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

CONSORT-C 2026

Item 6.2: Introduction – Background and Rationale

Describe available evidence on the efficacy/effectiveness of the intervention in children/adolescents

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:

- Existing evidence of efficacy/effectiveness of intervention in children/adolescents
- Whether paediatric evidence is available, yet uncertainty exists for children/adolescents overall or for specific age subgroups
- Whether evidence is only available in adults.

Examples:

"Burns to the thorax are at high risk for long-term pulmonary complications due to chest muscle contractures and chronic inflammation in both adolescents and young adults. Few studies have investigated the effects of arm cycling exercise in those individuals. For that reason, this study examined pulmonary function, functional capacity, and quality of life (QOL) in adolescents [ages 11-17 years] with thoracic burns subsequent to 2-month arm cycling exercise programme."

(Adapted, with ages added in square brackets.)

Abdelbasset WK, Elsayed SH, Nambi G, et al. Optimization of pulmonary function, functional capacity, and quality of life in adolescents with thoracic burns after a 2-month arm cycling exercise programme: A randomized controlled study. Burns 2022;48:78-84. doi:10.1016/j.burns.2021.03.010.

"Exogenous surfactant preparations have been successful in treating and preventing neonatal respiratory distress syndrome[reference] and are now considered standard of care. However, efficacy in older children and adults has been variable[reference]. A 21-center trial of intratracheal calfactant installation in children with [paediatric acute respiratory distress syndrome] PARDS demonstrated improved survival relative to placebo[reference]. Moreover, a post-hoc analysis suggested a potential benefit of calfactant in immunocompromised children with acute respiratory failure characterized by an oxygenation index (OI) between 13 and 37[reference]. Encouraged by these results, a double-blinded, randomized, controlled, multicenter trial was designed to evaluate the efficacy of calfactant relative to placebo in reducing mortality in immunosuppressed children with leukemia/lymphoma or following HCT for any indication with PARDS."

Thomas NJ, Spear D, Wasserman E, et al; CALIPSO Study Investigators and the Pediatric Acute Lung Injury and Sepsis Investigators Network. CALIPSO: A Randomized Controlled Trial of Calfactant for Acute Lung Injury in Pediatric Stem Cell and Oncology Patients. Biol Blood Marrow Transplant 2018;24:2479-86. doi:10.1016/j.bbmt.2018.07.023.

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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