CONSORT-Outcomes 2022 Extension items only (for separate completion of CONSORT 2010 and CONSORT-Outcomes 2022 items)

Section	Item No.	CONSORT-Outcomes item	Location Reported[b]
Methods			
Outcomes	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
	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, 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
Sample size	7a.1	Define and justify the target difference between treatment groups (eg, the minimal important difference)	Click to enter text
Statistical methods	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-Outcomes item	Location Reported[b]
	12a.4	Provide definition of outcome analysis population relating to protocol nonadherence (eg, as randomized analysis)	Click to enter text
Results			
Outcomes and estimation	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
Ancillary analyses	18.1	If there were any analyses that were not prespecified, explain why they were performed	Click to enter text or specify not applicable

[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 during trial report development.