

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1,2
Introduction			
Background and	2a	Scientific background and explanation of rationale	2, 3
objectives	2b	Specific objectives or hypotheses	3
Methods			0.4
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	3, 4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Not applicabl
Participants	4a	Eligibility criteria for participants	3,4
	4b	Settings and locations where the data were collected	3,4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	4, 5
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they	
		were assessed	5, 6
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Not applicable
Sample size	7a	How sample size was determined	7
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not applicable
Randomisation:			
Sequence	8a	Method used to generate the random allocation sequence	4
generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	4
Allocation concealment	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	
mechanism			4
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	4, 5
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	3

CONSORT 2010 checklist Page 1

Statistical methods of the similarity of interventions 4 Statistical methods to Statistical methods used to compare groups for primary and secondary outcomes 6,7 results 7 Statistical methods 12a Statistical methods used to compare groups for primary and secondary outcomes 7 Statistical methods 12b Methods for additional analyses, such as subgroup analyses and adjusted analyses 7 Statistical methods 12b Methods for additional analyses, such as subgroup analyses and adjusted analyses 7 Statistical methods 12b For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome 7,8 secruitment 8 Statistical methods 12b For each group, losses and exclusions after randomisation, together with reasons 8 Statistical methods 12b For each group, losses and exclusions after randomisation, together with reasons 8 Statistical methods 12b For each group, losses and exclusions after randomisation, together with reasons 8 Statistical methods 12b For each group, losses and exclusions after randomisation, together with reasons 8 Statistical methods 12b For each group, losses and exclusions after randomisation, together with reasons 8 Statistical methods 12b For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups 12b For each group, number of participants (denominator) included in each analysis and whether the analysis was 12b For each group, number of participants (denominator) included in each analysis and whether the analysis was 12b For each group, and the estimated effect size and its precision (such as 95% confidence interval) 12b For binary outcomes, presentation of both absolute and relative effect sizes is recommended 12b For binary outcomes, presentation of both absolute and relative effect sizes is recommended 12b For binary outcomes, presentation of both absolute and relative effect sizes is recommended 12b For binary outcomes, presentation of both absolute and rel
Statistical methods 12a Statistical methods used to compare groups for primary and secondary outcomes 6,7 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 7,8 Recruitment 13b For each group, losses and exclusions after randomisation, together with reasons 8 Recruitment 14b Dates defining the periods of recruitment and follow-up 7,8 Results 14b Why the trial ended or was stopped 8 Baseline data 15 A table showing baseline demographic and clinical characteristics for each group 9,10 Numbers analysed 16 For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups 8 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) 10-14 Ancillary analyses 18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory 12, 13 Harms 19 All important harm
Results Participant flow (a diagram is strongly recommended) 13b For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome 7,8
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 7,8 mode of the primary outcome 7,8 mode of the primary outcome 8 Recruitment recommended) 13b for each group, losses and exclusions after randomisation, together with reasons 8 8 Recruitment 14a Dates defining the periods of recruitment and follow-up 14b Why the trial ended or was stopped Not applicable Not applicable Baseline data 15 A table showing baseline demographic and clinical characteristics for each group 2 3, 10 Not applicable Numbers analysed of the primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) 8 Outcomes and estimation 15b For binary outcomes, presentation of both absolute and relative effect sizes is recommended 10-14 Ancillary analyses 15b For binary outcomes, presentation of both absolute and relative effect sizes is recommended 10-13 Ancillary analyses 15b For binary outcomes, presentation of both absolute and relative effect sizes is recommended 10-13 Harms 15b For binary outcomes, presentation of both absolute and relative effect sizes is recommended 10-13 12c 13 12c 13 Boscus
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 13b For each group, losses and exclusions after randomisation, together with reasons Recruitment 14a Dates defining the periods of recruitment and follow-up 14b Why the trial ended or was stopped Baseline data 15 A table showing baseline demographic and clinical characteristics for each group Numbers analysed 16 For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups 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) 17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended Ancillary analyses 18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory 19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) Not applicable 12, 13 12, 13 Discussion
diagram is strongly recommended) were analysed for the primary outcome 7,8 Recruitment 14a Dates defining the periods of recruitment and follow-up 7,8 Recruitment 14b Why the trial ended or was stopped Not applicable Baseline data 15 A table showing baseline demographic and clinical characteristics for each group 9, 10 Numbers analysed 16 For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups 8 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) 10-14 Ancillary analyses 18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory 12,13 Harms 19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) Not applicable Discussion Very specified from exploratory Not applicable
recommended) 13b For each group, losses and exclusions after randomisation, together with reasons Recruitment 14a Dates defining the periods of recruitment and follow-up 7,8 14b Why the trial ended or was stopped Not applicable Baseline data 15 A table showing baseline demographic and clinical characteristics for each group 9,10 Numbers analysed 5 For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups 8 Outcomes and 17a For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) 17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended 10-13 Ancillary analyses 18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory 12,13 Harms 19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) Not applicable 12,13 Discussion 15c Por each group, losses and exclusions after randomisation, together with reasons 15c Por each group in the periods of recruitment and follow-up 17,8 18 Por each group, number of participants (denominator) included in each analysis and whether the analysis was 8 8 Por each group, number of participants (denominator) included in each analysis and whether the analysis was 8 8 Por each group, number of participants (denominator) included in each analysis and whether the analysis was 9 p. 10 10-14 110-14
Recruitment 14a Dates defining the periods of recruitment and follow-up 7,8 14b Why the trial ended or was stopped Not applicable Baseline data 15 A table showing baseline demographic and clinical characteristics for each group 9, 10 Numbers analysed 5 For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups 8 Outcomes and estimation 7 For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) 10–14 17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended 110–13 Ancillary analyses 18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory 12,13 Harms 19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) Not applicable 14 To be subjected to the product of the produ
Harms 14b Why the trial ended or was stopped 14b Why the trial ended or was stopped 14b Why the trial ended or was stopped 15b A table showing baseline demographic and clinical characteristics for each group 15c A table showing baseline demographic and clinical characteristics for each group 16c For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups 17c For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) 17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended 17c Ancillary analyses 18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory 18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory 19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) Not applicable Discussion
Baseline data 15 A table showing baseline demographic and clinical characteristics for each group 9, 10 Numbers analysed 16 For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups 8 Outcomes and 17a For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) 17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended 10–13 Ancillary analyses 18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory 12, 13 Harms 19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) Not applicable Discussion
Numbers analysed 16 For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups Outcomes and 17a For each primary and secondary outcome, results for each group, and the estimated effect size and its estimation precision (such as 95% confidence interval) 17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended Ancillary analyses 18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory Harms 19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) Not applicable Discussion
by original assigned groups Outcomes and 17a For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) 17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended 17b Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory Harms 19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) Not applicable Discussion
estimation precision (such as 95% confidence interval) 17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended 17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended 10-13 Ancillary analyses 18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory 12, 13 Place Discussion
To binary outcomes, presentation of both absolute and relative effect sizes is recommended 17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended 18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory 19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) Not applicable Discussion
Ancillary analyses 18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory Harms 19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) Not applicable Discussion
pre-specified from exploratory Harms 19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) Discussion
Discussion
16
Limitations 20 Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses16
Generalisability 21 Generalisability (external validity, applicability) of the trial findings 14, 15
Interpretation 22 Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence 14-16
Other information
Registration 23 Registration number and name of trial registry4
Protocol 24 Where the full trial protocol can be accessed, if available4
Funding 25 Sources of funding and other support (such as supply of drugs), role of funders 17

^{*}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, seewww.consort-statement.org.

CONSORT 2010 checklist Page 2