Author(s): CMM/MN/AT
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Question: Should muscle tension in children 7 years and above and adults with a history of fainting vs control be used for reducing fainting during vaccine injections?
Settings: hospital, university
Bibliography: Brignole 2002, van Dijk 2006, Vogele 2003

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Muscle tension in children 7 years and above and adults with a history of fainting**	**Control**	**Relative (95% CI)**	**Absolute**		
Number with fainting over 12 month followup period (assessed with: self-report on a log book)												
1	randomised trials	serious[1]	no serious inconsistency	very serious[2]	serious[3]	none	31/98 (31.6%)	56/110 (50.9%)	RR 0.62 (0.44 to 0.88)	193 fewer per 1000 (from 61 fewer to 285 fewer)	⊕OOO VERY LOW	CRITICAL
								0%		-		
Number with fainting during procedure[4] (assessed with: observation by researcher)												
1	randomised trials	serious[5]	no serious inconsistency	very serious[6]	serious[3]	none	1/19 (5.3%)	9/19 (47.4%)	RR 0.11 (0.02 to 0.79)[4]	422 fewer per 1000 (from 99 fewer to 464 fewer)	⊕OOO VERY LOW	CRITICAL
								0%		-		
Number with fainting during procedure recovery (assessed with: observation by researcher)												
1	randomised trials	serious[5]	no serious inconsistency	very serious[6]	serious[7]	none	3/19 (15.8%)	2/19 (10.5%)	RR 1.5 (0.28 to 7.99)	53 more per 1000 (from 76 fewer to 736 more)	⊕OOO VERY LOW	CRITICAL
								0%		-		
Number of fainting episodes per patient per year (measured with: self-report log book; Better indicated by lower values)												
1	randomised	serious[1]	no serious	very serious[2]	serious[3]	none	98	110	-	SMD 3.32 lower (3.74 to 2.9	⊕OOO VERY	CRITICAL

	trials		inconsistency							lower)	LOW	
Time to recurrence of fainting (measured with: self-report log; Better indicated by higher values)												
1	randomised trials	serious[1]	no serious inconsistency	very serious[2]	serious[7]	none	31	56	-	SMD 0.33 lower (0.77 lower to 0.11 higher)	⊕OOO VERY LOW	CRITICAL
Fear Pre-procedure (post-intervention)[8] (measured with: validated tool (Symptom-Emotion-Checklist 0-100) ; Better indicated by lower values)												
1	randomised trials	serious[9]	no serious inconsistency	very serious[10]	serious[7]	none	11	11	-	SMD 0.95 higher (0.06 to 1.85 higher)[8,11]	⊕OOO VERY LOW	IMPORTANT
Fear Acute[8] (measured with: validated tool (Symptom-Emotion-Checklist 0-100) ; Better indicated by lower values)												
1	randomised trials	serious[9]	no serious inconsistency	very serious[10]	serious[7]	none	11	11	-	SMD 0.21 higher (0.63 lower to 1.05 higher)[8,11]	⊕OOO VERY LOW	IMPORTANT
Fear Recovery[8] (measured with: validated tool (Symptom-Emotion-Checklist 0-100) ; Better indicated by lower values)												
1	randomised trials	serious[9]	no serious inconsistency	very serious[10]	serious[7]	none	11	11	-	SMD 0.65 higher (0.21 lower to 1.52 higher)[8,11]	⊕OOO VERY LOW	IMPORTANT
Lightheadedness, Nausea, Sweaty hands, Racing heart (i.e., prodromal sign of fainting) (measured with: validated tool (each measured with Symptom-Emotion-Checklist 0-100) ; Better indicated by lower values)												
1	randomised trials	serious[9]	no serious inconsistency	very serious[10]	serious[7]	none	11	11[11]	-	not pooled	⊕OOO VERY LOW	IMPORTANT
Pain, Distress, Procedure Outcomes, Vaccine Compliance, Preference, Satisfaction (assessed with: no data were identified for these important outcomes)												
0	No evidence available					none	-	-	-	-		IMPORTANT
								0%		-		

[1] Clinicians collecting folllowup data were not blinded; participants were blinded; participants reported outcomes

[2] In included study (van Dijk 2006), patients had a confirmed history of vaso-vagal syncope but did not undergo vaccination or any other procedure. Naturally occurring syncopal episodes were recorded over a 12 month followup period.

[3] Sample size was below the recommended optimum information size (OIS) of 400 for an effect size of 0.2
[4] In excluded study (Vogele 2003), 2/11 individuals with a history of fainting in the control group (attention control) fainted while watching a surgical film vs. 0/11 individuals with a history of fainting in the intervention group (muscle tension).
[5] Clinicians collecting data were not blinded; participants were blinded; clinicians reported study outcomes.
[6] In included study (Brignole 2002), patients had a confirmed history of vaso-vagal syncope and underwent a procedure (tilt table testing).
[7] Confidence intervals cross the line of nonsignificance and the sample size was below the recommended optimum information size (OIS) of 400 for an effect size of 0.2
[8] Additional data provided by author (Vogele 2003)
[9] No blinding
[10] In included study (Vogele 2003), individuals with self-reported history of feeling faint at the sight of blood or injury received instruction in the intervention (muscle tension) or control (attention control) then watched a surgical film.
[11] In included study (Vogele 2003), sample size assumed to be 11/group.