

# Reporting checklist for randomised trial.

Based on the CONSORT guidelines.

		Reporting Item	Page Number
<b>Title and Abstract</b>			
Title	<a href="#">#1a</a>	Identification as a randomized trial in the title.	1
Abstract	<a href="#">#1b</a>	Structured summary of trial design, methods, results, and conclusions	1-2
<b>Introduction</b>			
Background and objectives	<a href="#">#2a</a>	Scientific background and explanation of rationale	4-5
Background and objectives	<a href="#">#2b</a>	Specific objectives or hypothesis	5
<b>Methods</b>			
Trial design	<a href="#">#3a</a>	Description of trial design (such as parallel, factorial) including allocation ratio.	5
Trial design	<a href="#">#3b</a>	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a, as no changes appeared after trial commencement
Participants	<a href="#">#4a</a>	Eligibility criteria for participants	6
Participants	<a href="#">#4b</a>	Settings and locations where the data were collected	5-6
Interventions	<a href="#">#5</a>	The experimental and control interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7
Outcomes	<a href="#">#6a</a>	Completely defined prespecified primary and secondary outcome measures, including how and	8-9

		when they were assessed	
Sample size	<a href="#">#7a</a>	How sample size was determined.	9
Sample size	<a href="#">#7b</a>	When applicable, explanation of any interim analyses and stopping guidelines	13
Randomization - Sequence generation	<a href="#">#8a</a>	Method used to generate the random allocation sequence.	9
Randomization - Sequence generation	<a href="#">#8b</a>	Type of randomization; details of any restriction (such as blocking and block size)	9
Randomization - Allocation concealment mechanism	<a href="#">#9</a>	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	9-10
Randomization - Implementation	<a href="#">#10</a>	Who generated the allocation sequence, who enrolled participants, and who assigned participants to interventions	9-10
Blinding	<a href="#">#11a</a>	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how.	10
Blinding	<a href="#">#11b</a>	If relevant, description of the similarity of interventions	10
Statistical methods	<a href="#">#12a</a>	Statistical methods used to compare groups for primary and secondary outcomes	12-13
Statistical methods	<a href="#">#12b</a>	Methods for additional analyses, such as subgroup analyses and adjusted analyses	13
Outcomes	<a href="#">#6b</a>	Any changes to trial outcomes after the trial commenced, with reasons	n/a, no changes to trial outcomes
<b>Results</b>			n/a, as no results are

available  
because the  
study has not  
been completed

Participant flow diagram (strongly recommended)	<a href="#">#13a</a>	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	n/a
Participant flow	<a href="#">#13b</a>	For each group, losses and exclusions after randomization, together with reason	n/a
Recruitment	<a href="#">#14a</a>	Dates defining the periods of recruitment and follow-up	n/a
Recruitment	<a href="#">#14b</a>	Why the trial ended or was stopped	n/a
Baseline data	<a href="#">#15</a>	A table showing baseline demographic and clinical characteristics for each group	n/a
Numbers analysed	<a href="#">#16</a>	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	n/a
Outcomes and estimation	<a href="#">#17a</a>	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	n/a
Outcomes and estimation	<a href="#">#17b</a>	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n/a
Ancillary analyses	<a href="#">#18</a>	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n/a
Harms	<a href="#">#19</a>	All important harms or unintended effects in each group (For specific guidance see CONSORT for harms)	n/a
<b>Discussion</b>			
Limitations	<a href="#">#20</a>	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	15-16
Interpretation	<a href="#">#22</a>	Interpretation consistent with results, balancing	15-16

		benefits and harms, and considering other relevant evidence	
Registration	<a href="#">#23</a>	Registration number and name of trial registry	2
Generalisability	<a href="#">#21</a>	Generalisability (external validity, applicability) of the trial findings	15-16
<b>Other information</b>			
Interpretation	<a href="#">#22</a>	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	15-16
Registration	<a href="#">#23</a>	Registration number and name of trial registry	2
Protocol	<a href="#">#24</a>	Where the full trial protocol can be accessed, if available	n/a, trial protocol is not available
Funding	<a href="#">#25</a>	Sources of funding and other support (such as supply of drugs), role of funders	3,4, 18

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