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	P1/L1,	Title,
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see Table 2)	P2/L2-28	Abstract
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	P3/L55-79	Introduction/paragraph1,2,
	2b	Specific objectives or hypotheses	P3/L80-L4/87	Introduction/paragraph3
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	P4L99-100	materials and
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A	we had no change
Participants	4a	Eligibility criteria for participants	P4/L97-109	material and methods
	4b	Settings and locations where the data were collected	P4L98-99	material and
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	P5/L120-142	materials and methods/paragraph3
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	P4/L109	materials and methods/paragraph2
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A	we had no change
Sample size	7a	How sample size was determined	N/A	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA	intern analysis was not
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence	N/A	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	P4/L104-107	materials and
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	P4/L104-107	materials and methods/paragraph2

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	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	this is open label study.
	11b	If relevant, description of the similarity of interventions	N/A	this is open label study.
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	P6/L168-174	materials and
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	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	P6/L177-181	resluts /paragraph1, Figure1.
	13b	For each group, losses and exclusions after randomisation, together with reasons	P6/L177-181	results/paragraph1,
Recruitment	14a	Dates defining the periods of recruitment and follow-up	P6/177-178	results/paragraph1
	14b	Why the trial ended or was stopped	N/A	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	P6/L181-P7/L188	results/paragraph1/Table1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	P6/L179-181	results/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)	P7/L188-208	results/paragraph2-4
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A	no binary outcome was
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	N/A	subgroup analysis was not performed.
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A	we had never important
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	P9/L256-276	discussion/paragraph 5
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	P8/L235-237,P9/L	discussion/paragraph3and
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	P8/L235-237,P9/L250-253	discussion/paragraph3and
Other information				
Registration	23	Registration number and name of trial registry	P4/L95-97	materials and

Protocol	24	Where the full trial protocol can be accessed, if available	additional file	submitted
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	P14/L390-392	Dealaration/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	P1/L1	title page
Authors *	Contact details for the corresponding author	P1/L11	title page
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	N/A	
Methods			
Participants	Eligibility criteria for participants and the settings where the data were collected	P2/L30	abstract
Interventions	Interventions intended for each group	P2/L32	abstract
Objective	Specific objective or hypothesis	P2/L26	abstract
Outcome	Clearly defined primary outcome for this report	P2/L34	abstract
Randomization	How participants were allocated to interventions	P2/L32	abstract
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	N/A	
Results			
Numbers randomized	Number of participants randomized to each group	P2/L39	abstract
Recruitment	Trial status		
Numbers analysed	Number of participants analysed in each group	P2/L39	abstract
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	P2/L40-44	abstract
Harms	Important adverse events or side effects	N/A	

Conclusions	General interpretation of the results	P2/L42-50	abstract
Trial registration	Registration number and name of trial register	P2/L51	abstract
Funding	Source of funding	N/A	

** 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.