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

Section/Topic	Item No.	CONSORT 2025 Statement	Item No.	CONSORT-Children and Adolescents (CONSORT-C) 2026 extension	Location reported
Title and abstract					
Title and structured abstract	1a	Identification as a randomised trial	1a.1*	Identify that it is a paediatric trial, and include age group(s)/range(s), interventions, and, if applicable, trial acronym	
	1b	Structured summary of the trial design, methods, results, and conclusions			
Open science					
Trial registration	2	Name of trial registry, identifying number (with URL) and date of registration			
Protocol and statistical analysis plan	3	Where the trial protocol and statistical analysis plan can be accessed			
Data sharing	4	Where and how the individual de-identified participant data (including data dictionary), statistical code and any other materials can be accessed			
Funding and conflicts of interest	5a	Sources of funding and other support (eg, supply of drugs), and role of funders in the design, conduct, analysis and reporting of the trial			
	5b	Financial and other conflicts of interest of the manuscript authors			
Introduction					
Background and rationale	6	Scientific background and rationale	6.1*†	Describe the prevalence/incidence of the disease or condition in children/adolescents	
			6.2	Describe available evidence on the efficacy/effectiveness of the intervention in children/adolescents	
			6.3*	Include a description of the research question or aim with a justification for undertaking the trial in children/adolescents	
Objectives	7	Specific objectives related to benefits and harms			
Methods					
Patient and public involvement	8	Details of patient or public involvement in the design, conduct and reporting of the trial			
Trial design	9	Description of trial design including type of trial (eg, parallel group, crossover), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)			
Changes to trial protocol	10	Important changes to the trial after it commenced including any outcomes or analyses that were not prespecified, with reason			
Trial setting	11	Settings (eg, community, hospital) and locations (eg, countries, sites) where the trial was conducted			
Eligibility criteria	12a	Eligibility criteria for participants	12a.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	

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			12a.2	Describe whether information about the trial was provided to participating children/adolescents and assent given/consent obtained, if appropriate for age	
	12b	If applicable, eligibility criteria for sites and for individuals delivering the interventions (eg, surgeons, physiotherapists)			
Intervention and comparator	13	Intervention and comparator with sufficient details to allow replication. If relevant, where additional materials describing the intervention and comparator (eg, intervention manual) can be accessed	13.1*†	Describe whether there is an intervention dose and/or formulation appropriate for the trial population, and if there were any adjustments made based on age, weight, or body surface area	
			13.2*†	Describe whether the trial interventions were delivered with help from a support person	
Outcomes	14	Prespecified 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	14.1*	Explain evidence supporting validity of selected outcomes and outcome measurement instruments in age group(s) included	
Harms	15	How harms were defined and assessed (eg, systematically, non-systematically)	15.1*†	Describe whether trial interventions and/or procedures induced fear, pain, distress, or were invasive, and what measures were taken to mitigate this	
Sample size	16a	How sample size was determined, including all assumptions supporting the sample size calculation			
	16b	Explanation of any interim analyses and stopping guidelines			
Randomisation:					
Sequence generation	17a	Who generated the random allocation sequence and the method used			
	17b	Type of randomisation and details of any restriction (eg, stratification, blocking and block size)			
Allocation concealment mechanism	18	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 were assigned			
Implementation	19	Whether the personnel who enrolled and those who assigned participants to the interventions had access to the random allocation sequence			
Blinding	20a	Who was blinded after assignment to interventions (eg, participants, care providers, outcome assessors, data analysts)			
	20b	If blinded, how blinding was achieved and description of the similarity of interventions			
Statistical methods	21a	Statistical methods used to compare groups for primary and secondary outcomes, including harms			

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	21b	Definition of who is included in each analysis (eg, all randomised participants), and in which group			
	21c	How missing data were handled in the analysis			
	21d	Methods for any additional analyses (eg, subgroup and sensitivity analyses), distinguishing prespecified from post hoc			
Results					
Participant flow, including flow diagram	22a	For each group, the numbers of participants who were randomly assigned, received intended intervention, and were analysed for the primary outcome			
	22b	For each group, losses and exclusions after randomisation, together with reasons			
Recruitment	23a	Dates defining the periods of recruitment and follow-up for outcomes of benefits and harms			
	23b	If relevant, why the trial ended or was stopped			
Intervention and comparator delivery	24a	Intervention and comparator as they were actually administered (eg, where appropriate, who delivered the intervention/comparator, how participants adhered, whether they were delivered as intended (fidelity))			
	24b	Concomitant care received during the trial for each group			
Baseline data	25	A table showing baseline demographic and clinical characteristics for each group	25.1†	Report number of children/adolescents in the trial by prespecified age group(s)	
Numbers analysed, outcomes and estimation	26	For each primary and secondary outcome, by group: • the number of participants included in the analysis • the number of participants with available data at the outcome time point • result for each group, and the estimated effect size and its precision (such as 95% confidence interval) for binary outcomes, presentation of both absolute and relative effect size			
Harms	27	All harms or unintended events in each group			
Ancillary analyses	28	Any other analyses performed, including subgroup and sensitivity analyses, distinguishing pre-specified from post hoc	28.1†	For each primary and secondary outcome, report results for each prespecified age group studied	
Discussion					
Interpretation	29	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	29.1	Highlight unanswered and new questions, and discuss potential future research	
Limitations	30	Trial limitations, addressing sources of potential bias, imprecision, generalisability, and, if relevant, multiplicity of analyses			

For optimal use of the CONSORT-Children and Adolescents (CONSORT-C) 2026 checklist, refer to the CONSORT-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