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

**Date:** 2015-03-12

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

**Settings:** outpatient clinics

**Bibliography:** Cramer-Berness 2005 a (1), Cramer-Berness 2005 (1), Gedam 2013 (1), Hillgrove-Stuart 2013 (1,2) (2008 thesis), Singh 2012 (1)

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| **Quality assessment** | | | | | | | **No of patients** | | **Effect** | | **Quality** | **Importance** |
| **No of studies** | **Design** | **Risk of bias** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other considerations** | **Directed toy distraction during vaccine injections** | **No treatment** | **Relative (95% CI)** | **Absolute** |
| **Distress Acute2 (measured with: validated tools (Modified Behavioural Pain Scale 0-10, Visual Analog Scale 0-10, Modified Objective Pain Scale 0-20, Faces, Legs, Activity,**  **Consolability, Cry 0-10) by researcher, parent; Better indicated by lower values)** | | | | | | | | | | | | |
| 5 | randomised trials | very serious3 | no serious inconsistency4 | no serious indirectness | serious5 | none | 296 | 253 | - | SMD 0.94 lower  (1.98 lower to 0.1 higher)2 |  VERY LOW | CRITICAL |
| **Distress Acute + Recovery (measured with: validated tool (Modified Behavioural Pain Scale 0-10) by researcher; Better indicated by lower values)** | | | | | | | | | | | | |
| 2 | randomised trials | serious6 | no serious inconsistency | no serious indirectness | serious5 | none | 81 | 79 | - | SMD 0.24 lower  (0.76 lower to  0.27 higher) |   LOW | CRITICAL |
| **Distress Recovery2 (measured with: validated tool (Modified Behavioural Pain Scale 0-10) by researchers; Better indicated by lower values)** | | | | | | | | | | | | |
| 1 | randomised trials | serious7 | no serious inconsistency | no serious indirectness | serious5 | none | 65 | 34 | - | SMD 0.06 lower  (0.47 lower to  0.36 higher)2 |   LOW | CRITICAL |
| **Distress Pre-procedure (measured with: validated tool (Modified Behavioural Pain Scale 0-10, Visual Analog Scale 0-10) by researcher/parent; Better indicated by lower values)** | | | | | | | | | | | | |
| 2 | randomised trials | serious7 | no serious inconsistency | no serious indirectness | serious5 | none | 81 | 79 | - | SMD 0.25 lower  (0.56 lower to  0.06 higher) |   LOW | CRITICAL |
| **Distress Pre-procedure + Acute + Recovery (measured with: validated tool () by researcher; Better indicated by lower values)** | | | | | | | | | | | | |

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| 1 | randomised trials | serious8 | no serious inconsistency | no serious indirectness | serious9 | none | 40 | 41 | - | SMD 0.47 lower  (0.91 to 0.02  lower) |   LOW | CRITICAL |
| **Parent Fear Pre-procedure (measured with: validated tool (Visual Analog Scale 0-10); Better indicated by lower values)** | | | | | | | | | | | | |
| 2 | randomised trials | serious6 | no serious inconsistency | no serious indirectness | serious5 | none | 81 | 79 | - | SMD 0.01 lower  (0.33 lower to  0.31 higher) |   LOW | IMPORTANT |
| **Parent Fear (measured with: validated tools (Visual Analog Scale 0-10) ; Better indicated by lower values)** | | | | | | | | | | | | |
| 2 | randomised trials | serious6 | no serious inconsistency | no serious indirectness | serious2 | none | 81 | 79 | - | SMD 0.46 lower  (0.77 to 0.14  lower) |   LOW | IMPORTANT |
| **Parent Use of Intervention10 (measured with: validated tool (checklist of behaviours) by researcher; Better indicated by lower values)** | | | | | | | | | | | | |
| 3 | randomised trials | very serious6 | no serious inconsistency | no serious indirectness | serious5 | none | 113 | 113 | - | SMD 1.52 higher  (1.06 to 1.98  higher)10 |  VERY LOW | IMPORTANT |
| **Child Use of Intervention2,10 (measured with: validated tools (checklist of behaviours) by researcher ; Better indicated by higher values)** | | | | | | | | | | | | |
| 1 | randomised trials | very serious7 | no serious inconsistency | no serious indirectness | serious9 | none | 65 | 34 | - | SMD 1.48 higher  (0.98 to 1.97  higher)2,10 |  VERY LOW | IMPORTANT |
| **Procedure Outcomes, 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 included studies (Cramer-Berness 2005, Cramer-Berness 2005 a, Hillgrove-Stuart 2013), parents were instructed in distraction

2 In study by Hillgrove-Stuart (2013), sample size for no treatment group divided by 2

3 Studies not consistently randomized; immunizer, parent, researcher not consistently blinded; outcome assessor not consistently blinded; inconsistent outcome reporting

4 Heterogeneity can be explained by differences in age (2 months - 3 years), vaccination details (technique, number of injections, co-intervention) and intervention

5 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

6 Immunizer not blinded; parent not clearly consistently blinded; outcome assessor not clearly consistently blinded

7 Immunizer and parent not blinded; outcome assessor blinded; selective outcome reporting

8 Immunizer and parent not blinded; parent blinded to hypothesis; outcome assessor blinded

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

10 Scores not standardized