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

**Date:** 2015-03-13

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

**Settings:** pediatric clinics

**Bibliography:** Basiri-Moghadam 2014 (2), Cramer-Berness 2005 (2), Ozdemir 2012, Singh 2012 (2)

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| **Quality assessment** | | | | | | | **No of patients** | | **Effect** | | **Quality** | **Importance** |
| **No of studies** | **Design** | **Risk of bias** | **Inconsistency** | **Indirectness** | **Imprecision** | **Other considerations** | **Non-directed toy distraction during vaccine injections** | **No treatment** | **Relative (95% CI)** | **Absolute** |
| **Distress Acute (measured with: tools (Faces Legs Activity Consolability Cry 0-10, Modified observation scale undefined 0-20, Visual Analog Scale 0-10) by researcher; Better indicated by lower values)** | | | | | | | | | | | | |
| 4 | randomised trials | very serious1 | serious2 | no serious indirectness | serious3 | none | 144 | 146 | - | SMD 0.93 lower  (1.86 lower to 0 higher) |  VERY LOW | CRITICAL |
| **Distress Acute + Recovery (measured with: validated tools (cry duration in seconds) by researcher; Better indicated by lower values)** | | | | | | | | | | | | |
| 2 | randomised trials | very serious1 | no serious inconsistency | no serious indirectness | serious4 | none | 68 | 68 | - | SMD 0.22 lower  (1.09 lower to  0.65 higher) |  VERY LOW | CRITICAL |
| **Distress Pre-procedure (measured with: validated tools (Modified Behavioural Pain Scale 0-10) by researcher ; Better indicated by lower values)** | | | | | | | | | | | | |
| 1 | randomised trials | serious5 | no serious inconsistency | no serious indirectness | serious4 | none | 38 | 38 | - | SMD 0.22 lower  (0.67 lower to  0.23 higher) |   LOW | CRITICAL |
| **Parent Fear Pre-procedure (measured with: validated tool (Visual Analog Scale 0-10); Better indicated by lower values)** | | | | | | | | | | | | |
| 1 | randomised trials | very serious5 | no serious inconsistency | no serious indirectness | serious4 | none | 38 | 38 | - | SMD 0.14 higher  (0.31 lower to  0.59 higher) |  VERY LOW | IMPORTANT |
| **Parent Fear (measured with: validated tool (Visual Analog Scale 0-10); Better indicated by lower values)** | | | | | | | | | | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 | randomised trials | serious5 | no serious inconsistency | no serious indirectness | serious4 | none | 38 | 38 | - | SMD 0.24 lower  (0.69 lower to  0.21 higher) |   LOW | IMPORTANT |
| **Procedure Outcomes, 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 Not consistently randomized; immunizer, parent, researcher not consistently blinded

2 Heterogeneity may be explained by differences intervention (mobile, rattle, music, tickling), age (2 months - 3 years), co-interventions (positioning, injection technique)

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

4 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

5 Immunizer not blinded; unclear if parent and outcome assessor blinded