Author(s): CMM/MN/AT Date: 2015-02-27

Question: Should in vivo exposure-based therapy for adults with high levels of needle fear vs placebo/control (muscle tension) be used for reducing vaccine injection fear in adults?

Settings: unclear

Bibliography: Ost 1991 (1)

Quality assessment						No of patients		Effect				
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	In vivo exposure- based therapy for adults with high levels of needle fear	Placebo/control (muscle tension)	Relative (95% CI)	Absolute	Quality	Importance
						e 0-30, Fear Surve er indicated by lov	ey Schedule 3rd Ed - wer values)	Blood Subscale 8-	40, Fear	Questionnaire	- Blood/l	njury
	randomised trials	serious ¹	no serious inconsistency	serious ²	serious ³	none	10	10	-	SMD 1.09 lower (2.04 to 0.14 lower)	⊕OOO VERY LOW	CRITICAL
			• •		•		re 0-30, Fear Survey dicated by lower valu		Blood Su	ıbscale 8-40, F	ear Ques	stionnaire -
	randomised trials	serious ¹	no serious inconsistency	serious ²	serious ⁴	none	10	10	-	SMD 0.28 lower (1.16 lower to 0.6 higher)	⊕OOO VERY LOW	CRITICAL
Fear (ge	neral) (meası	red with	: validated tool	(Fear Survey	Schedule 3rd	d Ed 76-380) ; Be	tter indicated by low	ver values)				
	randomised trials	serious ¹	no serious inconsistency	serious ²	serious ⁴	none	10	10	-	SMD 0.46 lower (1.35 lower to 0.43 higher)	⊕OOO VERY LOW	IMPORTANT
Fear (ge	neral) at 1 yea	ar follow	up (measured w	ith: validated	tool (Fear S	urvey Schedule 3	3rd Ed 76-380); Bette	er indicated by lowe	er values)		•	

	trials		inconsistency							lower to 0.38 higher)	LOW	
Fainting	' (measured v	vith: vali	dated tool (Fain	ting behaviou	ır during lab	-based fear-indu	cing task 0-4); Better	indicated by lower	values)			
	randomised trials	serious ⁶	no serious inconsistency	serious ²	serious ³	none	10	10	-	SMD 1.16 higher (0.19 to 2.12 higher) ⁵		IMPORTANT
Fainting	Fainting at 1 year followup ⁵ (measured with: validated tool (Fainting behaviour during lab-based fear-inducing task 0-4); Better indicated by lower values)											
	randomised trials	serious ⁶	no serious inconsistency	serious ²	serious ³	none	10	10	-	SMD 0.97 higher (0.03 to 1.91 higher) ⁵		IMPORTANT
Complia	Compliance (measured with: validated tool (Behavioural Avoidance Test); Better indicated by higher values)											
	randomised trials	serious ⁶	no serious inconsistency	serious ²	serious ⁴	none	10	10	-	SMD 0.80 lower (1.72 lower to 0.12 higher)	⊕000 VERY LOW	IMPORTANT
Compliance at 1 year followup (measured with: validated tool (Behavioural Avoidance Test); Better indicated by higher values)												
1	randomised trials	serious ⁶	no serious inconsistency	serious ²	serious ⁴	none	10	10	-	SMD 0.74 lower (1.66 lower to 0.17 higher)	⊕000 VERY LOW	IMPORTANT
Pain, Dis	tress, Proced	dure Out	comes, Memory	, Preference,	Satisfaction	(assessed with:	no data were identifi	ed for these import	ant outc	omes)		1
	No evidence available					none	-	- 0%	-	-		IMPORTANT

¹ Therapist and participants not blinded; outcome assessor not blinded

² Not vaccination or needle procedure; however, includes individuals with blood and injury phobia

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

⁴ 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

⁵ In included study (Ost 1991), the control group received instruction in a muscle tension technique, which may have had a benefit on this outcome (fainting)

⁶ Therapist and participant not blinded; unclear if outcome assessor blinded