Author(s): CMM/MN/AT
Date: 2015-02-27
Question: Should non in vivo (imaginal) exposure-based therapy for children with high levels of needle fear vs no treatment be used for reducing vaccine injection fear in children 7 - 17 years?[1]
Settings: university psychology clinic, university
Bibliography: Cornwall 1996, Muris 1998 (2)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Non in vivo (imaginal) exposure-based therapy for children with high levels of needle fear	No treatment	Relative (95% CI)	Absolute		
Fear (specific) (measured with: validated tools (Spider Phobia Questionnaire for children SF 0-15, Self Assessment Manikin 1-9, Fear Thermometer during lab-based fear inducing task 1-5, Fear Survey Schedule for Children Revised - Fear of the Unknown Subscale 19-57) ; Better indicated by lower values)												
2	randomised trials	serious[2]	no serious inconsistency[3]	very serious[4]	serious[5]	none	21	20	-	SMD 0.88 lower (1.7 to 0.05 lower)	⊕OOO VERY LOW	CRITICAL
Fear (specific) at 3 month followup (measured with: validated tool (Fear Survey Schedule for Children Revised - Fear of the Unknown Subscale 19-57); Better indicated by lower values)												
1	randomised trials	serious[2]	no serious inconsistency	very serious[6]	serious[5]	none	12	12	-	SMD 0.89 lower (1.73 to 0.04 lower)	⊕OOO VERY LOW	CRITICAL
Fear (general) (measured with: validated tools (Revised Children's Manifest Anxiety Scale 0-37, Fear Survey Schedule for Children Revised 80-240); Better indicated by lower values)												
1	randomised trials	serious[2]	no serious inconsistency	very serious[6]	serious[7]	none	12	12	-	SMD 0.68 lower (1.51 lower to 0.15 higher)	⊕OOO VERY LOW	IMPORTANT
Fear (general) at 3 month followup (measured with: validated tools (Revised Children's Manifest Anxiety Scale 0-37, Fear Survey Schedule for Children Revised 80-240); Better indicated by lower values)												
1	randomised	serious[2]	no serious	very serious[6]	serious[5]	none	12	12	-	SMD 0.93 lower (1.78 to 0.08	⊕OOO VERY	IMPORTANT

	trials		inconsistency							lower)	LOW	
Distress (specific) (measured with: validated tool (Darkness Fear Behaviour Questionnaire 0-20) by parent; Better indicated by lower values)												
1	randomised trials	serious[2]	no serious inconsistency	very serious[6]	serious[5]	none	12	12	-	SMD 1.85 lower (2.84 to 0.87 lower)	⊕OOO VERY LOW	IMPORTANT
Distress (specific) at 3 month followup (measured with: validated tool (Darkness Fear Behaviour Questionnaire 0-20) by parent; Better indicated by lower values)												
1	randomised trials	serious[2]	no serious inconsistency	very serious[6]	serious[5]	none	12	12	-	SMD 2.19 lower (3.24 to 1.14 lower)	⊕OOO VERY LOW	IMPORTANT
Compliance (measured with: validated tool (Behavioural Avoidance Test) ; Better indicated by higher values)												
2	randomised trials	serious[8]	no serious inconsistency[3]	very serious[4]	serious[7]	none	21	20	-	SMD 0.74 higher (0.82 lower to 2.31 higher)[9]	⊕OOO VERY LOW	IMPORTANT
Compliance at 3 month followup (measured with: validated tool (Behavioural Avoidance Test) ; Better indicated by higher values)												
1	randomised trials	serious[10]	no serious inconsistency	very serious[6]	serious[5]	none	12	12	-	SMD 1.76 higher (0.79 to 2.73 higher)	⊕OOO VERY LOW	IMPORTANT
Pain, Fainting, Procedure Outcomes, Parent Fear, Memory, Preference, Satisfaction (assessed with: no data were identified for these important outcomes)												
0	No evidence available					none	-	-	-	-		IMPORTANT
								0%		-		

[1] Included study by Muris (1998) investigated the effectiveness of single session exposure-based treatment; study by Cornwall (1996) investigated multiple session exposure-based treatment

[2] Therapists and participants not blinded; outcome assessor not blinded

[3] In 1 study (Muris 1998), the control group was a computer-based exposure task; in the other study (Cornwall 1996), the control group was a wait-list control

[4] Phobias included; spider, darkness

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

[6] Phobia included: darkness

[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] Therapists and participants not blinded: in 1 study (Muris 1998), unclear whether outcome assessor blinded; in another study (Cornwall 1996), outcome assessor not blinded

[9] Removal of the study by Muris (1998) leads to an SMD = 1.54 (0.61, 2.47)
[10] Therapists and participants not blinded; outcome assessor not blinded