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

SPIRIT-C 2026

Item 16.1: Outcomes

Explanation of the validity, reliability, feasibility, and responsiveness of the outcome measurement instruments for the prespecified age groups

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:

• Justification and relevance of the outcome measurement instrument(s) for the prespecified age/developmental group(s) and where relevant, the specific health condition
• Validity, reliability, responsiveness, and feasibility of trial outcome measurement instruments in the target population
• Who is assessing/reporting the outcomes or gathering the outcome data using the trial outcome measurement instrument, and whether the outcome measurement instrument(s) are child/adolescent centred (eg, if parent reported outcome, clearly specify whether the measure is a parent-proxy report of child outcomes, or a parent self-report).

Examples:

"Functional independence level: The WeeFIM (functional independence measure) instrument is a useful pediatric functional independence assessment tool for children aged 6 months to 7 years and for children with developmental disabilities aged 6 months to 21 years . . . The WeeFIM is a psychometrically sound instrument in terms of its reliability, validity, and responsiveness[reference] . . . Quality of life: The Short Form 36 (SF-36) is used to evaluate parents' quality of life; it is a widely used health status survey designed to assess quality of life by measuring the individual's self-perception of his/her own health status with 8 multi-item scales, including physical functioning, physical role functioning, bodily pain, general health, vitality, social functioning, emotional role functioning, and mental health, and one single item of health transition. It can be used to assess the quality of life for patients with various diseases or people in general. The reliability, validity, and sensitivity of the Chinese (simple) SF-36v2 have been verified[reference]."

Du Q, Salem Y, Liu HH, et al. A home-based exercise program for children with congenital heart disease following interventional cardiac catheterization: study protocol for a randomized controlled trial. Trials 2017;18:38. doi:10.1186/s13063-016-1773-7.

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