

Author(s): MS/KEB/KAB/AT

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Question: Should breathing without a toy distraction during vaccine injections vs control/no treatment be used for reducing vaccine injection pain in children >3 - 12 years?<sup>1,2</sup>

Settings: clinics

Bibliography: Cohen 2002 a, French 1994

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Breathing without a toy distraction during vaccine injections	Control/no treatment	Relative (95% CI)	Absolute		
<b>Pain<sup>3,4</sup> (measured with: validated tool (Faces Scale 1-5); Better indicated by lower values)</b>												
2	randomised trials	very serious <sup>5</sup>	no serious inconsistency	no serious indirectness	serious <sup>6</sup>	none	70	66	-	MD 0.27 lower (0.61 lower to 0.07 higher) <sup>3,4</sup>	⊕○○○ VERY LOW	CRITICAL
<b>Fear<sup>1,3</sup> (measured with: validated tool (Faces Scale 1-5); Better indicated by lower values)</b>												
1	randomised trials	very serious <sup>7</sup>	no serious inconsistency	no serious indirectness	serious <sup>6</sup>	none	31	30	-	MD 0.36 lower (0.86 lower to 0.15 higher) <sup>1,3</sup>	⊕○○○ VERY LOW	CRITICAL
<b>Distress Unclear<sup>3,4,8</sup> (measured with: validated tool (Observational Scale of Behavioural Distress, Child-Adult Medical Procedure Interacion Scale-Short Form) by researcher; Better indicated by lower values)</b>												
2	randomised trials	very serious <sup>5</sup>	no serious inconsistency	no serious indirectness	serious <sup>6</sup>	none	70	66	-	MD 0.27 lower (0.61 lower to 0.07 higher) <sup>3,4,8</sup>	⊕○○○ VERY LOW	IMPORTANT
<b>Procedure Outcomes, Use of Intervention, Parent Fear, Vaccine Compliance, Memory, Preference, Satisfaction (assessed with: no data were identified for these important outcomes)</b>												
0	No evidence available					none	-	-	-	-		IMPORTANT
								0%		-		

<sup>1</sup> In included study by Cohen (2002 a), children in the intervention (breathing) group were instructed in deep breathing and positive self-statements using a 7 minute video and then practiced with a research assistant. The control group received a placebo video without specific advice.

<sup>2</sup> In included study by French (1994), children in the intervention (breathing) group were verbally instructed in deep breathing, practiced with a research assistant and then were coached during the procedure; children in the control (no intervention) group did not receive any specific instruction and/or guidance. Children were immunized in groups of 4 at a time; alternate day allocation was employed to prevent contamination.

<sup>3</sup> Additional information and data provided by author (Cohen 2002 a)

<sup>4</sup> Additional information and data provided by author (French 1994)

<sup>5</sup> Not truly randomized; not consistently blinded; some selective outcome reporting

<sup>6</sup> Confidence interval crosses the line of nonsignificance and sample size was below the recommended optimum information size (OIS) of 400 for an effect size of 0.2

<sup>7</sup> Not truly randomized; child not blinded; immunizer and parent blinded; selective outcome reporting

<sup>8</sup> Scores were not standardized prior to meta-analysis