SPIRIT-Outcomes 2022 Extension items only (for separate completion of SPIRIT 2013 and SPIRIT-Outcomes 2022 items)[a]

Section	Item No.	SPIRIT-Outcomes 2022 item	Location Reported[b]
Methods: Participants, interventions, and outcomes			
Outcomes	12.1	Provide a rationale for the selection of the domain for the trial's primary outcome	Page 8
	12.2	If the analysis metric for the primary outcome represents within-participant change, define and justify the minimal important change in individuals	Page 10
	12.3	If the outcome data collected are continuous but will be analyzed as categorical (method of aggregation), specify the cutoff values to be used	Not applicable
	12.4	If outcome assessments will be performed at several time points after randomization, state the time points that will be used for analysis	Page 8-9
	12.5	If a composite outcome is used, define all individual components of the composite outcome	Not applicable
Sample size	14.1	Define and justify the target difference between treatment groups (eg, the minimal important difference)	Page 10
Methods: Data collection, management, and analysis			
Data collection methods	18a.1	Describe what is known about the responsiveness of the study instruments in a population similar to the study sample	Page 8-9
	18a.2	Describe who will assess the outcome (eg, nurse, parent)	Page 8-9
Statistical methods	20a.1	Describe any planned methods 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 an outcome)	Page 10

[a]It is strongly recommended that this checklist be read in conjunction with the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) Statement paper for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license and is reproduced with permission.

[b]Indicates page numbers and/or manuscript location: to be completed by authors during trial protocol development.

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