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	Line 3-4	Title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see Table 2)	Line32-50	Abstract
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Line 58-82	Introduction
	2b	Specific objectives or hypotheses	Line 82-86	Introduction
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Line 92-106	Methods/1
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Line 92-106	Methods/1
Participants	4a	Eligibility criteria for participants	Line 92-106	Methods/1
	4b	Settings and locations where the data were collected	Line 151-172	Methods/3
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Line 109-148	Methods/2
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	N/A	N/A
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Line 151-172	Methods/3
Sample size	7a	How sample size was determined	Line 92-106	Methods/1
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A	N/A
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence	Line 92-106	Methods/1
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Line 92-106	Methods/1
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	Line 109-148	Methods/2
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Line179-184	Methods/4
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Line179-184	Methods/4
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	Line189-197	Results/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	N/A	N/A
	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	N/A	N/A
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Line189-197	Results/1
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)	Line199-222	Results/2-5
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Line199-222	Results/2-5
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)	Line216-217	Results/2-4
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Line280-285	Discussion4
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Line248-272	Discussion3
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Line273-285	Discussion4
Other information				
Registration	23	Registration number and name of trial registry	N/A	N/A

Protocol	24	Where the full trial protocol can be accessed, if available	N/A	N/A
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Line 288-290	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	Line 3-4	Title
Authors *	Contact details for the corresponding author	Line 14-16	Authors
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	Line34-41	Abstract
Methods			
Participants	Eligibility criteria for participants and the settings where the data were collected	Line 92-106	Methods/1
Interventions	Interventions intended for each group	Line 109-148	Methods/2
Objective	Specific objective or hypothesis	Line 151-172	Methods/3
Outcome	Clearly defined primary outcome for this report	Line 151-172	Methods/3
Randomization	How participants were allocated to interventions	Line 92-106	Methods/1
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	Line189-197	Results/1
Recruitment	Trial status	N/A	N/A
Numbers analysed	Number of participants analysed in each group	Line189-197	Results/1
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	Line199-222	Results/2-5
Harms	Important adverse events or side effects	Line216-217	Results/2-4

Conclusions	General interpretation of the results	Line273-285	Discussion4
Trial registration	Registration number and name of trial register	N/A	N/A
Funding	Source of funding	Line 288-290	Funding

** 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: http://dx.doi.org/10.21037/apm-20-1995
*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.