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

SPIRIT-C 2026

Item 17.2: Harms – Efforts to reduce risk

Describe all efforts to reduce the child/adolescent's risk associated with trial participation

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:

- Any foreseen risk associated with participating in the trial
- Age appropriate efforts to reduce this foreseen risk
- How children/adolescents and/or parents were involved in planning/deciding on how to reduce harms.

Examples:

"During the first week, only [enteral nutrition] EN without supplemental [parenteral nutrition] PN will be provided to conform with current guidelines[reference]. Beyond day 7, if EN is insufficient (<80% of the target intake), parenteral macronutrients will be additionally provided through PN until EN reaches >80% of the target intake. If standard PN formulas are not suitable or are contraindicated for the patient, a tailor-made PN formula can be ordered by the dietician. To reduce the risk of refeeding syndrome on the first day of PN, half the target amount of PN will be provided[reference]."

Veldscholte K, Cramer ABG, de Jonge RCJ, Eveleens RD, Joosten KFM, Verbruggen SCAT. Continuous Versus Intermittent Nutrition in Pediatric Intensive Care Patients: Protocol for a Randomized Controlled Trial. JMIR Res Protoc 2022;11:e36229. doi:10.2196/36229.

"We do not expect any severe complications during the study. The medical equipment and insulin used during the study will be approved for clinical use. The most probable and harmful adverse effect during the postprandial period is hypoglycemia. Intensive glycemic control using both [continuous glucose monitoring] CGM and [self-monitoring of blood glucose] SMBG will be used against severe hypoglycemic events and will provide the most accurate glycemic measurements. Despite the inconvenience of having to monitor the blood glucose levels by doing multiple finger pricks, it is necessary to ensure the safety of the study procedure. Moreover, CGM-related minor local adverse events, such as the possibility of developing an infection, redness, bleeding, hypersensitivity, itching, irritation, or pain at the sensor site, may occur. CGM will be applied by qualified personnel to reduce the risk of complications."

Kowalczyk E, Dżygało K, Szypowska A. Super Bolus: a remedy for a high glycemic index meal in children with type 1 diabetes on insulin pump therapy?-study protocol for a randomized controlled trial. Trials 2022;23:240. doi:10.1186/s13063-022-06173-4. PubMed

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