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**Question:** Should multiple session in vivo exposure-based therapy vs single session in vivo exposure-based therapy be used for reducing vaccine injection fear in children 7 years and older and adults with high levels of needle fear?

**Settings:** university centre and unclear

**Bibliography:** Ost 1992, Vika 2009

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Multiple session in vivo exposure-based therapy	Single session in vivo exposure-based therapy	Relative (95% CI)	Absolute		
<b>Fear (specific) (measured with: validated tools (Mutilation Questionnaire 0-30, Anxiety during lab-based fear-inducing task 0-10, Injection Phobia Scale - Anxiety subscale 0-72 and Avoidance subscale 0-36, Fear Survey Schedule 3rd Ed - Injection item); Better indicated by lower values)</b>												
2	randomised trials <sup>1</sup>	serious <sup>2</sup>	no serious inconsistency	serious <sup>3</sup>	serious <sup>4</sup>	none	45	48	-	SMD 0.66 lower (1.08 to 0.24 lower)	⊕○○○ VERY LOW	CRITICAL
<b>Fear (specific) at 12 month followup (measured with: validated tools (Mutilation Questionnaire 0-30, Anxiety during lab-based fear-inducing task 0-10, Injection Phobia Scale - Anxiety subscale 0-72 and Avoidance subscale 0-36, Fear Survey Schedule 3rd Ed - Injection item); Better indicated by lower values)</b>												
2	randomised trials <sup>1</sup>	serious <sup>2</sup>	no serious inconsistency	serious <sup>3</sup>	serious <sup>5</sup>	none	42	41	-	SMD 0.37 lower (0.87 lower to 0.13 higher)	⊕○○○ VERY LOW	CRITICAL
<b>Fear (general) (measured with: validated tools (Fear Survey Schedule 3rd Ed 76-380, Beck Anxiety Inventory 0-63); Better indicated by lower values)</b>												
1	randomised trials	serious <sup>2</sup>	no serious inconsistency	serious <sup>3</sup>	serious <sup>5</sup>	none	19	20	-	SMD 0.15 higher (0.48 lower to 0.78 higher)	⊕○○○ VERY LOW	IMPORTANT
<b>Fear (general) at 12 month followup (measured with: validated tools (Fear Survey Schedule 3rd Ed 76-380, Beck Anxiety Inventory 0-63); Better indicated by lower values)</b>												
1	randomised trials	serious <sup>2</sup>	no serious inconsistency	serious <sup>3</sup>	serious <sup>5</sup>	none	18	20	-	SMD 0.04 higher (0.59 lower to 0.68)	⊕○○○ VERY	IMPORTANT

										higher)	LOW	
<b>Compliance (measured with: validated tool (Behaviour Avoidance Test); Better indicated by higher values)</b>												
2	randomised trials <sup>1</sup>	serious <sup>6</sup>	no serious inconsistency	serious <sup>3</sup>	serious <sup>5</sup>	none	45	48	-	SMD 0.14 higher (0.31 lower to 0.59 higher)	⊕000 VERY LOW	IMPORTANT
<b>Compliance at 12 month followup (measured with: validated tools (Behaviour Avoidance Test) ; Better indicated by higher values)</b>												
2	randomised trials <sup>1</sup>	serious <sup>6</sup>	no serious inconsistency	serious <sup>3</sup>	serious <sup>5</sup>	none	42	41	-	SMD 0.17 higher (0.55 lower to 0.88 higher)	⊕000 VERY LOW	IMPORTANT
<b>Compliance at 12 month followup (yes/no) (assessed with: validated tool (Voluntary blood donation or voluntary dental injection, yes/no))</b>												
1	randomised trials	serious <sup>7</sup>	no serious inconsistency	serious <sup>3</sup>	serious <sup>5</sup>	none	26/27 (96.3%)	23/28 (82.1%)	RR 1.17 (0.97 to 1.41)	140 more per 1000 (from 25 fewer to 337 more)	⊕000 VERY LOW	IMPORTANT
<b>Fainting (measured with: validated tool (Fainting behaviour during lab-based fear-inducing task 0-4); Better indicated by lower values)</b>												
1	randomised trials	serious <sup>2</sup>	no serious inconsistency	serious <sup>3</sup>	serious <sup>5</sup>	none	19	20	-	SMD 0.53 lower (1.17 lower to 0.11 higher)	⊕000 VERY LOW	IMPORTANT
<b>Fainting at 12 month followup (measured with: validated tool (Fainting behaviour during lab-based fear-inducing task 0-4); Better indicated by lower values)</b>												
1	randomised trials	serious <sup>2</sup>	no serious inconsistency	serious <sup>3</sup>	serious <sup>5</sup>	none	18	20	-	MD 0.00 higher (0.64 lower to 0.64 higher)	⊕000 VERY LOW	IMPORTANT
<b>Pain, Distress, Procedure Outcomes, Memory, Preference, Satisfaction (assessed with: no data were identified for these important outcomes)</b>												
0	No evidence available					none	-	-	-	-		IMPORTANT
								0%		-		

<sup>1</sup> In 2 included studies (Ost 1992, Vika 2009) 5 invivo sessions were compared to 1 invivo session. In Ost (1992), 5 sessions of approximately 1 hour per week were compared to 1 session of a maximum of 3 hours. In Vika (2009), no information was given for duration or timing of sessions.

<sup>2</sup> Therapist and participant not blinded; outcome assessor not blinded

<sup>3</sup> Not vaccination; however, includes individuals with blood injury injection phobia or high fear of needles/injections

<sup>4</sup> Sample size was below the recommended optimum information size (OIS) of 400 for an effect size of 0.2

<sup>5</sup> 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

<sup>6</sup> Therapist and participant not blinded; outcome assessor not consistently blinded

<sup>7</sup> Therapist and participant not blinded; outcome assessor blinded