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/Line31-32	Abstract/Paragraph2
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see Table 2)	Page1/Line31-54	Abstract/Paragraph2-4
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Page2/Line61-67	Introduction/Paragraph1
	2b	Specific objectives or hypotheses	Page3/Line77-80	Introduction/Paragraph1
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Page3/Line86-88	Methods/Paragraph1
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Page3/Line86-88	Methods/Paragraph1
Participants	4a	Eligibility criteria for participants	Page3/Line88-92	Methods/Paragraph2
	4b	Settings and locations where the data were collected	Page3/Line86-88	Methods/Paragraph1
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Page3/Line86-88	Methods/Paragraph1
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Page5/Line130-143	Methods/Paragraph5-7
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Page3/Line101-105	Methods/Paragraph2
Sample size	7a	How sample size was determined	Page3/Line86-88	Methods/Paragraph1
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA	NA
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence	Page3/Line99	Methods/Paragraph3
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Page3/Line99-101	Methods/Paragraph3
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	Page4/Line99-101	Methods/Paragraph3

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	NA	NA
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Page3/Line99-101	Methods/Paragraph3
	11b	If relevant, description of the similarity of interventions	NA	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Page5/Line146-148	Methods/Paragraph8
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Page5/Line146-148	Methods/Paragraph8
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	Page5/Line156-160	Results/Paragraph1
	13b	For each group, losses and exclusions after randomisation, together with reasons	NA	NA
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Page6/Line182-185	Results/Paragraph5
	14b	Why the trial ended or was stopped	NA	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Page5/Line160-162	Results/Paragraph1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Page5/Line163-167	Results/Paragraph2
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)	Page6/Line168-173	Results/Paragraph3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Page6/Line174-185	Results/Paragraph4
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA	NA
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Page8/Line236-243	Discussion/Paragraph6
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Page6/Line195-198	Discussion/Paragraph1
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Page7/Line195-198	Discussion/Paragraph2
Other information				
Registration	23	Registration number and name of trial registry	NA	NA

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

*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/Line3-5	Title/Paragraph1
Authors *	Contact details for the corresponding author	Page1/Line7-8	Authors/Paragraph1
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	NA	NA
Methods			
Participants	Eligibility criteria for participants and the settings where the data were collected	Page3/Line88-92	Methods/Paragraph1
Interventions	Interventions intended for each group	Page3/Line86-88	Methods/Paragraph1
Objective	Specific objective or hypothesis	Page3/Line79-81	Introductions/Paragraph1
Outcome	Clearly defined primary outcome for this report	Page3/Line95-96	Methods/Paragraph2
Randomization	How participants were allocated to interventions	Page3/Line99-101	Methods/Paragraph3
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	Page3/Line99-101	Methods/Paragraph3
Results			
Numbers randomized	Number of participants randomized to each group	Page5/Line160-162	Results/Paragraph1
Recruitment	Trial status	NA	NA
Numbers analysed	Number of participants analysed in each group	Page5/Line160-162	Results/Paragraph1
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	Page5/Line163-167	Results/Paragraph2
Harms	Important adverse events or side effects	NA	NA

Conclusions	General interpretation of the results	Page8/Line245-250	Conclusions/Paragraph1
Trial registration	Registration number and name of trial register	NA	NA
Funding	Source of funding	NA	NA

** 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/jtd-20-3274
*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.