Psychological interventions for reducing pain and distress during routine childhood immunizations: a systematic review

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CRD summary
This systematic review assessed psychological interventions for reducing pain and distress in children, during routine immunisations, and concluded that the evidence suggested that such interventions significantly reduced immunisation pain and distress. This was a well-conducted systematic review, but the poor quality of the included trials and the pooling of very small numbers of trials, limit the reliability of the conclusions.

Authors' objectives
To assess the efficacy of psychological interventions for reducing pain and distress in children during routine immunisations.

Searching
MEDLINE, PsycINFO, EMBASE, CINAHL, and the Cochrane Central Register of Controlled Trials (CENTRAL) were searched for articles from 2005 to 2008; search terms were reported. Trials identified in a previous systematic review, by the same review team and in the same databases, but from inception to 2005, were screened for relevance. Reference lists from all included studies were also reviewed for relevant studies. No language restrictions were applied, but studies only published as abstracts were not eligible for inclusion.

Study selection
Randomised controlled trials (RCTs) and quasi-RCTs were eligible for inclusion if they assessed the efficacy of psychological interventions for reducing pain and distress in children (aged zero to 18 years) during routine childhood immunisations. Trials had to assess procedural pain and distress, experienced by the child and measured by validated instruments, such as visual analogue scales (VAS) completed by either the child or by others.

The included trials assessed the following psychological interventions: breathing exercises, suggestion, child-directed distraction, parent-led distraction, nurse-led distraction, parent coaching, and combined cognitive-behavioural interventions. These trials included children aged from one month to 11 years; six trials focused on children under two years old and 14 focused on children aged two years or older.

Two reviewers assessed trials for inclusion in the review.

Assessment of study quality
The included trials were assessed using the Cochrane Collaboration's Risk of Bias tool, which covers sequence generation, allocation concealment, blinding, completeness of outcome data, selective outcome reporting, and presence of other potential biases. Trials were categorised as having a low, unclear, or high risk of bias. Two reviewers assessed the validity of the included trials and disagreements were resolved by consensus.

Data extraction
Data extraction was undertaken by one reviewer and checked by another. Where necessary, the original data were modified, using established methods; for example means and standard deviations were calculated from medians, ranges, and 95% confidence intervals. The data were extracted using an intention-to-treat approach, where possible.

Methods of synthesis
Where outcomes were measured using the same tool, they were combined statistically using a fixed-effect model. Mean differences and weighted mean differences, with 95% confidence intervals, were calculated for continuous data. Standardised mean differences, with 95% confidence intervals, were also calculated by combining the results where different tools measured the same construct, or those from individual trials to standardise them to a uniform scale. Relative risks and risk differences were calculated for categorical data. The number needed to treat was also calculated.
Statistical heterogeneity was assessed using the $X^2$ and $I^2$ statistics. In the presence of significant heterogeneity, analysis by subgroups, based on child age, was planned. Sensitivity analyses were planned by including and excluding trials with a high risk of bias, if they existed, according to the validity assessment results. Publication bias was assessed using funnel plots.

**Results of the review**

Twenty trials were included, with a total of 1,380 participants. Eighteen of the included trials had a high risk of bias.

Breathing exercises significantly reduced children's self-reported pain (SMD -0.43, 95% CI -0.76 to -0.09; two trials) and their distress measured by an observer (SMD -0.40, 95% CI -0.68 to -0.11; two trials) or by a nurse (SMD -0.57, 95% CI -0.98 to -0.17; two trials). They were not found to reduce the children's self-reported distress (two trials).

Suggestion was not found to reduce self-reported pain (two trials).

Child-directed distraction significantly reduced children's self-reported pain (SMD -0.28, 95% CI -0.54 to -0.03; three trials), but not observer-assessed pain (two trials).

Parent-led distraction significantly reduced observer-assessed distress (SMD -0.50, 95% CI -0.82 to -0.19; two trials), but not observer-assessed pain (two trials), parent-assessed distress (three trials), nor nurse-assessed distress (two trials).

Nurse-led distraction significantly reduced observer-assessed distress (SMD -0.40, 95% CI -0.68 to -0.12; three trials), parent-assessed distress (SMD -0.37, 95% CI -0.66 to -0.07; three trials) and nurse-assessed distress (SMD -0.42, 95% CI -0.70 to -0.14; three trials). There was significant statistical heterogeneity for both parent-assessed and nurse-assessed distress.

Parent coaching significantly reduced observer-assessed distress (SMD -0.71, 95% CI -1.02 to -0.39; two trials), but not observer-assessed pain (two trials).

Combined cognitive-behavioural interventions significantly reduced self-reported pain (SMD -0.75, 95% CI -1.03 to -0.48; three trials), observer-assessed distress (SMD -0.53, 95% CI -0.83 to -0.23; three trials) and parent-assessed distress (SMD -0.97, 95% CI -1.37 to -0.57; two trials). Significant heterogeneity was found for self-reported pain and parent-assessed distress.

**Authors' conclusions**

The evidence suggested that relatively simple psychological interventions, such as breathing exercises, child-directed distraction, nurse-led distraction, and combined cognitive-behavioural interventions, significantly reduced immunisation pain and distress in children.

**CRD commentary**

This review addressed a clear question that was supported by appropriate inclusion criteria. A number of databases were searched for relevant studies, with no language restrictions, reducing the potential for language bias. Only one source of unpublished data was searched and trials that were published only as abstracts were not eligible for inclusion, which increased the potential for publication bias. The authors stated that they assessed publication bias, but the results were not reported. Trials published prior to 2005 were identified from a previous systematic review, conducted by the same review team, but the inclusion criteria for this review were slightly different and it is not clear whether the earlier searches identified all the relevant trials for this review. The validity of the included trials was assessed using appropriate criteria and the results were adequately reported. Two reviewers selected trials, extracted the data, and assessed validity, reducing the potential for reviewer error and bias. Appropriate methods were used to combine the trials, but each meta-analysis only included two or three trials and there was significant statistical heterogeneity for some outcomes.

This was a well-conducted systematic review, but the poor quality of the included trials and the pooling of very small numbers of trials, limit the reliability of the conclusions.
Implications of the review for practice and research

**Practice:** The authors stated that parents and health care professionals should use psychological interventions, such as those identified in their review, during immunisation to ensure that children receive evidence-based pain relief.

**Research:** The authors stated that future trials of psychological interventions to reduce procedural pain and distress in children should have more rigorous designs, conduct, and reporting. They should focus on examining the degree to which parents and nurses administer interventions accurately and assessing the level of engagement of the child in these interventions. Future trials should also assess other psychological interventions, such as hypnosis, and which interventions work best for children of different ages and with different characteristics.

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