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/Line1-3	Title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see Table 2)	Page2/Line39-59	Abstract/Paragraph2-4
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Page3-4/Line68-129	Introduction/Paragraph1-3
	2b	Specific objectives or hypotheses	Page4/Line130-133	Introduction/Paragraph4
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Page5/Line141	Methods/Paragraph1
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	N/A Not needed	N/A Not needed
Participants	4a	Eligibility criteria for participants	Page5/Line142-148	Methods/Paragraph1
	4b	Settings and locations where the data were collected	Page5/Line148-150	Methods/Paragraph1
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Page5-9/Line157-273	Methods/Paragraph2-11
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Page7-8/Line225-273	Methods/Paragraph8-11
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A Not needed	N/A Not needed
Sample size	7a	How sample size was determined	Page9/Line277-281	Methods/Paragraph12
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A Not needed	N/A Not needed
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence	N/A	N/A
	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	Page7/Line211-222	Methods/Paragraph7
	11b	If relevant, description of the similarity of interventions	Page7/Line211-220	Methods/Paragraph7
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Page9/Line281-292	Methods/Paragraph12
	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	Page9/Line297-300	Results/Paragraph1 Figure1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure1	Figure1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page9/Line296	Results/Paragraph1
	14b	Why the trial ended or was stopped	N/A Not needed	N/A Not needed
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	Figure1	Figure1
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)	Page9-11/Line302-348	Results/Paragraph2-7
	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 Not needed	N/A Not needed
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	N/A Not needed	N/A Not needed
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Page13/Line421-430	Discussion/Paragraph5
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Page13/Line421-429	Discussion/Paragraph5
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Page11-13/Line352-420	Discussion/Paragraph1-4
Other information				
Registration	23	Registration number and name of trial registry	Page2/Line60	Abstract/Paragraph5

Protocol	24	Where the full trial protocol can be accessed, if available	Footnote	Footnote
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Page14/Line444-446	Acknowledgments

*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/Line1-3	Title/Paragraph1
Authors *	Contact details for the corresponding author	Page1/Line21-23	Title/Paragraph6
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	Page2/Line39-40	Abstract/Paragraph2
Methods			
Participants	Eligibility criteria for participants and the settings where the data were collected	N/A Not needed	N/A Not needed
Interventions	Interventions intended for each group	Page2/Line39-44	Abstract/Paragraph2
Objective	Specific objective or hypothesis	Page2/Line33-38	Abstract/Paragraph1
Outcome	Clearly defined primary outcome for this report	Page2/Line45-56	Abstract/Paragraph3
Randomization	How participants were allocated to interventions	N/A Not needed	N/A Not needed
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	N/A Not needed	N/A Not needed
Results			
Numbers randomized	Number of participants randomized to each group	Page2/Line39-40	Abstract/Paragraph2
Recruitment	Trial status	N/A Not needed	N/A Not needed
Numbers analysed	Number of participants analysed in each group	Page2/Line39-40	Abstract/Paragraph2
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	Page2/Line45-56	Abstract/Paragraph3
Harms	Important adverse events or side effects	N/A Not needed	N/A Not needed

Conclusions	General interpretation of the results	Page2/Line57-59	Abstract/Paragraph4
Trial registration	Registration number and name of trial register	Page2/Line60	Abstract/Paragraph5
Funding	Source of funding	N/A,In Acknowledgments	N/A,In Acknowledgments

** this item is specific to conference abstracts*

From: Hopewell S, Clarke M, Moher D, et al. CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. PLoS Med. 2008;5(1):e20

Article information: https://apm.amegroups.com/article/view/10.21037/apm-21-3862/rc
*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.