

Item 14.1: Outcomes

Explain evidence supporting validity of selected outcomes and outcome measurement instruments in age group(s) included

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:

- ✓ • Justification of the relevance and importance of trial outcomes to the participating age/developmental group(s)
- ✓ • Validity of the outcome measurement instrument for the prespecified age group(s)
- ✓ • Any (known) variability in validity of outcome measures across age ranges/age subgroups of trial participants; rationale for the selection of different outcome measures for each age subgroup
- ✓ • Describe who assesses the outcomes and whether the outcome measurement instrument(s) are child/adolescent centred (eg, if parent reported outcome, clearly specify if the measure is a parent proxy report of child outcomes, or a parent self-report).

Examples:

- ✓ *“Each patient also completed an age-appropriate [visual analog scale] VAS to determine their level of pain and anxiety before the procedure. Each VAS was scored on a scale from 0 to 10, with 10 indicating the worst pain or anxiety. Based on precedent and prior validation studies on VAS in children and adolescents^[reference], patients aged 4 to 7 years used a VAS that included both Wong-Baker FACES and a numerical rating scale, while patients aged 8 to 14 years were presented with a numerical rating scale only. When the provider was ready to begin the procedure, the video or game was initiated. The patient’s heart rate was continuously monitored throughout the procedure, and the highest and lowest heart rate were recorded to calculate change. After the procedure, patients completed the pain and anxiety VAS again. Heart rate has been used as a valid means to objectively quantify the physiologic response to pain and anxiety in children^[reference]. Furthermore, VAS measures are commonly used in children and adults to quantify subjective experiences of pain and anxiety^[reference].”*

Fabricant PD, Gross PW, Mackie AT, et al. Virtual Reality Distraction Is No Better Than Simple Distraction Techniques for Reducing Pain and Anxiety During Pediatric Orthopaedic Outpatient Procedures: A Randomized Controlled Trial. Clin Orthop Relat Res 2024;482:854-63. doi:10.1097/CORR.0000000000002889.

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