Author(s): KAB/KEB/CMM/AT/JP
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Question: Should verbal distraction vs control/no treatment be used for reducing vaccine injection pain in children >3 - 12 years?
Settings: clinic
Bibliography: Gonzalez 1993 (1), O'Laughlin 1995 (1)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Verbal distraction	Control/no treatment	Relative (95% CI)	Absolute		
Pain (measured with: validated tool (Oucher 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 0.27 lower (1.02 lower to 0.47 higher)	⊕⊕OO LOW	CRITICAL
Distress Pre-procedure + Acute + Recovery (measured with: validated tool (Observational Scale of Behavioral Distress 0-4) by researcher; Better indicated by lower values)												
2	randomised trials[4]	serious[5,6,7]	no serious inconsistency	no serious indirectness	serious[8]	none	21	25	-	SMD 1.22 lower (1.87 to 0.58 lower)	⊕⊕OO LOW	IMPORTANT
Use of intervention (measured with: validated tool (Child Adult Medical Procedure Interaction Scale 0-100) by researcher; Better indicated by higher values)												
1	randomised trials[1]	serious[5]	no serious inconsistency	no serious indirectness	serious[8]	none	14	14	-	SMD 3.02 higher (1.89 to 4.15 higher)	⊕⊕OO LOW	IMPORTANT
Use of intervention (yes/no)[9] (assessed with: observation of use of intervention by researcher (yes/no))												
1	randomised trials[4]	serious[5]	no serious inconsistency	no serious indirectness	serious[8]	none	7/7 (100%)	4/11 (36.4%)	RR 2.5 (1.18 to 5.3)	545 more per 1000 (from 65 more to 1000 more)	⊕⊕OO LOW	IMPORTANT
Fear (assessed with: no data were identified for this critically important outcome)												
0	No evidence					none	-	-	-	-		CRITICAL

	available											
Procedure Outcomes, Parent Fear, Vaccine Compliance, Memory, Preference, Satisfaction (assessed with: no data were identified for these important outcomes)												
0	No evidence available					none	-	-	-	-		IMPORTANT
								0%		-		
								0%		-		

[1] In included study (Gonzalez 1993), mothers in the intervention (education) 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

[3] 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

[4] In included study (O'Laughlin 1995), mothers in the intervention (education) group were instructed to read a handout describing distraction and then chose a method with their child and to begin using it when the immunizer picked up the needle

[5] immunizer and parent not blinded; researcher blinded to hypothesis; unclear whether child blinded

[6] In included study (O'Laughlin 1995), data missing for non-significant distress as assessed by nurse and researcher using global distress ratings (range, 1-9)

[7] Parent not blinded; immunizer not consistently blinded; researcher blinded; unclear whether child was blinded

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

[9] Contamination of the intervention (distraction) observed