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

SPIRIT-C 2026

Item 9a.1: Background and rationale – prevalence/incidence

Describe the prevalence/incidence of the disease or condition in children/adolescents

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:

- Prevalence and/or incidence of the condition in the designated trial population
- Known variability in prevalence and/or incidence for each included (sub)group
- Paediatric (sub)groups who are most affected by the disease or condition.

Examples:

"[Irritable bowel syndrome] IBS is a complex, chronic, functional disorder for which there is no cure. The condition is characterized by abdominal pain/discomfort and altered bowel habits; other symptoms may include nausea, vomiting, and bloating. IBS prevalence estimates in North America for adults and adolescents are between 10-15%[reference]. Boys and girls appear to be equally affected until late adolescence[reference], when sex differences emerge and women are twice as likely to be affected as men[reference]."

Evans S, Cousins L, Tsao JC, Sternlieb B, Zeltzer LK. Protocol for a randomized controlled study of Iyengar yoga for youth with irritable bowel syndrome. Trials 2011;12:15. doi:10.1186/1745-6215-12-15

"Complete catheter occlusion, where the catheter cannot be aspirated or injected into, affects 14%-36% of children undergoing cancer treatment with long-term [central venous access devices] CVAD devices,[reference] with an estimated incidence rate of 1.4 per 1000 catheter days."

Ullman A, Takashima M, Gibson V, et al. Preventing adverse events during paediatric cancer treatment: protocol for a multi-site hybrid randomised controlled trial of catheter lock solutions (the CLOCK trial). BMJ Open 2024;14:e085637. doi:10.1136/bmjopen-2024-085637.

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

The SPIRIT | CONSORT-C 2026 tip sheets are intended for non-commercial use only. No part of the materials may be used for commercial purposes.