Author(s): MS/KH/KAB/KEB/AT
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Question: Should video distraction vs no treatment be used for reducing vaccine injection pain in children >3 - 12 years?[1,2]
Settings: clinics
Bibliography: Cassidy 2002, Cohen 1997 (1,2), Cohen 1999 (1), Cohen 2015 (1), Luthy 2013 (1)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Video distraction	No treatment	Relative (95% CI)	Absolute		
Pain[3,4] (measured with: validated tool (Faces Pain Scale-Revised 0-100, Faces scale 1-5, 1-7, Visual Analog Scale 0-100); Better indicated by lower values)												
4	randomised trials	very serious[5,6,7]	no serious inconsistency[8]	no serious indirectness	serious[9]	none	158	121	-	SMD 0.88 lower (1.78 lower to 0.02 higher)[3]	⊕OOO VERY LOW	CRITICAL
Fear (measured with: validated tool (Visual Analog Scale 0-100); Better indicated by lower values)												
1	randomised trials	very serious[7,10]	no serious inconsistency	no serious indirectness	serious[11]	none	34	34	-	SMD 0.08 higher (0.25 lower to 0.41 higher)	⊕OOO VERY LOW	CRITICAL
Distress Pre-procedure + Acute + Recovery[3,12,13] (measured with: validated tools (Child-Adult Medical Procedure Interaction Scale-Revised, Behaviour coding 0-1) by researcher ; Better indicated by lower values)												
3	randomised trials	very serious[7,10,14]	no serious inconsistency[8]	no serious indirectness	serious[11]	none	127	93	-	SMD 0.58 lower (0.82 to 0.34 lower)[3,12]	⊕OOO VERY LOW	IMPORTANT
Distress Acute[3,12,15,16,17] (measured with: validated tools (Likert scale 1-5, Visual Analog Scale 0-100, Faces scale 0-5, Children's Hospital of Eastern Ontario Pain Scale 0-6) by researcher, immunizer, parent; Better indicated by lower values)												
5	randomised trials	very serious[5,6,7]	no serious inconsistency[18]	no serious indirectness	serious[11]	none	183	144	-	SMD 0.96 lower (1.85 to 0.08 lower)[3,12,15,16]	⊕OOO VERY LOW	IMPORTANT
Distress Pre-procedure[15,16] (measured with: validated tool (Children's Hospital of Eastern Ontario Pain Scale 0-6) by researcher; Better indicated by lower values)												

1	randomised trials	very serious[6,16,19]	no serious inconsistency	no serious indirectness	serious[11]	none	29	29	-	SMD 0.65 lower (1.18 to 0.12 lower)[15,16]	⊕OOO VERY LOW	IMPORTANT
Parent Fear[3] (measured with: validated tool (Likert scale 1-5); Better indicated by lower values)												
1	randomised trials	serious[20]	no serious inconsistency	no serious indirectness	serious[9]	none	63	29	-	SMD 2.18 lower (2.73 to 1.63 lower)[3]	⊕⊕OO LOW	IMPORTANT
Immunizer Fear (measured with: validated tool (Likert scale 1-5); Better indicated by lower values)												
2	randomised trials	very serious[7,10,14]	no serious inconsistency	no serious indirectness	serious[9]	none	97	63	-	SMD 0.00 higher (0.36 lower to 0.35 higher)	⊕OOO VERY LOW	IMPORTANT[21]
Child Use of Intervention Pre-procedure + Acute + Recovery[3,12,13] (measured with: validated tool Child-Adult Medical Procedure Interaction Scale-Revised, Behaviour coding 0-1) by researcher ; Better indicated by higher values)												
3	randomised trials	very serious[7,10,14]	no serious inconsistency[8]	no serious indirectness	serious[9]	none	127	93	-	SMD 2.6 higher (1.46 to 3.74 higher)[3,12,13]	⊕OOO VERY LOW	IMPORTANT
Child Use of Intervention Pre-procedure[12,22] (measured with: validated tool (video analysis of proportion of time watching television) by researcher; Better indicated by higher values)												
1	randomised trials	very serious[6,19]	no serious inconsistency	no serious indirectness	serious[9]	none	28	27	-	SMD 1.06 higher (0.5 to 1.63 higher)[12,22]	⊕OOO VERY LOW	IMPORTANT
Child Use of Intervention Acute[22] (measured with: validated tool (video analysis of proportion of time watching television) byr researcher; Better indicated by higher values)												
1	randomised trials	very serious[6,19]	no serious inconsistency	no serious indirectness	serious[9]	none	28	27	-	SMD 0.57 higher (0.03 to 1.11 higher)[22]	⊕OOO VERY LOW	IMPORTANT
Clinician Use of Intervention Pre-procedure + Acute + Recovery[3,12,13] (measured with: validated tool Child-Adult Medical Procedure Interaction Scale-Revised) by researcher ; Better indicated by higher values)												

2	randomised trials	very serious[7,10,14]	no serious inconsistency	no serious indirectness	serious[9]	none	97	63	-	SMD 0.80 higher (0.5 to 1.1 higher)[3,12,13]	⊕OOO VERY LOW	IMPORTANT
Parent Use of Intervention Pre-procedure + Acute + Recovery[3,13] (measured with: validated tool (Child-Adult Medical Procedure Interaction Scale-Revised, Behaviour coding 0-1)) by researcher ; Better indicated by higher values)												
2	randomised trials	serious[20]	no serious inconsistency	no serious indirectness	serious[9]	none	93	59	-	SMD 0.90 higher (0.55 to 1.24 higher)[3,13]	⊕⊕OO LOW	IMPORTANT
Parent Preferences[23] (assessed with: validated tool (questionnaire regarding preference for treatment))												
1	randomised trials	serious[20]	no serious inconsistency	no serious indirectness	serious[11]	none	20/26 (76.9%)	15/21 (71.4%)	RR 1.08 (0.76 to 1.52)[23]	57 more per 1000 (from 171 fewer to 371 more)	⊕⊕OO LOW	IMPORTANT
								0%		-		
Child Preferences[24] (measured with: questionnaire by researcher; Better indicated by lower values)												
1	randomised trials	very serious[7,10]	no serious inconsistency	no serious indirectness	[25]	none	0	-	-[24]	not pooled[24]		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 study by Cohen 1997, analysis (1) included parent and immunizer training and analysis (2) included immunizer training only

[2] In study by Cohen (1999), a cross-over design was used whereby children received 3 treatments (video distraction, topical anesthesia, or no treatment). Cohen 1999 (1) compares video distraction to no treatment.

[3] In study by Cohen (1997), sample size for control group divided by 2

[4] If only the data from the study by Cohen (1997) are included, whereby children self-selected the video, then the results are altered: SMD -2.24 (95% CI -2.79 to -1.68).

[5] Immunizer and child not consistently blinded; outcome assessors not consistently blinded

[6] In study by Cassidy (2002), there is the possibility of a treatment effect for children in the control group as they were instructed to look at a television also (which was not turned on)

[7] In study by Cohen (1999), children were together in groups of 3-5 which may have influenced results

[8] Heterogeneity can be explained by differences in age (4-11 years) and differences in intervention, intervention delivery, and immunization (e.g., number of injections)

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

[10] Immunizer and child aware of group assignment

[11] 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

[12] In study by Cohen 1999, scores were not standardized

[13] In study by Cohen 1997, scores were not standardized

[14] Outcome assessor not consistently blinded
[15] In study by Cassidy (2002), sample size assumed to be 29 per group
[16] In study by Cassidy (2002), only scores from Children's Hospital of Eastern Ontario Pain Scale included due to attrition bias
[17] Study by Luthy (2013) included some children < 3 years, which would not be expected to be able to provide self-report
[18] Heterogeneity can be explained by differences in age (2-11 years) and differences in intervention and intervention delivery
[19] Researcher present at procedure not blinded; unclear blinding of others
[20] No one is blinded during the conduct of the trial
[21] accepted as important outcome as may be regarded as a measure of satisfaction
[22] In study by Cassidy (2002), sample size assumed to be 28 for the intervention (distraction) group and 27 for the control (no treatment) group
[23] Sample size for the intervention (distraction) group assumed to 26 and sample size for the control (no treatment) group assumed to be 21
[24] In the study by Cohen (1999), children were asked about which treatment they preferred: 52% preferred distraction (1), 39% preferred topical anesthesia (another treatment condition in the trial, (2)) and 9% preferred no treatment
[25] Data not pooled