

Item 1a.1: Title

**Identify that it is a paediatric trial, and include age group(s)/range(s), interventions, and if applicable, trial acronym**

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

**Key elements for reporting this item:**

- Clearly indicate it is a paediatric trial with relevant terms (eg, paediatric, newborns, infants, children, young children, adolescents)
- (Sub) population accompanied by age range(s)
- Intervention(s)
- Acronym, if used.

**Examples:**

*“Effect of cryoanesthesia and sweet tasting solution in reducing injection pain in pediatric patients aged 7-10 years: a randomized controlled trial”*

Davangere Padmanabh SK, Gangurde VB, Jhamb V, Gori N. Effect of cryoanesthesia and sweet tasting solution in reducing injection pain in pediatric patients aged 7-10 years: a randomized controlled trial. *J Dent Anesth Pain Med* 2024;24:37-45. doi:10.17245/jdamp.2024.24.1.37.

*“Safety of the novel oral poliovirus vaccine type 2 (nOPV2) in infants and young children aged 1 to <5 years and lot-to-lot consistency of the immune response to nOPV2 in infants in The Gambia: a phase 3, double-blind, randomised controlled trial”*

Ochoge M, Futa AC, Umesi A, et al. Safety of the novel oral poliovirus vaccine type 2 (nOPV2) in infants and young children aged 1 to <5 years and lot-to-lot consistency of the immune response to nOPV2 in infants in The Gambia: a phase 3, double-blind, randomised controlled trial. *Lancet* 2024;403:1164-75. doi:10.1016/S0140-6736(23)02844-1.

*“A phase 2, randomized, double-blind, placebo-controlled trial of the efficacy and safety of soticlestat as adjunctive therapy in children aged 2-17 years [pediatric patients] with Dravet syndrome or Lennox-Gastaut syndrome: The ELEKTRA trial [ELEKTRA].”*

(Adapted version, with square brackets showing original text.)

Hahn CD, Jiang Y, Villanueva V, et al. A phase 2, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of soticlestat as adjunctive therapy in pediatric patients with Dravet syndrome or Lennox-Gastaut syndrome (ELEKTRA). *Epilepsia* 2022;63:2671-83. doi:10.1111/epi.17367

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](https://doi.org/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](https://doi.org/10.1136/bmj-2025-085063)

More resources are available at: <https://lab.research.sickkids.ca/enrich/reporting-standards/spirit-consort-c/>.  
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