

Item 15.1: Harms

Describe whether trial interventions and/or procedures induced fear, pain, distress, or were invasive, and what measures were taken to mitigate this

Title and abstract	1a.1	Title and structured abstract
Introduction	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>
Methods	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
Results	25.1	Baseline data
	28.1	Ancillary analyses
Discussion	29.1	Interpretation

Key elements for reporting this item:

- Efforts taken to reduce harms such as fear, pain, or distress in both the experimental group and the comparator group
- Specific strategies applied to reduce pain, discomfort, distress, and invasiveness of procedures
- If available, evidence on interventions and procedures used to mitigate any potential harms of participation.

Examples:

“In compliance with current [neonatal intensive care unit] NICU’s best evidence and practice recommendations^[reference] and as per the protocol approved by the Institutional Ethics Board [to reduce pain inflicted by the procedure] all twins in each of the participating NICU’s regardless of group assignment received 1 dose of 24% sucrose 2 minutes before the heel lance and were also offered a pacifier. Additional (rescue) doses of 24% sucrose were offered as deemed necessary by the nurse caring for the twins as per usual care practice (ie, if the infant exhibited behavioral pain responses and Premature Infant Pain Profile scores exceeded 6).”

(Adapted version, with square brackets showing inserted detail.)

Campbell-Yeo ML, Johnston CC, Joseph KS, et al. Co-bedding between preterm twins attenuates stress response after heel lance: results of a randomized trial. *Clin J Pain* 2014;30:598-604. doi:10.1097/AJP.000000000000015.

“According to the ICCS [International Children’s Continence Society] guide for reducing pain and anxiety in children during cystometry, both groups watched the video of The Pinkfong Company’s “Shark Family” immediately upon entering the urodynamic study room. In both groups, at least one parent was present during the procedure. In addition, the parents were allowed to touch the children in all ways except parental holding, gently stroke or caress them, talk to them, and use a pacifier if they wanted to soothe them.”

Park J, Lee H, Han SW, Choi EK. Effects of parental holding on pain response in young children during cystometry: A randomized controlled trial. *Neurourol Urodyn* 2024;43:196-204. doi:10.1002/nau.25284.

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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/>.

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