	Number of participants randomized to each group	Fig1	Fig1
Recruitment	Trial status	page13 line273-294	Results para2
Numbers analysed	Number of participants analysed in each group	page12 line262-271	Results para1
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	Table2	Table2
Harms	Important adverse events or side effects	no	no

Conclusions	General interpretation of the results	page18 line 394-404	Conclusions
Trial registration	Registration number and name of trial register	Page4line94-96	Results para1
Funding	Source of funding	page2line48-51	Funding

** 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.