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Question: Should breathing with a toy distraction during vaccine injections vs control/no treatment be used for reducing vaccine injection pain in children >3 - 12 years?¹

Settings: health department clinic

Bibliography: Beran 2013, Blount 1992, Bowen 1999 (1,2), Krauss 1997, Manimala 2000 (1), Sparks 2001 (2) (1998 thesis)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Breathing with a toy distraction during vaccine injections	Control/no treatment	Relative (95% CI)	Absolute		
Fear Pre-procedure (measured with: validated tool (Faces scale 1-5); Better indicated by lower values)												
1	randomised trials	very serious ²	no serious inconsistency	no serious indirectness	serious ³	none	28	27	-	SMD 0.53 lower (1.07 lower to 0.01 higher)	⊕000 VERY LOW	CRITICAL
Pain (measured with: validated tools (Faces Pain Scale-Revised 0-10, Oucher Pain Scale 0-5); Better indicated by lower values)												
2	randomised trials	very serious ⁴	no serious inconsistency	no serious indirectness	serious ⁵	none	61	62	-	SMD 0.49 lower (0.85 to 0.13 lower)	⊕000 VERY LOW	CRITICAL
Fear^{6,7} (measured with: validated tool (Faces scale 1-6); Better indicated by lower values)												
1	randomised trials	very serious ⁸	no serious inconsistency	no serious indirectness	serious ³	none	59	21	-	SMD 0.60 lower (1.22 lower to 0.02 higher) ^{6,7}	⊕000 VERY LOW	CRITICAL
Distress Acute^{6,7} (measured with: validated tools (Faces Pain Scale-Revised 0-10, Faces pain scale 1-6) by researchers, parents, immunizer; Better indicated by lower values)												
2	randomised trials	very serious ⁴	no serious inconsistency	no serious indirectness	serious ⁵	none	87	50	-	SMD 0.80 lower (1.17 to 0.42 lower) ^{6,7}	⊕000 VERY LOW	IMPORTANT

Distress Pre-procedure + Acute + Recovery⁹ (measured with: validated tools (Child-Adult Medical Procedure Interaction Scale distress and restraint sub-scales, Behavioral Approach-Avoidance and Distress Scale distress subscale 0-20, Child Medical Distress Scale) by researcher; Better indicated by lower values)												
4	randomised trials	very serious ^{4,10}	no serious inconsistency	no serious indirectness	serious ⁵	none	111	111	-	SMD 0.55 lower (0.82 to 0.28 lower)	⊕000 VERY LOW	IMPORTANT
Parent Fear Pre-procedure (measured with: validated tool (Visual Analog Scale 0-10); Better indicated by lower values)												
1	randomised trials	very serious ²	no serious inconsistency	no serious indirectness	serious ³	none	28	27	-	SMD 0.32 lower (0.85 lower to 0.22 higher)	⊕000 VERY LOW	IMPORTANT
Parent Fear (measured with: validated tool (Likert scale 1-5); Better indicated by lower values)												
1	randomised trials	very serious ²	no serious inconsistency	no serious indirectness	serious ⁵	none	28	27	-	SMD 0.06 lower (0.59 lower to 0.47 higher)	⊕000 VERY LOW	IMPORTANT
Child Use of Intervention^{11,12} (measured with: validated tool (Child-Adult Medical Procedure Interaction Scale) by researcher; Better indicated by higher values)												
2	randomised trials	very serious ⁴	no serious inconsistency	no serious indirectness	serious ³	none	58	57	-	SMD 2.05 higher (1.58 to 2.52 higher) ¹¹	⊕000 VERY LOW	IMPORTANT
Parent Use of Intervention (measured with: validated tool (Child-Adult Medical Procedure Interaction Scale) by researcher; Better indicated by higher values)												
1	randomised trials	very serious ²	no serious inconsistency	no serious indirectness	serious ⁵	none	28	27	-	SMD 1.10 higher (0.53 to 1.67 higher)	⊕000 VERY LOW	IMPORTANT
Child Preferences¹³ (measured with: questions to child ; Better indicated by higher values)												
1	randomised trials	serious ¹⁴	no serious inconsistency	no serious indirectness		none	28	-	- ¹³	not pooled ¹³		IMPORTANT
Parent Preferences¹⁵ (measured with: question to parents; Better indicated by higher values)												

1	randomised trials	serious ¹⁴	no serious inconsistency	no serious indirectness		none	28	-	- ¹⁵	not pooled ¹⁵		IMPORTANT
Procedure Outcomes, Vaccine Compliance, Memory, Satisfaction (assessed with: no data were identified for these important outcomes)												
0	No evidence available					none	-	-	-	-		IMPORTANT
								0%		-		

¹ In 3 included studies (Blount 1992, Krauss 1997, Manimala 2000), there was verbal or video instruction directed to parents and children prior to the procedure

² Not truly random; parent and researcher not blinded; immunizer blinded to hypothesis; unclear if child blinded; contamination of intervention (distraction) in control (no treatment) group

³ Confidence interval crosses line of nonsignificance and sample size was below the recommended optimum information size (OIS) of 400 for an effect size of 0.2

⁴ Not consistently randomized; not blinded

⁵ Sample size was below the recommended optimum information size (OIS) of 400 for an effect size of 0.2

⁶ In study by Bowen (1999), analysis (1) included children included blowing with a party blower (intervention) versus no treatment; analysis (2) included children blowing with a pinwheel (intervention) versus no treatment.

⁷ The control (no treatment) group for the included study (Bowen 1999) is divided by 2

⁸ Not truly randomized; not blinded

⁹ Scores from Krauss (1997) not standardized

¹⁰ In 1 included study (Blount 1992), not all measures that assessed this construct could be combined for inclusion in the meta-analysis due to selective outcome reporting

¹¹ Scores from Blount (1992) not standardized

¹² Scores from Manimala (2000) not standardized

¹³ In study by Beran (2013), 25/28 (89%) of children in the intervention (breathing with robot) group reported they would like the intervention again in the future

¹⁴ Immunizer, parent, child not blinded

¹⁵ In study by Beran (2013), 25/28 (89%) of parents in the intervention (breathing with robot) group reported they would like the intervention again in the future