

Reporting checklist for randomised trial.

Based on the CONSORT guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the CONSORT reporting guidelines, and cite them as:

Schulz KF, Altman DG, Moher D, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials

		Reporting Item	Page Number
Title and Abstract			
Title	#1a	Identification as a randomized trial in the title.	1
Abstract	#1b	Structured summary of trial design, methods, results, and conclusions	4
Introduction			
Background and objectives	#2a	Scientific background and explanation of rationale	6
Background and objectives	#2b	Specific objectives or hypothesis	7
Methods			
Trial design	#3a	Description of trial design (such as parallel, factorial) including allocation ratio.	27
Trial design	#3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a

Participants	#4a	Eligibility criteria for participants	27
Participants	#4b	Settings and locations where the data were collected	27
Interventions	#5	The experimental and control interventions for each group with sufficient details to allow replication, including how and when they were actually administered	27-29
Outcomes	#6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	30-32
Sample size	#7a	How sample size was determined.	32
Sample size	#7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomization - Sequence generation	#8a	Method used to generate the random allocation sequence.	33
Randomization - Sequence generation	#8b	Type of randomization; details of any restriction (such as blocking and block size)	33
Randomization - 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	33
Randomization - Implementation	#10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to interventions	33
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Blinding	#11b	If relevant, description of the similarity of interventions	27-29

Statistical methods	#12a	Statistical methods used to compare groups for primary and secondary outcomes	32-33
Statistical methods	#12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	33
Outcomes	#6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
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Participant flow diagram (strongly recommended)	#13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	43
Participant flow	#13b	For each group, losses and exclusions after randomization, together with reason	43
Recruitment	#14a	Dates defining the periods of recruitment and follow-up	8, 44
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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)	11,13
Outcomes and estimation	#17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
Ancillary analyses	#18	Results of any other analyses performed, including subgroup analyses and adjusted	11-18

		analyses, distinguishing pre-specified from exploratory	
Harms	#19	All important harms or unintended effects in each group (For specific guidance see CONSORT for harms)	19-21
Discussion			
Limitations	#20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	23
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Registration	#23	Registration number and name of trial registry	NCT02231879 clinicaltrials.gov
Generalisability	#21	Generalisability (external validity, applicability) of the trial findings	24-25
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Interpretation	#22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	26
Registration	#23	Registration number and name of trial registry	NCT02231879 clinicaltrials.gov
Protocol	#24	Where the full trial protocol can be accessed, if available	NCT02231879 clinicaltrials.gov
Funding	#25	Sources of funding and other support (such as supply of drugs), role of funders	36

Notes:

- 23: NCT02231879 clinicaltrials.gov
- 24: NCT02231879 clinicaltrials.gov The CONSORT checklist is distributed under the terms of the Creative Commons Attribution License CC-BY. This checklist was completed on 26. June 2023 using <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)