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

SPIRIT-C 2026

Item 13.1: Trial setting

Describe any adaptations put in place to support inclusion and participation of 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:

- Adaptations, processes, or procedures to promote inclusion and retention, with respect to trial visit timing, environmental adjustments, data collection, and diverse ways to communicate information and address questions
- How the need for such adaptations was determined, whether with involvement of participants, caregivers, or community partners
- Whether adaptations need to be considered in the data analysis.

Examples:

"To make the trial accessible and inclusive for people from diverse backgrounds, with different ways of communicating and thinking about information, and with varying resources, we have developed a suite of adaptations that can be deployed, as required, to tailor [the trial recruitment and consenting for individuals]. These adaptations have been carefully designed with [child and family partners] from across communities, ethnic and cultural backgrounds, and sexes – and with different ways of communicating and thinking. The adaptations relate to how we describe, present and share information about the trial; the ways in which we enable [young people] and parents to ask questions and learn more about the trial; and how we receive consent. The adaptations will be available to all clusters and be deployed at an agreement of the cluster [principal investigator] PI, their delegates, the parent(s), and/or the trial team, as appropriate. The suite of adaptations includes the following, and can be combined as appropriate:

- *Translated materials and information, including picture communication.*
- *An interpreter.*
- *Audio format of the key materials.*
- *In-person support to access and process information, explain and answering questions.*
- *Sharing materials with another person, and leaving them a copy that they can share and communicate about with others.*
- *Making clear, workable plans for support that the parent can access for completing the trial questionnaires.*
- *An option for verbal consent, audio recorded".*

(Adapted from the Children's Early Self-care Support (CHESS) trial, with square brackets showing inserted detail.)

National Institute for Health and Care Research. Investigating the clinical and cost-effectiveness of CHildren's Early Self-care Support in children with neurodisability: the CHESS cluster randomised controlled trial. 2024. https://www.fundingawards.nihr.ac.uk/award/NIHR15

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