

Item 12a.2: Eligibility criteria

**Describe whether information about the trial was provided to participating children/adolescents and assent given/consent obtained, if appropriate for age**

<b>Title and abstract</b>	1a.1	Title and structured abstract
<b>Introduction</b>	6.1	Background and rationale <i>Prevalence/incidence</i>
	6.2	Background and rationale <i>Efficacy/effectiveness</i>
	6.3	Background and rationale <i>Research question or aim</i>
<b>Methods</b>	12a.1	Eligibility criteria <i>Justification for including multiple age groups</i>
	12a.2	Eligibility criteria <i>Age-appropriate trial information</i>
	13.1	Intervention and comparator <i>Dose/formulation</i>
	13.2	Intervention and comparator <i>Intervention delivery</i>
	14.1	Outcomes
	15.1	Harms
	<b>Results</b>	25.1
28.1		Ancillary analyses
<b>Discussion</b>	29.1	Interpretation

**Key elements for reporting this item:**

- Age group(s) or developmental stage(s) for which the material was prepared
- How information was prepared to be developmentally appropriate for the target population
- Where the developmentally appropriate materials can be found, or whether available on request.

**Examples:**

*“If individuals were aged younger than 18 years, parents or guardians provided written informed consent and the individual provided assent; to address potential issues of coercion, the assent document included the following statement: “Your doctors and your parents cannot make you be in this study if you don’t want to be in it.” Individuals aged 18 years and older provided written informed consent. The study, including the informed consent and assent process, was done with attention to ethical issues specific to adolescent tobacco cessation, and in accordance with the general principles set forth in the International Ethical Guidelines for Biomedical Research Involving Human Subjects, Guidelines for Good Clinical Practice, and the Declaration of Helsinki.”<sup>[reference]</sup>”*

Gray KM, Rubinstein ML, Prochaska JJ, et al. High-dose and low-dose varenicline for smoking cessation in adolescents: a randomised, placebo-controlled trial. *Lancet Child Adolesc Health* 2020;4:837-45. doi:10.1016/S2352-4642(20)30243-1.

*“Parents were provided with an “Information Sheet for Parents” and children were provided with an age-appropriate “Information Sheet for Children,” which was read to them by the researcher. Children and parents were provided with the opportunity to ask questions when necessary and reminded that they were free to withdraw from the study at any time, without penalty or impact on their care at the hospital. The information sheets also functioned as an assent form for children. A parental consent form was provided to the parents. Consent forms and assent forms asked participants to consent/assent to partaking in and being video recorded during the research.”*

Newell A, Keane J, McGuire BE, et al. Interactive Versus Passive Distraction and Parent Psychoeducation as Pain Management Techniques During Pediatric Venepuncture: A Randomized Controlled Trial. *Clin J Pain* 2018;34:1008-16. doi:10.1097/AJP.0000000000000628.

Statement (co-published in *The BMJ*, *JAMA Pediatrics*, and *The Lancet Child and Adolescent Health*): Baba A, Smith M, Potter BK, et al. CONSORT-Children and Adolescents (CONSORT-C) 2026 Extension Statement: Enhancing the Reporting and Impact of Paediatric Randomised Trials. *BMJ* 2026;392:e085061. doi: [10.1136/bmj-2025-085061](https://doi.org/10.1136/bmj-2025-085061)

Explanation and Elaboration: Baba A, Smith M, Potter BK, et al. CONSORT-C 2026 explanation and elaboration: recommendations for enhancing the reporting and impact of paediatric randomised trials. *BMJ* 2026;392:e085063. doi: [10.1136/bmj-2025-085063](https://doi.org/10.1136/bmj-2025-085063)

More resources are available at: <https://lab.research.sickkids.ca/enrich/reporting-standards/spirit-consort-c/>. The SPIRIT | CONSORT-C 2026 tip sheets are intended for non-commercial use only. No part of the materials may be used for commercial purposes.