

Author(s): CMM/DL/AT

Date: 2015-03-21

Question: Should repeated reassurance vs control be used for reducing vaccine injection pain in individuals of all ages?

Settings: clinics (hospital and outpatient)

Bibliography: Gonzalez 1993 (2), Manimala 2000 (2)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Repeated reassurance	Control	Relative (95% CI)	Absolute		
Pain (measured with: validated tool (Oucher scale 0-10); Better indicated by lower values)												
1	randomised trials ¹	serious ²	no serious inconsistency	no serious indirectness	serious ³	none	14	14	-	SMD 0.18 lower (0.92 lower to 0.56 higher)	⊕⊕⊕⊕ LOW	CRITICAL
Fear Pre-procedure (measured with: validated tool (FACES scale 1-5) ; Better indicated by lower values)												
1	randomised trials ⁴	very serious ^{5,6,7}	no serious inconsistency	no serious indirectness	serious ³	none	27	27	-	SMD 0.18 lower (0.71 lower to 0.36 higher)	⊕⊕⊕⊕ VERY LOW	CRITICAL
Distress Pre-Procedure + Acute + Recovery (measured with: validated tool (Observation Scale of Behavioral Distress-Revised: Child Restraint 0-1, Child Adult Medical Procedure Interaction Scale: Child Distress 0-1) by researcher; Better indicated by lower values)												
2	randomised trials ^{1,4}	very serious ^{2,6,7,8}	no serious inconsistency	no serious indirectness	serious ³	none	41	41	-	SMD 0.10 higher (0.33 lower to 0.54 higher)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
Parent Fear Pre-procedure (measured with: validated tool (Visual Analog Scale 0-10); Better indicated by lower values)												
1	randomised trials ⁴	very serious ^{5,6,7}	no serious inconsistency	no serious indirectness	serious ³	none	27	27	-	SMD 0.52 lower (1.06 lower to 0.03 higher)	⊕⊕⊕⊕ VERY LOW	IMPORTANT
Parent Fear (measured with: validated tool (Likert Scale 1-5); Better indicated by lower values)												
1	randomised	very	no serious	no serious	serious ⁹	none	27	27	-	SMD 0.98 higher (0.42 to 1.55)	⊕⊕⊕⊕ VERY	IMPORTANT

	trials ⁴	serious ^{5,6,7}	inconsistency	indirectness						higher)	LOW	
Use of Intervention (measured with: validated tool (Child Adult Medical Procedure Interaction Scale 0-1) by researcher; Better indicated by higher values)												
2	randomised trials ^{1,4}	very serious ^{2,6,7}	no serious inconsistency ¹⁰	no serious indirectness	serious ³	none	41	41	-	SMD 1.62 higher (0.62 lower to 3.85 higher)	⊕○○○ VERY LOW	IMPORTANT
Procedure Outcomes, Vaccine Compliance, Memory, Preference, Satisfaction (assessed with: no data were identified for these important outcomes)												
0	No evidence available					none	-	-	-	-		IMPORTANT
								0%		-		

¹ In included study (Gonzalez 1993), mothers in the intervention (reassurance) group were given oral instructions, then listened to a demonstration audiotape, then practiced with help and received prompts during the procedure

² Parent not blinded; immunizer and researcher blinded to hypothesis; unclear whether child blinded; contamination of intervention (reassurance) 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 In included study (Manimala 2000), parents in the intervention (reassurance) group received instruction, demonstration, and practiced with the child present; a poster was placed in the treatment room and parents were reminded during the procedure

⁵ Parent and researcher not blinded; immunizer blinded to hypothesis; unclear if child blinded

⁶ In study by Manimala (2000), randomization was by alternating order

⁷ In study by Manimala (2000), children were exposed to modeling of a needle procedure and reassurance during parent training prior to the vaccination which may have obscured differences between groups

⁸ In study by Gonzalez (1993), there was contamination of the intervention (reassurance) in the control (no treatment) group

⁹ Sample size was below the recommended optimum information size (OIS) of 400 for an effect size of 0.2

¹⁰ Heterogeneity may be explained by differences in methods of training