

Item 14a.1: Eligibility criteria

Provide a justification for including multiple age groups or children/adolescents at different developmental stages, and address potential age or development-related differences in treatment effects

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|-----------------------------------|-------|-------------------------------------------------------------|
| 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:

- Age groups of eligible participants, and justification on how selected age range(s) enabled the trial to meet its objective
- If age groups are not used, applicable developmental stages
- Any differences in expected treatment effects and risk-benefit profile accounted for related to age or developmental stage(s)
- If any relevant (sub)group is excluded from the trial, include the reason for exclusion.

Examples:

“Eligible pediatric patients: (1) aged 4–12 years; (2) scheduled to undergo venipuncture; and (3) can understand Chinese and follow instructions. Potential participants will be excluded according to the following: (1) identified cognitive and learning problems in their medical record; (2) sensory impairment to pain (such as spinal bifida); (3) identified contact precautions; and (4) previous history of seizures or motion sickness. This study selects 4-12-year-old patients because they experience high level of distress in venipuncture procedure (4) and distraction is efficacious in this age group[reference]. Younger patients will not be included because of their possible limited cognitive and verbal capacity to respond to the questionnaires.”

Wong CL, Lui MMW, Choi KC. Effects of immersive virtual reality intervention on pain and anxiety among pediatric patients undergoing venipuncture: a study protocol for a randomized controlled trial. *Trials* 2019;20:369. doi:10.1186/s13063-019-3443-z.

See the [E&E](#) for more examples.

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)

More resources are available at: <https://lab.research.sickkids.ca/enrich/reporting-standards/spirit-consort-c/>.

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