



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	page 1/line 3	title page/line 3
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see Table 2)	page 3/line 41-62	abstract/line 41-62
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	page 4/line 66-81	introduction/paragraph
	2b	Specific objectives or hypotheses	page 4/line 83-86	introduction/paragraph
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	page 5/line 91-97	Figure 1
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA- no change original	NA- no change
Participants	4a	Eligibility criteria for participants	page 5/line 91	methods/paragraph 1
	4b	Settings and locations where the data were collected	page 5/line 91-92	methods/paragraph 1
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	page 5-6/line 92-126	methods/paragraph 1-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	page 6/line 122-6	methods/paragraph 8
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA- no change	NA- no change
Sample size	7a	How sample size was determined	pg13/line 276-9	discussion/paragraph
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA- no interim	NA- no interim
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence	page 5/line 94	methods/paragraph 1
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	page 5/line 94	methods/paragraph 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	page 5/line 94	methods/paragraph 1

Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	page 5/line 92	methods/paragraph 1
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	page 5/line 106 and page 6/line 114-5	methods/paragraph 3,5
	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	page 7/line 128-131	statistical <input type="checkbox"/>
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	NA- no subgroup	NA- no subgroup
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	page 7/line 143	figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	figure 1	figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	page 6/line 126	methods/paragraph 8
	14b	Why the trial ended or was stopped	NA- trial ended when <input type="checkbox"/>	NA- trial ended when the <input type="checkbox"/>
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	table 1	table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	table 2	table 2
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)	table 2	table 2
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	table 2	table 2
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	NA	NA
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	page 13/line 275	discussion/paragraph
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	page 10-14/line	discussion/paragraph
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	page 10-14/line	discussion/paragraph
Other information				
Registration	23	Registration number and name of trial registry	NA as this is an <input type="checkbox"/>	NA as this is an <input type="checkbox"/>

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	page 14/line 295	Acknowledgements/para ⁺

*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	page 1/line 3	title page/ line 3
Authors *	Contact details for the corresponding author	page 1/ line 16	title page/ line 16
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	figure 1	figure 1
Methods			
Participants	Eligibility criteria for participants and the settings where the data were collected	page 5/line 91-92	methodology/
Interventions	Interventions intended for each group	page 5-6/line 91-126	methodology/paragraph 1 ⁺
Objective	Specific objective or hypothesis	page 4-5/line 83-86	introduction/paragrap ⁺
Outcome	Clearly defined primary outcome for this report	page 4-5/ line 85-86	methodology/
Randomization	How participants were allocated to interventions	page 5/line 92-7	methodology/
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	page 5/line 106 ⁺	methodology/paragraph 3 ⁺
Results			
Numbers randomized	Number of participants randomized to each group	figure 1	figure 1
Recruitment	Trial status	page 7/line 143	results/paragraph 1
Numbers analysed	Number of participants analysed in each group	table 2	table 2
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	table 2	table 2
Harms	Important adverse events or side effects	NA- no harm exposed as ⁺	NA- no harm exposed as ⁺

Conclusions	General interpretation of the results	page 14/line 290	conclusion/paragraph
Trial registration	Registration number and name of trial register	NA as this is an 	NA as this is an 
Funding	Source of funding	page 14/line 295	acknowledgements/parag 

** 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/gs-20-476>.

*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. 