

Author(s): AT/CMM

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Question: Should an external vibrating device and cold vs no treatment be used for reducing vaccine injection pain in children > 3 - 17 years?

Settings: school, outpatient clinic

Bibliography: Berberich 2009, Canbulat 2015

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	An external vibrating device and cold	No treatment	Relative (95% CI)	Absolute		
Pain¹ (measured with: validated tool (Faces Pain Scale-Revised 0-10, Wong Baker Faces Scale 0-10, Visual Analog Scale 0-10); Better indicated by lower values)												
2	randomised trials	serious ²	no serious inconsistency	no serious indirectness	serious ³	none	72	73	-	SMD 1.23 lower (1.58 to 0.87 lower) ¹	⊕⊕⊕⊕ LOW	CRITICAL
Distress Acute (measured with: validated tools (Faces Pain Scale - Revised 0-10, Faces Legs Activity Crying Consolability 0-10, Children Fear Scale 0-4, Wong Baker Faces Scale 0-10) by immunizer/researcher/observer/parent; Better indicated by lower values)												
2	randomised trials	serious ²	no serious inconsistency	no serious indirectness	serious ³	none	72	73	-	SMD 2.26 lower (2.83 to 1.68 lower)	⊕⊕⊕⊕ LOW	IMPORTANT
Procedure Outcomes, Vaccine Compliance, Preference, Satisfaction (assessed with: no data were identified for these important outcomes)												
0	No evidence available					none	-	-	-	-		IMPORTANT
								0%		-		
Fear pre-procedure (measured with: validated tool (Children Fear Scale 0-4)⁴; Better indicated by lower values)												
1	randomised trials	serious ²	no serious inconsistency	no serious indirectness	serious ⁵	none	52	52	-	SMD 0.28 higher (0.11 lower to 0.66 higher)	⊕⊕⊕⊕ LOW	CRITICAL
Distress pre-procedure (measured with: validated tool (Children Fear Scale 0-4) by observer/researcher⁴; Better indicated by lower values)												
1	randomised	serious ²	no serious	no serious	serious ⁵	none	52	52	-	SMD 0.02 lower (0.37 lower to 0.4	⊕⊕⊕⊕	IMPORTANT

	trials		inconsistency	indirectness						higher)	LOW	
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¹ Additional data provided by author (Canbulat 2015)

² Immunizer not blinded, child not blinded; outcome assessor not blinded

³ Sample size was below the recommended optimum information size (OIS) of 400 for an effect size of 0.2

⁴ Timing of this assessment unclear (i.e., whether pre- or post-intervention)

⁵ 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