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Question: Should in vivo 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?<sup>1</sup>

Settings: university and unclear setting

Bibliography: Flatt 2010, Leutgeb 2012, Muris 1998 (1), Ollendick 2009, Ost 2001 (1,2)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	In vivo exposure-based therapy for children with high levels of needle fear	No treatment	Relative (95% CI)	Absolute		
<b>Fear (specific) (measured with: validated tools (Spider Phobia Questionnaire for Children SF 0-15 and full version 0-31, Self Assessment Manikin during lab-based fear inducing task 1-9, Subjective Units of Distress during lab-based fear inducing task 0-8); Better indicated by lower values)</b>												
4	randomised trials	serious <sup>2</sup>	no serious inconsistency <sup>3</sup>	very serious <sup>4</sup>	serious <sup>5</sup>	none	150	85	-	SMD 1.71 lower (2.72 to 0.7 lower)	⊕000 VERY LOW	CRITICAL
<b>Fear (general)<sup>6</sup> (measured with: validated tools (Revised Children Manifest Anxiety Scale 0-37, State Trait Anxiety Inventory for Children 20-60, Fear Survey Schedule for Children Revised 80-240, Multidimensional Anxiety Scale for Children 0-117, Children's Anxiety Sensitivity Index 18-54); Better indicated by lower values)</b>												
4	randomised trials	very serious <sup>7</sup>	no serious inconsistency	very serious <sup>4</sup>	serious <sup>8</sup>	none	158	88	-	SMD 0.03 lower (0.29 lower to 0.23 higher) <sup>6</sup>	⊕000 VERY LOW	IMPORTANT
<b>Compliance<sup>9</sup> (measured with: validated tool (Behavioural Avoidance Test) ; Better indicated by higher values)</b>												
4	randomised trials	serious <sup>2</sup>	no serious inconsistency <sup>3</sup>	very serious <sup>4</sup>	serious <sup>5</sup>	none	152	79	-	SMD 1.55 higher (0.44 to 2.65 higher) <sup>9</sup>	⊕000 VERY LOW	IMPORTANT
<b>Child Satisfaction<sup>10</sup> (measured with: rating scale 0-8; Better indicated by higher values)</b>												
1	randomised trials	serious <sup>2</sup>	no serious inconsistency	very serious <sup>11</sup>	serious <sup>5</sup>	none	85	70	- <sup>10</sup>	not pooled <sup>10</sup>	⊕000 VERY LOW	IMPORTANT

Parent Satisfaction <sup>12</sup> (measured with: rating scale 0-8; Better indicated by higher values)												
1	randomised trials	serious <sup>2</sup>	no serious inconsistency	very serious <sup>11</sup>	serious <sup>5</sup>	none	85	70	-. <sup>12</sup>	not pooled <sup>12</sup>	⊕○○○ VERY LOW	IMPORTANT
Pain, Distress, Fainting, Procedure Outcomes, Parent Fear, Memory, Preference (assessed with: no data were identified for these important outcomes)												
0	No evidence available					none	-	-	-	-		IMPORTANT
								0%		-		

<sup>1</sup> All included studies investigated the effectiveness of massed exposure treatment.

<sup>2</sup> Therapists and participants not blinded; outcome assessor not blinded

<sup>3</sup> Differences in the comparison groups may explain heterogeneity; all included studies used a wait-list control group except for Muris (1998), which used a computer-based exposure control group

<sup>4</sup> Phobias included: Spider, Various (including blood injection injury phobia n=20)

<sup>5</sup> Sample size was below the recommended optimum information size (OIS) of 400 for an effect size of 0.2

<sup>6</sup> In 1 included study (Ollendick 2009), data were combined for participants in 2 countries

<sup>7</sup> Therapists and participants not blinded; outcome assessor not blinded; In 1 study (Flatt 2010), there was the potential for attrition bias and incomplete data due to unclear summary statistics

<sup>8</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>9</sup> In 1 included study (Ost 2001), pre-treatment differences were observed in the Behavioural Avoidance Test for analysis 1

<sup>10</sup> Children reported higher satisfaction with exposure-based treatment than educational support treatment (SMD= 0.66, 95% CI: 0.33, 0.98)

<sup>11</sup> Phobias included: Various (not blood injection injury phobia)

<sup>12</sup> Parents reported higher satisfaction with exposure-based treatment than educational support treatment (SMD = 0.87, 95% CI: 0.54, 1.20)