

Item 15a.3: Intervention and comparator – Intervention delivery

Describe whether the trial interventions will be delivered with help from a support person

Administrative information	1a.1	Title and structured summary
Open science	6.1	Data sharing
Introduction	9a.1	Background and rationale <i>Prevalence/incidence</i>
	9a.2	Background and rationale <i>Extrapolation</i>
	9a.3	Background and rationale <i>Research question or aim</i>
Methods	13.1	Trial setting
	14a.1	Eligibility criteria
	15a.1	Intervention and comparator <i>Dose/formulation</i>
	15a.2	Intervention and comparator <i>Adaptations</i>
	15a.3	Intervention and comparator <i>Intervention delivery</i>
	16.1	Outcomes
	17.1	Harms <i>Mitigation measures</i>
	17.2	Harms <i>Efforts to reduce risk</i>
	20.1	Recruitment <i>Impact of trial participation</i>
	20.2	Recruitment <i>Recognition for trial participation</i>
Ethics	32a.1	Consent or assent
	34.1	Ancillary and post-trial care

Key elements for reporting this item:

- To what extent assistance is required from a support person and how they will be involved
- Who the support person is and if there is any specific training for the support individuals(s) to deliver the intervention, or to support the participant during intervention delivery
- Where appropriate, who will determine the requirement for help, and who will determine who the support person will be
- Whether help is required for the intervention only during trial conduct, or also afterwards if intervention is continued after the trial.

Examples:

“Caregivers will be instructed to administer a dose, based on need as assessed by the caregiver (i.e., for preverbal children) or expressed by the child (i.e., for verbal children), every 8 h to a maximum of three doses in a 24-h period. A dose should only be administered if it is felt the child is nauseated or experiencing ongoing vomiting and hence would be beneficial. Caregivers will be given a study medication diary to track the administration of study medication doses and a discharge instruction sheet explaining the primary benefits of medication use, how to contact the study team, study requirements, and health care provider follow-up criteria.”

Freedman SB, Williamson-Urquhart S, Heath A, et al; KidsCAN-Pediatric Emergency Research Canada (PERC) Innovative Pediatric Clinical Trials DOSE-AGE Study Group. Multi-dose Oral Ondansetron for Pediatric Gastroenteritis: study Protocol for the multi-DOSE oral ondansetron for pediatric Acute GastroEnteritis (DOSE-AGE) pragmatic randomized controlled trial. *Trials* 2020;21:435. doi:10.1186/s13063-020-04347-6.

“Social support for participation in all program activities will be provided by teachers, parents, and students throughout the intervention period. For example, teachers will verbally encourage students to join in the break-time games, there will be posters pinned at the exit points of the classroom reminding students to complete their home activities and to be active at lunch and recess, Fit-4-Fun leaders (students) will be asked to encourage other students to participate in activities and to make the equipment available for use, and parents will be asked to support and encourage their child at home.”

Eather N, Morgan PJ, Lubans DR. Improving health-related fitness in children: the Fit-4-Fun randomized controlled trial study protocol. *BMC Public Health* 2011;11:902. doi:10.1186/1471-2458-11-902. 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](https://doi.org/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](https://doi.org/10.1136/bmj-2025-085064)