SPIRIT | CONSORT CHILDREN & ADOLESCENTS
Reporting Guidelines for Child Health Trials

SPIRIT-C 2026

Item 15a.1: Intervention and comparator – Dose/formulation

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

Administrative information	1a.1	Title and structured summary	✓
Open science	6.1	Data sharing	✓
Introduction	9a.1	Background and rationale *Prevalence/incidence*	✓
	9a.2	Background and rationale *Extrapolation*	✓
	9a.3	Background and rationale *Research question or aim*	✓
Methods	13.1	Trial setting	✓
	14a.1	Eligibility criteria	✓
	15a.1	Intervention and comparator *Dose/formulation*	◀
	15a.2	Intervention and comparator *Adaptations*	
	15a.3	Intervention and comparator *Intervention delivery*	
	16.1	Outcomes	
	17.1	Harms *Mitigation measures*	
	17.2	Harms *Efforts to reduce risk*	
	20.1	Recruitment *Impact of trial participation*	
	20.2	Recruitment *Recognition for trial participation*	
Ethics	32a.1	Consent or assent	
	34.1	Ancillary and post-trial care	

Key elements for reporting this item:

For both the experimental and comparator intervention:
- How the dose and/or formulation is appropriate for the target population
- Provide any available dose/exposure data from paediatric studies or regulatory agencies supporting the choice
- Adjustments made to the intervention dose or formulation, based on trial participant's age, weight, or body surface area
- Efforts to make the formulation palatable and acceptable for participants, or how this will be assessed
- Possible palatability and bioavailability differences between different formulations.

Examples:

"Nano-curcumin (Exir Nano Sina Drug Company, Iran) is prepared as nano micelle in the form of 70 mg of drops in 1 cc, and the placebo with the same color, taste, and odor. To adjust the drug dose for different ages and considering that the maximum acceptable dose based with the most significant impact and minimum side effects was 80 mg, the required amount will be obtained for each subject based on the ratio of the body surface area of the patients. The curcumin and placebo glasses have been labeled A and B by Exir Nano Sina company, respectively, and made available to the patients through a double-blind design. Curcumin or placebo will be administered orally alone or with sweetened water once daily at bedtime and at a fixed dose for 3 months."

Talebi S, Safarian M, Jaafari MR, et al. The effects of nano-curcumin as a nutritional strategy on clinical and inflammatory factors in children with cystic fibrosis: the study protocol for a randomized controlled trial. Trials 2021;22:292. doi:10.1186/s13063-021-05224-6

See the E&E for more examples.

Statement (co-published in *The BMJ, JAMA Pediatrics, and The Lancet Child and Adolescent Health*): 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. doi: 10.1136/bmj-2025-085062

Explanation and Elaboration: Baba A, Smith M, Potter BK, et al. SPIRIT-C 2026 explanation and elaboration: recommendations for enhancing the reporting and impact of paediatric randomised trials. BMJ 2026;392:e085064. doi: 10.1136/bmj-2025-085064