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

SPIRIT-C 2026

Item 34.1: Ancillary and post-trial care

Describe plans for assessing outcomes and harms beyond the formal study completion date

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:

- Planned outcomes (including harms) that will be assessed, with methods and frequency of assessment
- Duration of follow-up past formal trial completion date
- How and when results of extended monitoring will be available
- If no plans, desired follow-up length to capture important long term outcomes, and any plans to seek funding for future follow-up or provide a rationale for not needing to conduct long term follow-up.

Examples:

"On a monthly base, assessments of bipolar psychopathology ([Structured Clinical Interview for DSM Disorders] SCID, [Young Mania Rating Scale] YMRS, [Inventory of Depressive Symptomatology, clinician version] IDS-C30) are conducted by the rater who is blind to the patients' group assignment. A post-trial follow-up of four weeks per patient follows subsequently after the end of the 72 weeks intervention phase."

Mühlbauer E, Bauer M, Ebner-Priemer U, et al. Effectiveness of smartphone-based ambulatory assessment (SBAA-BD) including a predicting system for upcoming episodes in the long-term treatment of patients with bipolar disorders: study protocol for a randomized controlled single-blind trial. BMC Psychiatry 2018;18:349. doi:10.1186/s12888-018-1929-y.

" Follow up of the participants in this randomized controlled trial will be complete at the end of the 3-year study period. No evaluation of potential long-term sequelae is planned with available funding. However, efforts to enable ten-year follow up are recommended due to uncertainty about the long-term impacts of the intervention on the cardiovascular system; we plan to submit a grant to the International Society of Paediatric Oncology (SIOP)."

Expert Consensus Example

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