SPIRIT | CONSORT OUTCOMES
Reporting Guidelines for Trial Outcomes

CONSORT-Outcomes 2022 Checklist (for combined completion of CONSORT 2010 and CONSORT-Outcomes 2022 items)[a]

Section	Item No.	CONSORT 2010 Item	CONSORT-Outcomes 2022 item	Location Reported[b]
Title and abstract				
Title and abstract	1a	Identification as a randomized trial in the title	-	Click to enter text
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstract)	-	Click to enter text
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	-	Click to enter text
	2b	Specific objectives or hypotheses	-	Click to enter text
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation	-	Click to enter text
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	-	Click to enter text
Participants	4a	Eligibility criteria for participants	-	Click to enter text
	4b	Settings and locations where the data were collected	-	Click to enter text
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered (for specific guidance see TIDieR checklist and guide)	-	Click to enter text
Outcomes	6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	-	Click to enter text
	6a.1		Provide a rationale for the selection of the domain for the trial's primary outcome	Click to enter text
	6a.2		Describe the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, mean, proportion), and the time point for each outcome	Click to enter text or specify not applicable

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	6a.3		If the analysis metric for the primary outcome represents within-subject change, define and justify the minimal important change in individuals	Click to enter text or specify not applicable
	6a.4		If the outcome data were continuous, but were analyzed as categorical (method of aggregation), specify the cutoff values used	Click to enter text or specify not applicable
	6a.5		If outcome assessments were performed at several time points after randomization, state the time points used for analysis	Click to enter text or specify not applicable
	6a.6		If a composite outcome was used, define all individual components of the composite outcome	Click to enter text or specify not applicable
	6a.7		Identify any outcomes that were not prespecified in a trial registry or protocol	Click to enter text
	6a.8		Provide a description of the study instruments used to assess the outcome (eg, questionnaires, laboratory tests) along with reliability, validity, and responsiveness in a population similar to the study sample	Click to enter text or specify not applicable
	6a.9		Describe who assessed the outcome (eg, nurse, parent), and any qualifications or trial-specific training necessary to administer the study instruments to assess the outcome	Click to enter text or specify not applicable
	6a.10		Describe any processes used to promote outcome data quality during data collection (eg, duplicate measurements) and after data collection (eg, range checks of outcome data values), or state where details can be found	Click to enter text
	6b	Any changes to trial outcomes after the trial commenced, with reasons	-	Click to enter text
Sample size	7a	How sample size was determined	-	Click to enter text
	7a.1		Define and justify the target difference between treatment groups (eg, the minimal important difference)	Click to enter text

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	7b	When applicable, explanation of any interim analyses and stopping guidelines	-	Click to enter text or specify not applicable
Randomization				
Sequence generation	8a	Method used to generate the random allocation sequence	-	Click to enter text
	8b	Type of randomization; details of any restriction (such as blocking and block size)	-	Click to enter text
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	-	Click to enter text
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	-	Click to enter text
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	-	Click to enter text
	11b	If relevant, description of the similarity of interventions	-	Click to enter text
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	-	Click to enter text
	12a.1		Describe any methods used to account for multiplicity in the analysis or interpretation of the primary and secondary outcomes (eg, coprimary outcomes, same outcome assessed at multiple time points, or subgroup analyses of one outcome)	Click to enter text or specify not applicable
	12a.2		State and justify any criteria for excluding any outcome data from the analysis and reporting, or report that no outcome data were excluded	Click to enter text
	12a.3		Describe methods to assess patterns of missingness (eg, missing not at random), and describe the methods to handle missing outcome items or entire assessments	Click to enter text or specify not applicable

Section	Item No.	CONSORT 2010 Item	CONSORT-Outcomes 2022 item	Location Reported[b]
	12a.4		Provide definition of outcome analysis population relating to protocol nonadherence (eg, as randomized analysis)	Click to enter text
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	-	Click to enter text
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 analyzed for the primary outcome	-	Click to enter text
	13b	For each group, losses and exclusions after randomization, together with reasons	-	Click to enter text
Recruitment	14a	Dates defining the periods of recruitment and follow-up	-	Click to enter text
	14b	Why the trial ended or was stopped	-	Click to enter text
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	-	Click to enter text
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned group	-	Click to enter text
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% CI)	-	Click to enter text
	17a.1		Include results for all prespecified outcome analyses or state where results can be found if not in this report	Click to enter text
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	-	Click to enter text
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	-	Click to enter text or specify not applicable
	18.1		If there were any analyses that were not prespecified, explain why they were performed	Click to enter text or specify not applicable
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	-	Click to enter text

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Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	-	Click to enter text
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	-	Click to enter text
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	-	Click to enter text
Other Information				
Registration	23	Registration number and name of trial registry	-	Click to enter text
Protocol	24	Where the full trial protocol can be accessed, if available	-	Click to enter text
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	-	Click to enter text

[a]It is strongly recommended that this checklist be read in conjunction with the CONSORT-Outcomes and CONSORT Statement papers for important clarification on the items. The CONSORT Statement checklist is distributed under the terms of the Creative Commons Attribution License.
[b]Indicates page numbers and/or manuscript location: to be completed by authors.