SPIRIT-Children and Adolescents (SPIRIT-C) 2026 Fillable Checklist

From: Baba A, Smith M, Potter BK, et al. SPIRIT-Children and Adolescents (SPIRIT-C) 2026 Extension Statement: Enhancing the Reporting and Usefulness of Paediatric Randomised Trial Protocols. *BMJ* 2026;392:e085062

Section/Topic	Item No.	SPIRIT 2025 Statement	Item No.	SPIRIT-Children and Adolescents (SPIRIT-C) 2026 extension	Location reported
Administrative information					
Title and structured summary	1a	Title stating the trial design, population, and interventions, with identification as a protocol	1a.1*	Identify that it is a paediatric trial protocol, and include age group(s)/range(s), interventions, and, if applicable, trial acronym	
	1b	Structured summary of trial design and methods, including items from the World Health Organization Trial Registration Data Set			
Protocol version	2	Version date and identifier			
Roles and responsibilities	3a	Names, affiliations, and roles of protocol contributors			
	3b	Name and contact information for the trial sponsor			
	3c	Role of trial sponsor and funders in design, conduct, analysis, and reporting of trial; including any authority over these activities			
	3d	Composition, roles, and responsibilities of the coordinating site, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable			
Open science					
Trial registration	4	Name of trial registry, identifying number (with URL), and date of registration. If not yet registered, name of intended registry			
Protocol and statistical analysis plan	5	Where the trial protocol and statistical analysis plan can be accessed			
Data sharing	6	Where and how the individual de-identified participant data (including data dictionary), statistical code, and any other materials will be accessible	6.1	Describe whether individual participant data will be shared with others not directly involved in the trial, and how the child/adolescent's and/or family's confidentiality will be respected within the study	
Funding and conflicts of interest	7a	Sources of funding and other support (eg, supply of drugs)			
	7b	Financial and other conflicts of interest for principal investigators and steering committee members			
Dissemination policy	8	Plans to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, reporting in trial registry, plain language summary, publication)			
Introduction					
Background and rationale	9a	Scientific background and rationale, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	9a.1*†	Describe the prevalence/incidence of the disease or condition in children/adolescents	
			9a.2†	Describe the potential for extrapolation from other paediatric populations or adult data, or why extrapolation is not considered appropriate	
			9a.3*	Include a description of the research question or aim with a justification for undertaking the trial in children/adolescents	
	9b	Explanation for choice of comparator			
Objectives	10	Specific objectives related to benefits and harms			

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Methods: Patient and public involvement, trial design					
Patient and public involvement	11	Details of, or plans for, patient or public involvement in the design, conduct, and reporting of the trial			
Trial design	12	Description of trial design including type of trial (eg, parallel group, crossover), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)			
Methods: Participants, interventions, and outcomes					
Trial setting	13	Settings (eg, community, hospital) and locations (eg, countries, sites) where the trial will be conducted	13.1†	Describe any adaptations put in place to support inclusion and participation of children/adolescents	
Eligibility criteria	14a	Eligibility criteria for participants	14a.1*†	Provide a justification for including multiple age groups or children/adolescents at different developmental stages, and address potential age or development-related differences in treatment effects	
	14b	If applicable, eligibility criteria for sites and for individuals who will deliver the interventions (eg, surgeons, physiotherapists)			
Intervention and comparator	15a	Intervention and comparator with sufficient details to allow replication including how, when, and by whom they will be administered. If relevant, where additional materials describing the intervention and comparator (eg, intervention manual) can be accessed	15a.1*†	Describe whether there is an intervention dose and/or formulation appropriate for the trial population, and if there are any adjustments made based on age, weight, or body surface area	
			15a.2†	Give rationale for adapting interventions used in other paediatric populations or adults for the present trial	
			15a.3*†	Describe whether the trial interventions will be delivered with help from a support person	
	15b	Criteria for discontinuing or modifying allocated intervention/comparator for a trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)			
	15c	Strategies to improve adherence to intervention/comparator protocols, if applicable, and any procedures for monitoring adherence (eg, drug tablet return, sessions attended)			
	15d	Concomitant care that is permitted or prohibited during the trial			
Outcomes	16	Primary and secondary outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome	16.1*	Explanation of the validity, reliability, feasibility, and responsiveness of the outcome measurement instruments for the prespecified age groups	
Harms	17	How harms are defined and will be assessed (eg, systematically, non-systematically)	17.1*†	Describe whether trial interventions and/or procedures will induce fear, pain, distress, or are invasive, and what measures are taken to mitigate this	
			17.2	Describe all efforts to reduce the child/adolescent's risk associated with trial participation	

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Participant timeline	18	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Fig 1 in SPIRIT 2025)			
Sample size	19	How sample size was determined, including all assumptions supporting the sample size calculation			
Recruitment	20	Strategies for achieving adequate participant enrolment to reach target sample size	20.1	Describe the anticipated impact of trial participation on the child/adolescent's daily life	
			20.2	Describe how participating children/adolescents will be given recognition for trial participation	
Methods: Assignment of interventions					
Randomisation:					
Sequence generation	21a	Who will generate the random allocation sequence and the method used			
	21b	Type of randomisation (simple or restricted) and details of any factors for stratification. To reduce predictability of a random sequence, other details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enroll participants or assign interventions			
Allocation concealment mechanism	22	Mechanism used to implement the random allocation sequence (eg, central computer/telephone; sequentially numbered, opaque, sealed containers), describing any steps to conceal the sequence until interventions are assigned			
Implementation	23	Whether the personnel who will enrol and those who will assign participants to the interventions will have access to the random allocation sequence			
Blinding	24a	Who will be blinded after assignment to interventions (eg, participants, care providers, outcome assessors, data analysts)			
	24b	If blinded, how blinding will be achieved and description of the similarity of interventions			
	24c	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial			
Methods: Data collection, management, and analysis					
Data collection methods	25a	Plans for assessment and collection of trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of trial instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be accessed, if not in the protocol			
	25b	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			

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Data management	26	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be accessed, if not in the protocol			
Statistical methods	27a	Statistical methods used to compare groups for primary and secondary outcomes, including harms			
	27b	Definition of who will be included in each analysis (eg, all randomised participants), and in which group			
	27c	How missing data will be handled in the analysis			
	27d	Methods for any additional analyses (eg, subgroup and sensitivity analyses)			
Methods: Monitoring					
Data monitoring committee	28a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and funder; conflicts of interest and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed			
	28b	Explanation of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial			
Trial monitoring	29	Frequency and procedures for monitoring trial conduct. If there is no monitoring, give explanation			
Ethics					
Research ethics approval	30	Plans for seeking research ethics committee/institutional review board approval			
Protocol amendments	31	Plans for communicating important protocol modifications to relevant parties			
Consent or assent	32a	Who will obtain informed consent or assent from potential trial participants or authorised proxies, and how	32a.1†	Provide information on whether developmentally appropriate materials with understandable information on the trial process will be provided to participants in obtaining informed consent or assent, and state where materials can be found or if available on request	
	32b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable			
Confidentiality	33	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial			
Ancillary and post-trial care	34	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	34.1†	Describe plans for assessing outcomes and harms beyond the formal study completion date	

For optimal use of the SPIRIT-Children and Adolescents (SPIRIT-C) 2026 checklist, refer to the SPIRIT-C 2026 Explanation and Elaboration (E&E) document.

* New item pertains to both SPIRIT-C 2026 and CONSORT-C 2026; † Report item if applicable or state explicitly that it is not applicable