

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

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>	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)	3-4
<b>Introduction</b> Background and objectives	2a	Scientific background and explanation of rationale	5-7
	2b	Specific objectives or hypotheses	7
<b>Methods</b>	3a	Description of trial design (such as parallel, factorial) including allocation ratio	8
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	8-9
	4a	Eligibility criteria for participants	8
	4b	Settings and locations where the data were collected	8
	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	9-11
<b>Outcomes</b>	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
	7a	How sample size was determined	n/a
<b>Sample size</b>	7b	When applicable, explanation of any interim analyses and stopping guidelines	8
	<b>Randomisation:</b>		8
	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8
<b>Allocation concealment mechanism</b>	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	8
	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
<b>Blinding</b>	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	9

Statistical methods

11b assessing outcomes) and how

12a If relevant, description of the similarity of interventions

12b Statistical methods used to compare groups for primary and secondary outcomes

Methods for additional analyses, such as subgroup analyses and adjusted analyses

10-11

11

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

13b For each group, losses and exclusions after randomisation, together with reasons

14a Dates defining the periods of recruitment and follow-up

14b Why the trial ended or was stopped

15 A table showing baseline demographic and clinical characteristics for each group

16 For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups

12, Figure 1

Figure 1

n/a

Table 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)

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

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n/a

n/a

Ancillary analyses

19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)

n/a

Harms

19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)

n/a

**Discussion**

Limitations

20 Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses

15-16

16

Generalisability

21 Generalisability (external validity, applicability) of the trial findings

15-16

Interpretation

22 Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence

4

**Other information**

Registration

23 Registration number and name of trial registry

4

Protocol

24 Where the full trial protocol can be accessed, if available

n/a

Funding

25 Sources of funding and other support (such as supply of drugs), role of funders

18-19

\*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