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

SPIRIT-C 2026

Item 20.1: Recruitment – Impact of trial participation

Describe the anticipated impact of trial participation on the child/adolescent's daily life

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:

- Anticipated impact of trial participation on the child and family's daily life
- Mitigation strategies that are put in place.

Examples:

"Participants will be asked to consume 125 mL of study drink per day for 6 weeks. Both intervention and control drinks are supplied in plain packaging and delivered chilled using the same courier company. During the intervention, participants will be asked to maintain their usual diet and daily routine. Drinks are distributed to participants at the beginning of the study and at the midpoint to allow for adequate storage space in the fridge. Participants will be asked to consume drinks every day for the duration of the study. The drink can be taken on its own, with food, or combined into a smoothie. Recipe ideas for how to combine the drink into smoothie drinks or bowls are provided."

Lawrence K, Fibert P, Hobbs J, et al. Randomised controlled trial of the effects of kefir on behaviour, sleep and the microbiome in children with ADHD: a study protocol. BMJ Open 2023;13:e071063. doi:10.1136/bmjopen-2022-071063.

"We anticipate that the participants will miss one day of school per week for the duration of their participation in the trial in order to attend the study clinic. For the duration of the trial, participants will need around 15 minutes per day to complete an eDiary. Participants might feel fatigued the day after the first few trial visits which could have implications for their level of engagement in school or extracurricular activities."

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