

Item 1a.1: Title

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

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



Key elements for reporting this item:

- Clear indication that it is a paediatric trial protocol with relevant terms (eg, paediatric, newborn, infants, children, young children, adolescents)
- (Sub)population accompanied by age range(s)
- Intervention(s)
- Acronym, if used.

Examples:

“Vagus nerve stimulation for pediatric patients with intractable epilepsy between 3 and 6 years of age: study protocol for a double-blind, randomized control trial.”

Ji T, Yang Z, Liu Q, et al. Vagus nerve stimulation for pediatric patients with intractable epilepsy between 3 and 6 years of age: study protocol for a double-blind, randomized control trial. *Trials* 2019;20:44. doi:10.1186/s13063-018-3087-4.

“Reducing disparities in behavioral health treatment in pediatric primary care: a randomized controlled trial comparing Partnering to Achieve School Success (PASS) to usual ADHD care for children ages 5 to 11 – study protocol.”

Mautone JA, Holdaway A, Chan W, et al. Reducing disparities in behavioral health treatment in pediatric primary care: a randomized controlled trial comparing Partnering to Achieve School Success (PASS) to usual ADHD care for children ages 5 to 11 - study protocol. *BMC Prim Care* 2024;25:225. doi:10.1186/s12875-024-02473-7.

“Evaluating the efficacy of a multistrain probiotic supplementation for prevention of neonatal sepsis in 0-2-month-old low birth weight infants in India-the “ProSPoNS” Study protocol for a phase III, multicentric, randomised, double-blind, placebo-controlled trial.”

Sinha AP, Gupta SS, Poluru R, et al; ProSPoNS study Group. Evaluating the efficacy of a multistrain probiotic supplementation for prevention of neonatal sepsis in 0-2-month-old low birth weight infants in India-the “ProSPoNS” Study protocol for a phase III, multicentric, randomized, double-blind, placebo-controlled trial. *Trials* 2021;22:242. doi:10.1186/s13063-021-05193-w.

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](https://doi.org/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](https://doi.org/10.1136/bmj-2025-085064)