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

CONSORT-C 2026

Item 13.1: Intervention and comparator

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

Title and abstract	1a.1	Title and structured abstract
Introduction	6.1	Background and rationale *Prevalence/incidence*
	6.2	Background and rationale *Efficacy/effectiveness*
	6.3	Background and rationale *Research question or aim*
Methods	12a.1	Eligibility criteria *Justification for including multiple age groups*
	12a.2	Eligibility criteria *Age-appropriate trial information*
	13.1	Intervention and comparator *Dose/formulation*
	13.2	Intervention and comparator *Intervention delivery*
	14.1	Outcomes
	15.1	Harms
Results	25.1	Baseline data
	28.1	Ancillary analyses
Discussion	29.1	Interpretation

Key elements for reporting this item:

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

Examples:

"In the experimental condition, infants received music therapy in addition to standard care support (described below) (. . .) the music therapist utilized the electronic stethoscope Thinklabs One Digital Stethoscope (manufacturer location: Centennial, CO, USA) to record the mother's heartbeat. The sample of sung maternal voice was combined with a sample of the mother's heartbeat and looped into a 5-min arrangement using music editing software (. . .) the 5-min recording of the maternal lullaby singing with heartbeat was played immediately after the exam. Dayton Audio B652 bookshelf speakers placed on a bed-level cart were used for recorded intervention playback. Speakers were placed at the feet or head of the infant when possible for binaural playback. Decibel levels were monitored throughout the recorded intervention via the BAFX Decibel Meter. Loudness of the recorded intervention was adjusted as needed to maintain 60 A-weighted decibels (dBA) at the infant's head and per music use guidelines for preterm infants[reference]."

Corrigan MJ, Keeler JR, Miller HD, Ben Khallouq BA, Fowler SB. Music therapy and retinopathy of prematurity screening: using recorded maternal singing and heartbeat for post exam recovery. J Perinatol 2020;40:1780-8. doi:10.1038/s41372-020-0719-9.

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. CONSORT-Children and Adolescents (CONSORT-C) 2026 Extension Statement: Enhancing the Reporting and Impact of Paediatric Randomised Trials. BMJ 2026;392:e085061. doi: 10.1136/bmj-2025-085061

Explanation and Elaboration: Baba A, Smith M, Potter BK, et al. CONSORT-C 2026 explanation and elaboration: recommendations for enhancing the reporting and impact of paediatric randomised trials. BMJ 2026;392:e085063. doi: 10.1136/bmj-2025-085063