

Item 6.1: Introduction – Background and Rationale

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

Title and abstract	1a.1	Title and structured abstract
Introduction	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>
Methods	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
Results	25.1	Baseline data
	28.1	Ancillary analyses
Discussion	29.1	Interpretation

Key elements for reporting this item:

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

Examples:

“Daytime urinary incontinence is common and occurs in 17% of school-aged children, with 2% wetting at least twice per week.”^[reference]

Caldwell PHY, Kerr M, Hamilton S, Teixeira-Pinto A, Craig JC. An Alarm Watch for Daytime Urinary Incontinence: A Randomized Controlled Trial. *Pediatrics* 2022;149:e2021053863. doi:10.1542/peds.2021-053863.

“Pectus excavatum is the most common chest wall malformation, and the incidence rate is approximately 1 in 400 in young adults and children.”^[reference]

Chen T, Xu Y, Chen Y, Chen S, Zhang Y. Analgesic Effectiveness of Truncal Plane Blocks in Patients Undergoing the Nuss Procedure: A Randomized Controlled Trial. *Pain Ther* 2024;13:909-17. doi:10.1007/s40122-024-00627-0.

“Irritable bowel syndrome (IBS) and functional abdominal pain (syndrome) (FAP(S)) are functional gastrointestinal disorders (FGIDs) that are characterized by chronic or recurrent abdominal pain in absence of an underlying organic disorder causing the symptoms^[reference]. These disorders affect approximately 20% of children in Western countries and are also prevalent in Asian countries such as Sri Lanka and China, affecting 12.5 to 20% of school-aged children^[reference].”

Rutten JM, Vlieger AM, Frankenhuys C, et al. Gut-directed hypnotherapy in children with irritable bowel syndrome or functional abdominal pain (syndrome): a randomized controlled trial on self exercises at home using CD versus individual therapy by qualified therapists. *BMC Pediatr* 2014;14:140. doi:10.1186/1471-2431-14-140.

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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)

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