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

SPIRIT-C 2026

Item 15a.2: Intervention and comparator - Adaptations

Give rationale for adapting interventions used in other paediatric populations or adults for the present trial

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:

- Evidence that the original intervention or comparator worked elsewhere with details about the context(s) and populations in which it has been evaluated
- The rationale for adapting intervention or comparator to trial population and context with consideration of the intervention-context fit of existing intervention(s) and mapping of similarities and differences between original and new contexts and populations
- How adaptations were made, piloted, and evaluated and how the intervention or comparator was implemented, (based on ADAPT), or where this information can be found
- Level of confidence on the validity of the adaptations made.

Examples:

"GMT [goal management training] is a manualised cognitive remediation intervention that utilises metacognitive strategies to enhance executive and attentional processes[reference]. It focuses on mechanisms of inhibitory control by teaching problem-solving skills, inhibition strategies, and mindfulness techniques, making it a suitable approach for individuals with [attention-deficit/hyperactivity disorder] ADHD [reference] Approximately 80 studies have documented the efficacy of GMT on adult patients with traumatic brain injury, spina bifida, multiple sclerosis, stroke, post-traumatic stress disorder (PTSD) affective disorders, as well as adults with ADHD[reference]. GMT has yet to be tested on adolescents with ADHD, but a paediatric version of the GMT manual for children and adolescents has been developed and tested with promising results [reference]. Moreover, a recent study showcased encouraging outcomes using a GMT-based program for adolescents with executive dysfunction complaints[reference]."

Dyresen A, Stubberud J, Fjermestad KW, Haugen I, Øie MG. Executive control training for adolescents with ADHD: Study protocol for a randomised controlled trial. Contemp Clin Trials 2024;136:107404. doi:10.1016/j.cct.2023.107404.

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