**Author(s):** RPR/AT

**Date:** 2015-03-13

**Question:** Should directed video distraction during vaccine injections vs no treatment be used for reducing vaccine injection pain in children up to 3 years?1

**Settings:** clinics

**Bibliography:** Cohen 2002, Cohen 2006 (1,2), Cohen 2006 a, Gedam 2013 (2)

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Quality assessment** | | | | | | | **No of patients** | | **Effect** | | **Quality** | **Importance** |
| **No of studies** | **Design** | **Risk of bias** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other considerations** | **Directed video distraction during vaccine injections** | **No treatment** | **Relative (95% CI)** | **Absolute** |
| **Distress Acute2 (measured with: validated tools (Modified Behavioural Pain Scale 0-10, Faces, Leg, Activity, Consolability, Cry 0-10, Visual Analog Scale 0-100) by**  **researchers, clinicians; Better indicated by lower values)** | | | | | | | | | | | | |
| 3 | randomised trials | very serious3 | no serious inconsistency4 | no serious indirectness | serious5 | none | 237 | 219 | - | SMD 0.63 lower  (1.53 lower to  0.27 higher)2 |   VERY LOW | CRITICAL |
| **Distress Recovery (measured with: validated tool (Modified Behavioural Pain Scale 0-10) by researcher; Better indicated by lower values)** | | | | | | | | | | | | |
| 1 | randomised trials | serious6 | no serious inconsistency | no serious indirectness | serious5 | none | 49 | 41 | - | SMD 0.20 lower  (0.62 lower to  0.21 higher) |   LOW | CRITICAL |
| **Distress Acute + Recovery2 (measured with: validated tool (Measure of Adult and Infant Soothing and Distress 0-1) by researcher; Better indicated by lower values)** | | | | | | | | | | | | |
| 1 | randomised trials | no serious risk of bias7 | no serious inconsistency | no serious indirectness | serious8 | none | 63 | 63 | - | SMD 0.68 lower  (1.04 to 0.32  lower)2 |   MODERATE | CRITICAL |
| **Distress Pre-procedure + Acute9,10 (measured with: validated tool (Modified Behavioural Pain Scale 0-10) by researcher; Better indicated by lower values)** | | | | | | | | | | | | |
| 1 | randomised trials11 | very serious12 | no serious inconsistency | no serious indirectness | serious5 | none | 42 | 42 | - | SMD 0.15 lower  (0.58 lower to  0.27 higher)9,10 |   VERY LOW | CRITICAL |
| **Distress Pre-procedure2 (measured with: validated tool (Measure of Adult and Infant Soothing and Distress 0-1, Modified Behavioural Pain Scale 0-10) by researcher;**  **Better indicated by lower values)** | | | | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 2 | randomised trials | serious13 | no serious inconsistency | no serious indirectness | serious8 | none | 112 | 104 | - | SMD 0.49 lower  (0.76 to 0.22  lower)2 |   LOW | CRITICAL |
| **Child Use of Intervention2 (measured with: validated tool (Measure of Adult and Infant Soothing and Distress 0-1, proportion of time behaviour observed 0-1) by researcher; Better indicated by higher values)** | | | | | | | | | | | | |
| 2 | randomised trials | serious3 | no serious inconsistency | no serious indirectness | serious8 | none | 112 | 104 | - | SMD 1.36  higher (0.38 to  2.34 higher)2 |   LOW | IMPORTANT |
| **Procedure Duration (measured with: validated tool (seconds using stopwatch/video) by researcher; Better indicated by lower values)** | | | | | | | | | | | | |
| 1 | randomised trials | very serious6 | no serious inconsistency | no serious indirectness | serious8 | none | 49 | 41 | - | SMD 0.50  higher (0.08 to  0.92 higher) |   VERY LOW | IMPORTANT |
| **Parent Fear, Use of Intervention, Vaccine Compliance, Memory, Preference, Satisfaction (assessed with: no data were identified for these important outcomes)** | | | | | | | | | | | | |
| 0 | No evidence available |  |  |  |  | none | - | - | - | - |  | IMPORTANT |
|  | 0% | - |

1 In 3 of the 4 included studies (Cohen 2002, Cohen 2006, Cohen 2006 a), nurse immunizers were instructed in distraction prior to commencement of the study and in 1 study (Cohen

2006 a) parents were also instructed in distraction; in all included studies, children were encouraged to engage in the distraction

2 In 1 study (Cohen 2006 a), the sample size/group was assumed to be equal

3 Studies not consistently randomized; Immunizer, parent not consistently blinded; outcome assessor, however, blinded to study hypotheses

4 Heterogeneity can be explained by differences in age of child (1 month - 3 years) and intervention (type of video) and its implementation

5 Confidence interval crosses line of nonsignificance and sample size was below the recommended optimum information size (OIS) of 400 for an effect size of 0.2

6 Not truly random; immunizer, parent, observer blinded to hypothesis

7 Unclear whether parent blinded; observer and immunizer blinded to hypothesis

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

9 The sample size/group was assumed to be equal

10 Although 50% of children in analysis (1) were included in analysis (2), data were treated as independent

11 In study by Cohen 2006 (1,2), analysis (3) compared the intervention (directed video distraction) to control (no treatment) at 12 months, and analysis (4) compared the intervention (directed video distraction) to control (no treatment at 18 months. The data are considered independent due to the loss of 50% of the study sample.

12 Not truly random; unclear whether immunizer and parent are blinded; outcome assessor blinded; loss of 50% of sample from analysis (1) at 12 month vaccinations to analysis (2) at

18 month vaccinations

13 Not consistently truly random; unclear whether consistently blinded