Author(s): CMM/KAB/AT
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Question: Should a breathing intervention (cough) vs no treatment be used for reducing vaccine injection pain in children >3 - 17 years?[1]
Settings: clinic
Bibliography: Wallace 2010

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	A breathing intervention (cough)	No treatment	Relative (95% CI)	Absolute		
Pain [2] (measured with: validated tool (Visual Analog Scale 0-100); Better indicated by lower values)												
1	randomised trials	serious[3]	no serious inconsistency	no serious indirectness	serious[4]	none	68	68	-	SMD 0.17 lower (0.41 lower to 0.07 higher)[2]	⊕⊕OO LOW	CRITICAL
Distress Acute[2,5] (measured with: validated tools (Visual Analog Scale 0-100) by nurse/parent; Better indicated by lower values)												
1	randomised trials	serious[6]	no serious inconsistency	no serious indirectness	serious[4]	none	68	68	-	SMD 0.22 lower (0.46 lower to 0.02 higher)[2,5]	⊕⊕OO LOW	IMPORTANT
Child Satisfaction[2,7] (measured with: 8-item questionnaire 8-48; Better indicated by higher values)												
1	randomised trials	serious[6]	no serious inconsistency	no serious indirectness	serious[8]	none	0	-	-[2,7]	not pooled[2,7]	⊕⊕OO LOW	IMPORTANT
Fear (assessed with: no data were identified for this critically important outcome)												
0	No evidence available					none	-	-	-	-		CRITICAL
Procedure Outcomes, Use of Intervention, Vaccine Compliance, Memory, Preference, Satisfaction (assessed with: no data were identified for these important outcomes)												
0	No evidence available					none	-	-	-	-		IMPORTANT
								0%		-		

[1] In study by Wallace (2010), a cross-over design was used. Two age groups were combined: 4-5 years (n=22) and 11-13 years (n=46)
[2] Additional data and study details provided by author (Wallace 2010)
[3] Operator and participant not blinded
[4] 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
[5] Sample size was assumed to be 68
[6] Participants not blinded; immunizers blinded to hypothesis
[7] In included study (Wallace 2010), older children (i.e., 11-13 years) reported satisfaction with the intervention. The mean (SD) satisfaction score was 35.26 (9.28) (n=42 out of 46). Higher scores equal more satisfaction; the maximum score that could be achieved was 48.
[8] Sample size was below the recommended optimum information size (OIS) of 400 for an effect size of 0.2