SPIRIT checklist

Section / item	Item		Page
Administrative information			
Title	1		1
Trial registration	2a	Trial identifier and registry name.	2, 18
	2b	All items from the World Health Organization Trial Registration Data Set	18
Protocol version	3		1
Funding	4		18
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1, 18
	5b	Name and contact information for the trial sponsor	NA
	5c	Role of study sponsor and funders, if any, in study design	NA
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable	7-9
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4, 5
	6b	Explanation for choice of comparators	
Objectives	7		5
Trial design	8		1,2, 4-6
Methods: Participants, interventions, and outcomes			
Study setting	9		6
Eligibility criteria	10		6
Interventions	11a	Interventions for each group	6,7
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant	10,11
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence	8
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	6, 7
Outcomes	12		9-14
Participant timeline	13		6-8
Sample size	14		15
Recruitment	15		6
Methods: Assignment of interventions (for controlled trials)			
Sequence generation	16a	Method of generating the allocation sequence, and list of any factors for stratification.	7-8
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence	7-8
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	7, 17

Blinding (masking)	17a	Who will be blinded after assignment to interventions and how	7
	17b	If blinded, circumstances under which unblinding is permissible and procedure for revealing a participant's allocated intervention during the trial	NA
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality along with their reliability and validity, if known.	7-10
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	7-10
Data management	19		12
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	15
	20b	Methods for any additional analyses	15
	20c	Definition of analysis population relating to protocol non-adherence and any statistical methods to handle missing data	15
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC)	17
	21b	Description of any interim analyses and stopping guidelines	15, 16
Harms	22		17
Auditing	23		16
Ethics and dissemination			
Research ethics approval	24		16
Protocol amendments	25		NA
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how	16
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA
Confidentiality	27		13, 16
Declaration of interests	28		17
Access to data	29		17
Ancillary and post-trial care	30		13-14
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups including any publication restrictions	18
	31b	Authorship eligibility guidelines and any intended use of professional writers	NA

	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	16
Appendices			
Informed consent materials	32		NA
Biological specimens	33		NA