

Psychological Interventions for Reducing Pain and Distress During Routine Childhood Immunizations: A Systematic Review

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ABSTRACT

Background: Immunizations are a common source of pain and distress for children. Psychological interventions consist of a variety of techniques for relaxing and distracting children during immunization with the goal of reducing pain and distress.

Objective: We conducted a systematic review to determine the efficacy of various psychological strategies for reducing pain and distress in children during routine immunizations.

Methods: MEDLINE, PsycINFO, EMBASE, CINAHL, and the Cochrane Central Register of Controlled Trials databases were searched to identify randomized controlled trials (RCTs) and quasi-RCTs that determined the effect of psychological interventions on pain and distress during injection of vaccines in children 0 to 18 years of age, using validated child self-reported pain or observer-reported assessments of child distress or pain. We examined the efficacy of 7 psychological interventions: (1) breathing exercises; (2) suggestion; (3) child-directed distraction; (4) parent-led distraction; (5) nurse-led distraction; (6) parent coaching; and (7) combined cognitive-behavioral interventions. All meta-analyses were performed using a fixed-effects model.

Results: Twenty RCTs involving 1380 infants and children (1 month to 11 years of age) were included in the systematic review. Breathing exercises were effective in reducing children's self-reported pain (standardized mean difference [SMD], -0.43 ; 95% CI, -0.76 to -0.09 ; $P = 0.01$), observer-rated distress (SMD, -0.40 ; 95% CI, -0.68 to -0.11 ; $P = 0.007$), and nurse-reported distress (SMD, -0.57 ; 95% CI, -0.98 to

-0.17 ; $P = 0.005$). Self-reported distress ratings appeared to be lower with breathing exercises, but the difference was not statistically significant. No evidence was found to support suggestion as a psychological intervention for reducing pain associated with pediatric immunization. Child-directed distraction was effective in reducing self-reported pain (SMD, -0.28 ; 95% CI, -0.54 to -0.03 ; $P = 0.03$). Parent-led distraction was effective in reducing observer-rated distress (SMD, -0.50 ; 95% CI, -0.82 to -0.19 ; $P = 0.002$), but not other measures of pain or distress. Nurse-led distraction was effective in reducing distress ratings as assessed by the observer (SMD, -0.40 ; 95% CI, -0.68 to -0.12 ; $P = 0.005$), the parent (SMD, -0.37 ; 95% CI, -0.66 to -0.07 ; $P = 0.01$), and the nurse (SMD, -0.42 ; 95% CI, -0.70 to -0.14 ; $P = 0.004$). Parent coaching was effective in reducing observer-rated distress (SMD, -0.71 ; 95% CI, -1.02 to -0.39 ; $P < 0.001$), but not other measures of pain or distress. Combined cognitive-behavioral interventions were effective in reducing children's self-reported pain (SMD, -0.75 ; 95% CI, -1.03 to -0.48 ; $P < 0.001$), observer-rated distress (SMD, -0.53 ; 95% CI, -0.83 to

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Accepted for publication May 6, 2009
doi:10.1016/j.clinthera.2009.07.023
0149-2918/\$ - see front matter

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−0.23; $P < 0.001$), and parent-rated distress (SMD, −0.97; 95% CI, −1.37 to −0.57; $P < 0.001$). The methodologic quality of the included trials was generally poor, with 18 (90%) of the 20 studies rated as having a high risk of bias.

Conclusions: Evidence suggests that breathing exercises, child-directed distraction, nurse-led distraction, and combined cognitive-behavioral interventions are effective in reducing the pain and distress associated with routine childhood immunizations. Although additional well-designed trials examining psychological interventions are needed, parents and health care professionals should be advised to incorporate psychological interventions to reduce the pain and distress experienced by children during immunization. (*Clin Ther.* 2009;31[Suppl B]:S77–S103) © 2009 Excerpta Medica Inc.

Key words: vaccine, immunization, pain, infant, child, psychological interventions.

INTRODUCTION

Immunizations are the most common painful medical procedure for children.¹ Decades of research have found that an individual's experience of pain involves a complex interaction of the pain stimulus with psychological and social factors.² This conceptualization of pain has led to numerous advances in pharmacologic interventions for procedures such as immunizations, as well as a growing body of literature on non-pharmacologic management of pediatric procedural pain, including physical, operator-dependent, and psychological interventions (see the articles by Taddio et al³ and Shah et al⁴ in this supplement).

Psychological interventions are recommended for use in managing children's procedural pain, and these interventions are typically cognitive-behavioral in orientation.⁵ *Cognitive-behavioral therapy* is an umbrella term for interventions that use methods of change derived from a theoretical base in behavioral learning theory and cognitive psychology, and are aimed at modifying emotions, behaviors, and cognitions. Cognitive-behavioral interventions for procedural pain in children make use of techniques for distracting and relaxing the child and often involve the child's parents and health care professionals, either as coaches or facilitators for the interventions. Distraction in particular has been touted as a key intervention for immunization pain.¹ A number of literature reviews have highlighted

the importance and value of psychological interventions for reducing pediatric procedural pain and distress.^{5–8}

Powers⁵ concluded that cognitive-behavioral therapy is a well-established treatment for pediatric procedural pain. We recently completed a comprehensive systematic review for the Cochrane Collaboration involving psychological interventions for managing various types of procedural pain and distress (resulting from immunization, venipuncture, bone marrow aspiration, intravenous line insertion, or lumbar puncture) in children between 2 and 18 years of age.^{9,10} The review investigated a broad range of psychological interventions and found the most support for distraction, hypnosis, and combined cognitive-behavioral interventions.^{9,10} Because the purpose of that review was to examine the efficacy of various psychological interventions across a broad range of medical procedures, it did not provide information regarding the efficacy of psychological interventions when applied specifically to pediatric immunization pain and distress.

The objective of the present review was to identify and synthesize randomized controlled trials (RCTs) and quasi-RCTs that examined the efficacy of different psychological interventions for reducing injection pain and distress in children 0 to 18 years of age during routine childhood immunizations. The interventions of interest were: (1) breathing exercises; (2) suggestion; (3) child-directed distraction; (4) parent-led distraction; (5) nurse-led distraction; (6) parent coaching; and (7) combined cognitive-behavioral interventions.

MATERIALS AND METHODS

Search Strategy

We revised our previous review^{9,10} by: (1) selecting only trials that focused exclusively on immunization pain; (2) expanding the age range to include infants and toddlers (ie, 0–2 years of age), who routinely undergo immunization; (3) considering quasi-RCTs in addition to RCTs; (4) updating the search to identify trials that were published since our first review was conducted (ie, from 2005–2008); and (5) providing a more detailed examination of the efficacy of different types of distraction (ie, child-directed vs parent-led vs nurse-led) that were used during immunization. Trials identified in our previous systematic review^{9,10} were screened by 2 reviewers (L.S.U. and C.M.M.) for appropriateness for inclusion in the current review. New searches were performed using the OVID search plat-

form in the following databases: MEDLINE, PsycINFO, EMBASE, CINAHL, and the Cochrane Central Register of Controlled Trials. The titles and abstracts for all additional citations retrieved from the new search were printed and scanned manually by 2 reviewers (A.T. and C.T.C.). The reviewers identified articles to be retrieved in full, and those articles were further assessed for eligibility by 2 reviewers (C.T.C. and C.M.M.). Reference lists from all included studies were reviewed in search of additional trials (A.T. and C.T.C.). No language restrictions were imposed. Search terms used to identify studies from the various databases for inclusion in this review are provided in the appendix.

Selection

Inclusion Criteria

The review included: (1) children 0 to 18 years of age undergoing immunization with a vaccine that required injection in any setting (hospital or community); (2) RCTs or studies with a quasi-randomized study design, whereby the effect of a specific psychological intervention was determined (the psychological interventions had to be compared with a control or comparison group, and the trials had to include the data necessary for pooling in a meta-analysis, such as means and SDs); and (3) outcomes (pain and distress experienced by the child) measured using validated techniques. We included studies published as full reports or short reports, as well as published academic theses.

Exclusion Criteria

Studies in which the outcome of interest was not clearly defined or was focused on an outcome other than procedural pain and distress (eg, general anxiety) were excluded. We also excluded published abstracts, letters, commentaries, and editorials.

Primary Outcome

The primary outcome was pain or distress experienced by the child during *vaccine injection* (defined as needle puncture through the skin and injection of vaccine material), as assessed by the child using validated tools (self-report), or by others (parent, nurse, physician, or observer) using 1-item scales and/or more comprehensive behavioral measures. Examples of validated self-report measures included: a visual analog scale (VAS), the Oucher,¹¹ and the Faces Pain Scale (FPS).¹² An example of a 1-item observational mea-

sure is a VAS used by a parent, nurse, or observer to rate either pain or distress, whereas more comprehensive behavioral measures included the Children's Hospital of Eastern Ontario Pain Scale (CHEOPS),¹³ the Child-Adult Medical Procedure Interaction Scale-Revised (CAMPIS-R),¹⁴ and the Observational Scale of Behavioral Distress-Revised (OSBD-R).¹⁵ In addition, some trials reported data on idiosyncratic outcomes (eg, number of children in clinically significant pain, number of children restrained); this information was included and analyzed where possible. When trials provided ratings of pain or distress at various time points, we chose the time point occurring during the immunization. When this was not provided, we chose the first outcome immediately following the immunization. In 1 trial,¹⁶ it was not clear whether the distress measure was taken before or after application of the intervention; therefore, we opted to include this outcome to be conservative.

Validity Assessment

The included trials were not masked to the reviewers. None of the trials included in the review were completed by any of the reviewers; thus, the reviewers were not in a position to review their own work. The methodologic quality of the studies was assessed by 2 reviewers (C.M.M. and C.T.C.) using the Cochrane Collaboration's "Risk of Bias" tool.¹⁷ The included domains were: sequence generation; allocation concealment; blinding of outcome assessors and patients; completeness of outcome data; selective outcome reporting; and other potential biases. Methodologic quality criteria were assessed using: *yes* (low risk of bias), *no* (high risk of bias), or *unclear* (lack of information or uncertainty about the potential for bias).

Given some of the idiosyncrasies that can arise in quality assessment of trials of psychological interventions (eg, difficulties in blinding), we created operational definitions for each of these domains that made them clearer to code in the context of the trials included in this review. For example, for blinding, to receive a *yes* (low risk of bias), the paper had to state that all participants in the study (children, parents, health care professionals, coders, and researchers) were blinded and that blinding was achieved. If the paper reported that some measures were taken to blind or reduce some aspect of bias associated with awareness of assignment (eg, if the paper stated that coders were unaware of study hypotheses) but did not

acknowledge any other aspect of blinding (eg, whether the health care professionals present during the immunization were blinded), the paper received an *unclear* risk of bias. The paper received a *no* if it did not report any form of blinding or if the assignment method (eg, alternating, time of day) and/or coding procedure (eg, coders needed to code audio and video, which would provide insight into assignment) precluded blinding. An overall summary of the risk of bias for individual studies was then made, based on the following criteria: *low* (low risk of bias for all but 1 of the key items and no unclear designations); *unclear* (unclear risk of bias for ≥ 1 key item); or *high* (high risk of bias for ≥ 2 key items and/or high risk of bias for 1 key item in combination with ≥ 1 unclear designation). Discrepancies were resolved by consensus.

Data Abstraction

Data from each eligible study were extracted individually from custom-made data summary sheets (designed specifically for psychological interventions) by 1 reviewer (L.S.U.) and entered into the database; the entries were checked for accuracy by a second reviewer (C.T.C.). The data were then entered into the data analysis system by a third person (A.T.). Modification of original data was done as needed on a predefined, restricted basis according to established methods.¹⁸ For example, means (SDs) were calculated from medians, ranges, and 95% CIs.¹⁸ Data were abstracted using an intent-to-treat (ITT) approach; however, if ITT results were not available, a per-protocol approach was used for data presentation.

Study Characteristics

We included randomized and quasi-randomized studies that compared psychological interventions with a placebo or control group for pain management during needle puncture and vaccine injection in children 0 to 18 years of age. Outcome measures included pain or distress, as assessed by the children themselves and/or parents, nurses, physicians, or observers using validated tools.

Clinical heterogeneity was assessed by noting the differences among studies in the following variables: age group (population), country, intervention, type of vaccine, injection method, simultaneous use of other pain-reducing strategies, and outcome assessments.

Data Synthesis

Data synthesis was performed using qualitative and quantitative (meta-analytic) methods. All statistical analyses were conducted using Review Manager (RevMan) version 5.0, the statistical software provided by the Cochrane Collaboration (Copenhagen, Denmark).¹⁷ Data were combined for outcomes that were measured using the same tool, regardless of who performed the assessment (eg, nurse, physician, observer), except for child and parent assessments, which were reported separately. If data were available for multiple raters using the same tool, the scores were aggregated for the same rater(s).

For continuous data, mean differences (MDs) and weighted MDs (WMDs) were calculated along with 95% CIs. Standardized MDs (SMDs) and 95% CIs were also computed by combining the results from different tools measuring the same construct (pain) or from individual studies to standardize results of studies to a uniform scale. The SMD expresses the size of the intervention effect in each study relative to the variability observed in that study. Values were rated as follows: <0.40 , small; 0.40 to 0.70, moderate; and >0.70 , large.¹⁷ For categorical data, relative risks (RRs) and risk differences (RDs) were reported. The number needed to treat (NNT) was determined. All meta-analyses were performed using a fixed-effects model.¹⁷

Study heterogeneity was assessed using I^2 and χ^2 tests. For I^2 , the following template was used to judge the results regarding heterogeneity: 0% to 40%, may not be important; 30% to 60%, may be moderate; 50% to 90%, may be substantial; and 75% to 100%, may be considerable.¹⁷ For all I^2 values $>40\%$, the magnitude and accompanying P value from the χ^2 test were considered in the overall interpretation.¹⁷ We planned a priori subgroup or single-study analyses based on child age (ie, younger vs older children, as determined by the child's ability to provide self-reports) if heterogeneity was judged considerable.

If appropriate, a sensitivity analysis was performed by including and excluding studies with a high likelihood of bias, as assessed by the Risk of Bias tool.¹⁷ Funnel plots were performed to assess the possibility of publication bias if there were sufficient trials (>10).¹⁷

RESULTS

Of the 28 trials included in the previous review by Uman et al,^{9,10} 10 trials met criteria to also be included in the current review. In the updated search,

304 references were retrieved from the 5 databases. All references were saved in an EndNote library, which identified 94 duplicates. The remaining 210 references were reviewed to determine whether they met the inclusion criteria for the current review, and 10 new trials were identified. As a result, 20 unique trials^{16,19–37} met the inclusion criteria for the systematic review. Data were missing from 1 study,³⁶ which would have precluded inclusion of the study in our systematic review; however, we had contacted the primary author as part of our previous review^{9,10} and therefore had the information needed for analysis in this review. A flow diagram depicting the results of our literature search is provided in **Figure 1**.

The included studies were classified into the following categories of psychological interventions: (1) breathing exercises (ie, breathing unassisted or with the assistance of a party blower or bubble blowing; could also be augmented by parent or medical staff encouragement to engage in the breathing exercise) ($n = 4$)^{16,19–21}; (2) suggestion (ie, telling the children something that would make them believe that the procedure would hurt less) ($n = 2$)^{22,23}; (3) child-directed distraction (ie, distraction directed at the child by means of a video, music, or story played via headphones) ($n = 3$)^{23–25}; (4) parent-led distraction (ie, parents instructed on how to distract the child using age-appropriate toys, videos, etc) ($n = 4$)^{26–29}; (5) nurse-led distraction (ie, nurses instructed on how to distract the child using age-appropriate toys) ($n = 4$)^{30–33}; (6) parent coaching (ie, parents instructed to provide assistance to the child using different techniques, not limited to distraction) ($n = 3$)^{27,34,35}; and (7) combined cognitive-behavioral interventions (ie, some combination of different types of cognitive and behavioral interventions; could involve just the child or both the child and parent) ($n = 4$)^{23,30,36,37}.

Four studies^{23,25,27,30} were included in >1 category. Three of the studies^{23,27,30} included >1 type of psychological intervention group (in comparison to a control) (eg, a child-directed distraction group, a suggestion group, and a combined cognitive-behavioral group); therefore, these trials were included in separate analyses for each intervention. One trial²⁵ compared 2 types of child-directed distraction (musical story and spoken story) versus a control; hence, data from both of these distraction groups were included in the analysis of child-directed distraction. Also, because 1 of the trials that examined nurse-led distraction³³

involved a crossover (within-subjects) design with a group of 39 children who received a series of 3 injections over a 6-month period, it could not be included in the quantitative data analyses.

The 20 unique trials included 1380 infants and children. The age of the participants ranged from 1 month to 11 years, with 14 trials focused on children (≥ 2 years of age) and 6 trials focused on infants and toddlers (< 2 years). None of the trials included adolescents. Studies were conducted in various health clinics and pediatric practices. Approval by an ethics committee was reported in 5 of the 20 studies; however, given that many of the papers were published at a time when reporting ethical approval was not required, we did not exclude these trials from analysis.

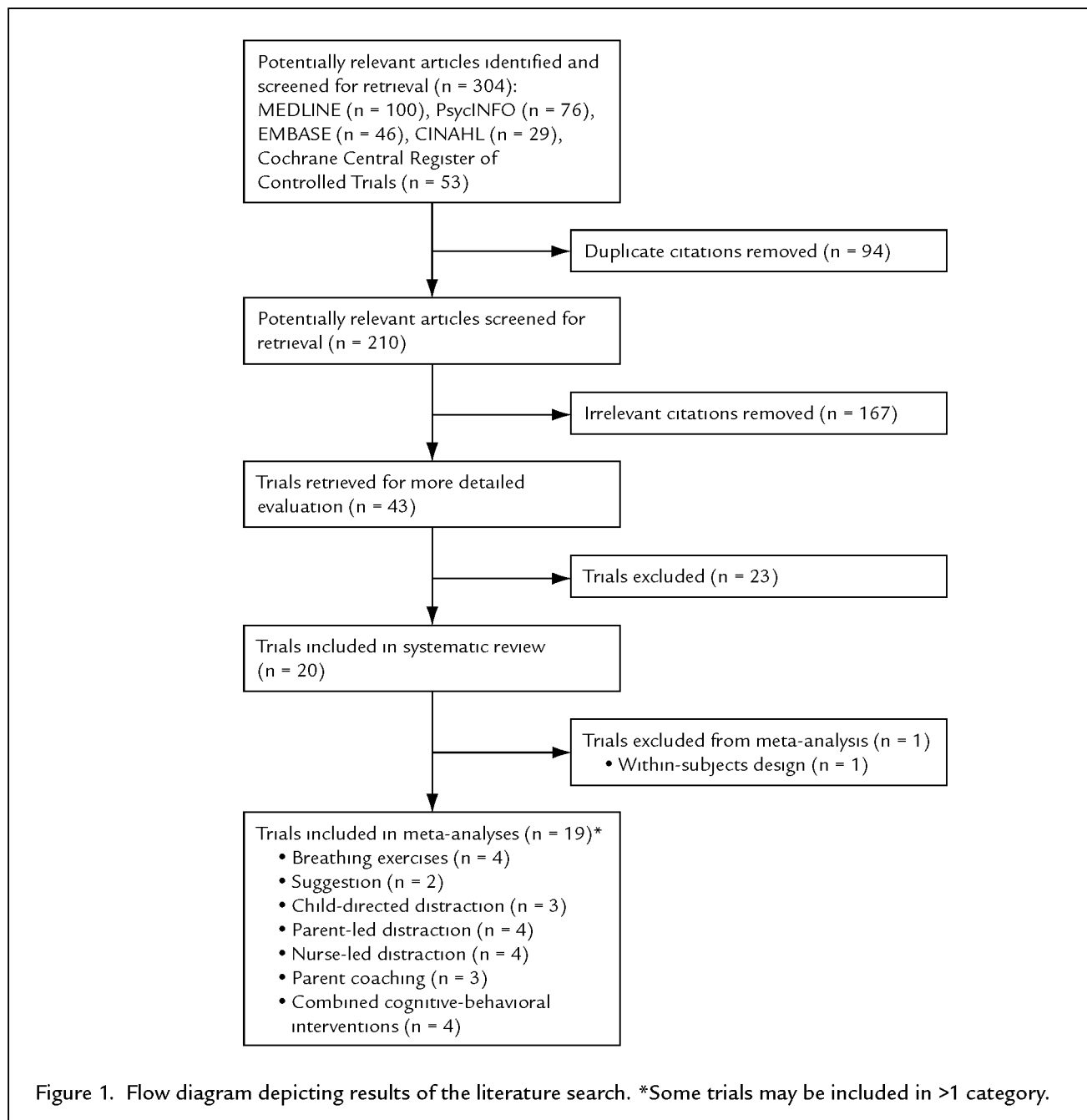
Characteristics of the included trials are provided in **Table I**.^{16,19–37} Results of methodologic quality (Risk of Bias) assessments of the included trials are presented in **Table II**.^{16,19–37} The methodologic quality of the included trials was generally poor, with 18 (90%) of the 20 studies rated as having a high risk of bias. Differences of opinion arose concerning 3 of the trials; decisions regarding those trials were reached through discussion and consensus.

Breathing Exercises

Two studies^{19,21} examined children's self-reported pain using a VAS or the Oucher; the SMD was -0.43 (95% CI, -0.76 to -0.09 ; $P = 0.01$) (**Figure 2**). Heterogeneity was not significant for this outcome. Two studies^{16,21} examined children's self-reported distress using a VAS or the Child Medical Fear Scale; the SMD was -0.34 (95% CI, -0.72 to 0.03 ; $P = \text{NS}$). Heterogeneity was significant for this outcome ($\chi^2 = 5.47$; $P = 0.02$; $I^2 = 82\%$); hence, the results were analyzed separately. In the study by Bowen and Dammeyer,¹⁶ the SMD was -0.89 (95% CI, -1.48 to -0.30 ; $P = 0.003$). The study by Sparks²¹ reported an SMD of 0.02 (95% CI, -0.46 to 0.51 ; $P = \text{NS}$).

Two studies each examined observer-rated distress using the OSBD-R or the Child Medical Distress Scale (CMDS),^{19,20} and nurse-reported distress using a Likert Scale or the CMDS.^{16,20} The SMDs were -0.40 (95% CI, -0.68 to -0.11 ; $P = 0.007$) and -0.57 (95% CI, -0.98 to -0.17 ; $P = 0.005$), respectively. Heterogeneity was not significant for either analysis.

In summary, evidence suggested that breathing exercises were effective in reducing children's self-reported pain, observer-rated distress, and nurse-reported dis-



stress. Breathing exercises were effective in reducing children's self-reported distress in 1¹⁶ of the 2 relevant studies but not in the other study.²¹

Suggestion

Two studies^{22,23} examined self-reported pain using a color tool and a VAS. The MD was -0.23 (95% CI, -0.51 to 0.04 ; $P = \text{NS}$). Heterogeneity was not

significant for this outcome. There was no evidence that suggestion was effective in reducing pain from immunization.

Child-Directed Distraction

Self-reported pain was examined in 3 studies^{23–25} using the FPS or a VAS. As noted, the study by Noguchi²⁵ was included twice because of its inclusion

Table I. Characteristics of the trials included in the systematic review (N = 20).

Author, Year, Country	Intervention Category	Included in Meta- Analysis	Population Enrolled, Setting	Exclusion Criteria	Intervention	Outcomes
Breathing Exercises						
Bowen and Dammeyer, ¹⁶ 1999, US	Breathing exercises: party blower	Yes	N = 50; 3–6 y; flu clinic	Non- English- speaking families	Party blower (n = 29), control (n = 21)	Child VAS (distress), nurse Likert Scale (distress), data from an additional intervention group (pinwheel) were not included in this review due to missing values
French et al, ¹⁹ 1994, US	Breathing exercises: taking a deep breath (with investigator prompting)	Yes	N = 75; 4–7 y; immunization clinic	NR	Blowing out air (n = 39), control (n = 36)	Child VAS (pain), observer OSBD-R (distress)
Krauss, ²⁰ 1996 dissertation, US	Breathing exercises: party blower, taught via video (with parent prompting)	Yes	N = 50; 4–7 y; health department	NR	Videotape (n = 25), control (n = 25)	Nurse CMDS (distress), observer (researcher) CMDS (distress)
Sparks, ²¹ 2001, US	Breathing exercises: bubble blowing (with clinic staff encouragement)	Yes	N = 66; 4–6 y; medical clinic	NR	Bubble group (n = 33), control (n = 33)	Child CMFS (distress) and Oucher (pain)
Suggestion						
Eland, ²² 1981, US	Suggestion: children told that an aerosol spray would make the shot hurt less	Yes	N = 40; 4–5 y; private pediatrician practice	NR	Frigiderm (n = 20), air (n = 20)	Child 4-point color tool (pain)

(continued)

Table I (continued).

Author, Year, Country	Intervention Category	Included in Meta- Analysis	Population Enrolled, Setting	Exclusion Criteria	Intervention	Outcomes
Fowler-Kerry and Lander, ^{2,3*} 1987, Canada	Suggestion: children told the experimenter would help them during the injection	Yes	N = 120; 4–6 y; community health clinic	NR	Suggestion (n = 40), control (n = 80)	Child 4-point VAS (pain); 2 other intervention groups (distraction and distraction + suggestion) were included
Child-Directed Distraction						
Fowler-Kerry and Lander, ^{2,3*} 1987, Canada	Child-directed distraction: music played via headphones	Yes	N = 120; 4–6 y; community health clinic	NR	Distraction (n = 40), control (n = 80)	Child 4-point VAS (pain); 2 other intervention groups (suggestion and distraction + suggestion) were included
Cassidy et al, ²⁴ 2002, Canada	Child-directed distraction: watching a videotaped cartoon	Yes	N = 59; 5 y; urban pediatric clinic	Previously immunized with preschool DPTP vaccine; previously hospitalized; presence of any acute or chronic condition	Distraction (n = 31), control (n = 28)	Child FPS (pain), observer CHEOPS (pain), no. of children in clinically significant pain
Noguchi, ²⁵ 2006, US	Child-directed distraction: spoken story vs musical story played via headphones (with visual aids)	Yes	N = 62; 4–6 y; medical clinic	NR	Spoken story (n = 21), musical story (n = 21), control (n = 20)	Child 6-point FPS (pain) and self-reported (pain), observer 6-point FPS (pain) and OSBD–R (distress), observer-reported (pain); 2 distraction groups (1 nonmusical, 1 spoken story) were included

(continued)

Table I (continued).

Author, Year, Country	Intervention Category	Included in Meta- Analysis	Population Enrolled, Setting	Exclusion Criteria	Intervention	Outcomes
Parent-Led Distraction						
Cohen et al, ²⁶ 2006, US	Parent-led distraction: parent instruction in distraction, cartoon video	Yes	N = 136; 1–21 mo; health care facility	NR	Distraction (n = 68), control (n = 68)	Parent and nurse VAS (distress), observer MAISD (distress during immunization) and MAISD (total distress)
Cramer-Berness and Friedman, ^{27*} 2005, US	Parent-led distraction: brief instruction in distraction, use of age-appropriate toys	Yes	N = 81; 2 mo–2 y; health clinic	NR	Distraction (n = 40), typical care (n = 41)	Parent VAS (distress), observer MBPS (pain); another intervention group (parent coaching) was included
Cramer-Berness, ²⁸ 2005, US	Parent-led distraction: training in distraction with dolls and age-appropriate toys, practice	Yes	N = 79; 2 mo–2 y; clinic	NR	Audiovisual distraction (n = 41), typical care (n = 38)	Parent VAS (distress), observer MBPS (pain)
Gonzalez et al, ²⁹ 1993, US	Parent-led distraction: instruction on how to verbally distract child, modeling, practice	Yes	N = 28; 3–7 y; pediatric clinic	NR	Distraction (n = 14), control (n = 14)	Child Oucher (pain), nurse 5-point MFBR (distress), observer OSBD-R (distress)
Nurse-Led Distraction						
Cohen et al, ^{30*} 1997, US	Nurse-led distraction: 15-min training program and video cartoon	Yes	N = 60; 4–6 y; rural health clinic	NR	Nurse coaching (n = 31), standard care (n = 29)	Child 5-point FPS, parent 10-point Likert Scale (distress), nurse 10-point Likert Scale (distress), observer CAMPIS-R (distress); another intervention group (combined cognitive-behavioral interventions) was included

(continued)

Table I (continued).

Author, Year, Country	Intervention Category	Included in Meta- Analysis	Population Enrolled, Setting	Exclusion Criteria	Intervention	Outcomes
Cohen, ⁴¹ 2002, US	Nurse-led distraction: 15-min training program about distraction, use of video cartoon or age-appropriate toys (rattles, dolls)	Yes	N = 90; 2 mo–3 y; rural health clinic	NR	Distraction (n = 49), control (n = 41)	Parent VAS (distress), nurse VAS (distress), observer MBPS (distress)
Cohen et al, ⁴² 2006, US	Nurse-led distraction: 15-min training in how to use distraction, use of video cartoon and age-appropriate toys; told to avoid using distress-promoting behaviors	Yes	N = 56; 12 mo; rural health department	NR	Distraction (n = 28), control (n = 28)	Parent VAS (distress), nurse VAS (distress), observer MBPS (distress)
Cohen et al, ⁴³ 1999, US	Nurse-led distraction: 15-min training program, use of video cartoon	No	N = 78; 8–11 y; school health clinic	NR	Coach and distract (n = 39), control (n = 39)	Not included in quantitative data analyses because this study used a crossover (within-subjects) design
Parent Coaching						
Cramer-Berness and Friedman, ^{27*} 2005, US	Parent coaching: “supportive care”; parents were told that immunizations are stressful and were encouraged to do what they normally would do	Yes	N = 83; 2 mo–2 y; health clinic	NR	Supportive care (n = 42), typical care (n = 41)	Observer MBPS (pain) and MBPS total (distress), parent VAS (distress); another intervention group (parent-led distraction) was included

(continued)

Table I (continued).

Author, Year, Country	Intervention Category	Included in Meta- Analysis	Population Enrolled, Setting	Exclusion Criteria	Intervention	Outcomes
Bustos et al, ³⁴ 2008, Australia	Parent coaching: 1-page information sheet about coping behaviors (humor, nonprocedural talk, coping prompts)	Yes	N = 50; 5–7 mo; hospital outpatient immunization clinic	Poor grasp of English language	Intervention (n = 25), standard care (n = 25)	Observer NFCS (pain), cry duration
Felt et al, ³⁵ 2000, US	Parent coaching: information sheet about different techniques to use with infants (eg, toys, parent voice, pacifier, rocking)	Yes	N = 79; 2–24 mo; urban pediatric practice	NR	Intervention (n = 42), control (n = 37)	Observer duration of distress (distress)
Combined Cognitive-Behavioral Interventions						
Cohen et al, ³⁶ 2002, US	Combined cognitive- behavioral interventions: video instruction in deep breathing and positive self- statements for child, video modeling, practice	Yes	N = 61; 3–6 y; health department	NR	Coping skills (n = 31), control (n = 30)	Child 5-point FPS (pain) and 5-point FPS (distress), parent VAS (distress)
Fowler-Kerry and Lander, ^{2,3*} 1987, Canada	Combined cognitive- behavioral interventions: distraction using music played via headphones; children were told the experimenter would help them during the injection	Yes	N = 120; 4–6 y; community health clinic	NR	Distraction and suggestion (n = 40), control (n = 80)	Child VAS (pain); 2 other intervention groups (distraction and suggestion, used separately) were included
(continued)						

Table I (continued).

Author, Year, Country	Intervention Category	Included in Meta- Analysis	Population Enrolled, Setting	Exclusion Criteria	Intervention	Outcomes
Cohen et al, ^{40*} 1997, US	Combined cognitive-behavioral interventions: 15-min training program and video cartoon for nurses, and 15-min child and parent training in video distraction, practice, and feedback	Yes	N = 61; 4–6 y; rural health clinic	NR	Nurse coaching and parent/child training (n = 32), standard care (n = 29)	Child 5-point FPS (pain), parent 10-point Likert Scale (distress), nurse 10-point Likert Scale (distress); another intervention group (nurse-led distraction) was included
Blount et al, ⁴⁷ 1992, US	Combined cognitive-behavioral interventions: parent rationale and coaching, use of party blower, parent modeling and role playing, child role playing, child distraction with toys, puzzles, or books	Yes	N = 60; 3–7 y; local health department	NR	Treatment (n = 30), control (n = 30)	Observer BAADS (distress), proportion restrained

VAS = visual analog scale; NR = not reported; OSBD-R = Observational Scale of Behavioral Distress-Revised; CMDS = Child Medical Distress Scale; CMFS = Child Medical Fear Scale; DPTP = diphtheria, pertussis, tetanus, and polio; FPS = Faces Pain Scale; CHEOPS = Children's Hospital of Eastern Ontario Pain Scale; MAISD = Measure of Adult and Infant Soothing and Distress; MBPS = Modified Behavioral Pain Scale; MFBRS = Modified Frankl Behavior Rating Scale; CAMPIS-R = Child-Adult Medical Procedure Interaction Scale-Revised; NFCS = Neonatal Facial Coding System; BAADS = Behavioral Approach-Avoidance and Distress Scale.

*Study included in >1 category.

Table II. Assessment of risk of bias in the trials included in the systematic review (N = 20).

Author, Year, Country	Adequate Sequence Generation	Allocation Concealment	Blinding of Outcome Assessors and Patients	Incomplete Outcome Data Addressed	Free of Selective Reporting	Free of Other Bias	Overall Risk
Breathing Exercises							
Bowen and Dammeyer, ¹⁶ 1999, US	No	No	No	Unclear	No	Unclear	High
French et al, ¹⁹ 1994, US	No	No	No	No	No	Unclear	High
Krauss, ²⁰ 1996 dissertation, US	Yes	No	No	Yes	Yes	Unclear	High
Sparks, ²¹ 2001, US	No	No	No	No	Yes	Unclear	High
Suggestion							
Eland, ²² 1981, US	Yes	Unclear	No	Yes	Yes	Unclear	High
Fowler-Kerry and Lander, ^{2,3*} 1987, Canada	Yes	Unclear	Unclear	Yes	Yes	Unclear	Unclear
Child-Directed Distraction							
Fowler-Kerry and Lander, ^{2,3*} 1987, Canada	Yes	Unclear	Unclear	Yes	Yes	Unclear	Unclear
Cassidy et al, ²⁴ 2002, Canada	Yes	Unclear	No	No	Yes	Unclear	High
Noguchi, ²⁵ 2006, US	Yes	Unclear	No	No	Yes	Unclear	High
Parent-Led Distraction							
Cohen et al, ²⁶ 2006, US	Yes	Yes	No	Yes	Yes	Unclear	High
Cramer-Berness and Friedman, ^{27*} 2005, US	Yes	Unclear	No	Unclear	Yes	Unclear	High
Cramer-Berness, ²⁸ 2005, US	Yes	No	No	Unclear	Yes	Unclear	High

(continued)

Table II (continued).

Author, Year, Country	Adequate Sequence Generation	Allocation Concealment	Blinding of Outcome Assessors and Patients	Incomplete Outcome Data Addressed	Free of Selective Reporting	Free of Other Bias	Overall Risk
Gonzalez et al, ²⁹ 1993, US	Yes	Unclear	No	Unclear	Yes	Unclear	High
Nurse-led Distraction							
Cohen et al, ^{30*} 1997, US	No	No	No	Yes	Yes	Unclear	High
Cohen, ³¹ 2002, USA	No	No	No	Unclear	Yes	Unclear	High
Cohen et al, ³² 2006, US	No	No	No	Unclear	Yes	Unclear	High
Cohen et al, ³³ 1999, US	Yes	No	No	Unclear	Yes	Unclear	High
Parent Coaching							
Cramer-Berness and Friedman, ^{27*} 2005, US	Yes	Unclear	No	Unclear	Yes	Unclear	High
Bustos et al, ³⁴ 2008, Australia	Yes	Unclear	Unclear	Yes	Yes	Unclear	Unclear
Felt et al, ³⁵ 2000, US	Unclear	Unclear	Unclear	Yes	Yes	Unclear	Unclear
Combined Cognitive-Behavioral Interventions							
Cohen et al, ³⁶ 2002, US	No	No	Unclear	Unclear	No	Unclear	High
Fowler-Kerry and Lander, ^{23*} 1987, Canada	Yes	Unclear	Unclear	Yes	Yes	Unclear	Unclear
Cohen et al, ^{30*} 1997, US	No	No	No	Yes	Yes	Unclear	High
Blount et al, ³⁷ 1992, US	Yes	Unclear	No	Yes	No	Unclear	High

No = high risk of bias; Unclear = lack of information or uncertainty about the potential for bias; Yes = low risk of bias.

*Study included in >1 category.

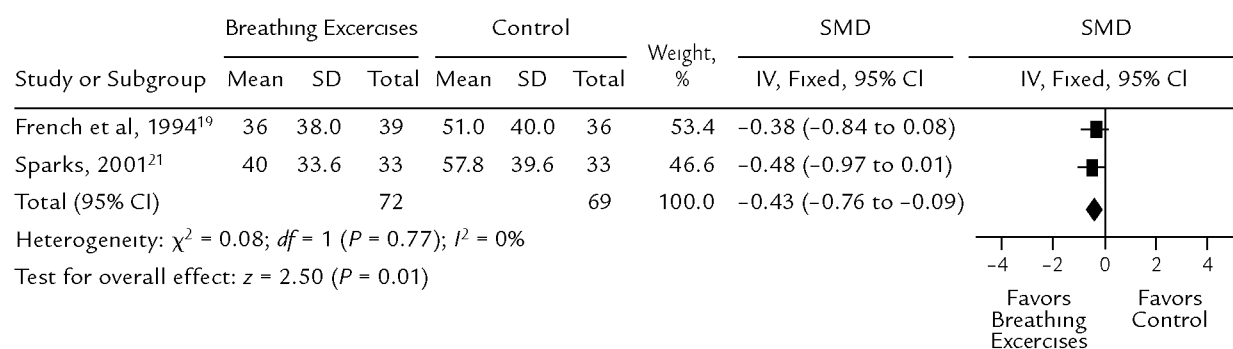


Figure 2. Effects of breathing exercises on self-reported pain. SMD = standardized mean difference; df = degrees of freedom.

in 2 separate child-directed distraction study groups (ie, musical story and spoken story, each played via headphones). The SMD was -0.28 (95% CI, -0.54 to -0.03 ; $P = 0.03$) (Figure 3). Heterogeneity was not significant for this outcome.

Two studies^{24,25} reported observer-rated pain using the FPS or the CHEOPS for 3 separate intervention groups. Again, the study by Noguchi²⁵ was included twice. The SMD was -0.32 (95% CI, -0.65 to 0.02 ; $P = \text{NS}$). Heterogeneity was not significant for this outcome. Observer-rated distress using the OSBD-R was reported in the study by Noguchi²⁵; the MD was -0.46 (95% CI, -2.38 to 1.46 ; $P = \text{NS}$).

In the study by Cassidy et al,²⁴ the number of children with significant pain (FPS scores ≥ 3) was provided. The RR was 0.62 (95% CI, 0.23 to 1.62 ; $P = \text{NS}$) for children who received distraction compared with those who did not. The RD was -0.11 (95% CI, -0.33 to 0.10 ; $P = \text{NS}$).

In summary, child-directed distraction was effective in reducing self-reported pain. Observer-rated pain appeared to be lower with this intervention, but the difference was not statistically significant.

Parent-Led Distraction

Two studies^{27,28} examined observer-rated pain using the Modified Behavioral Pain Scale (MBPS); the

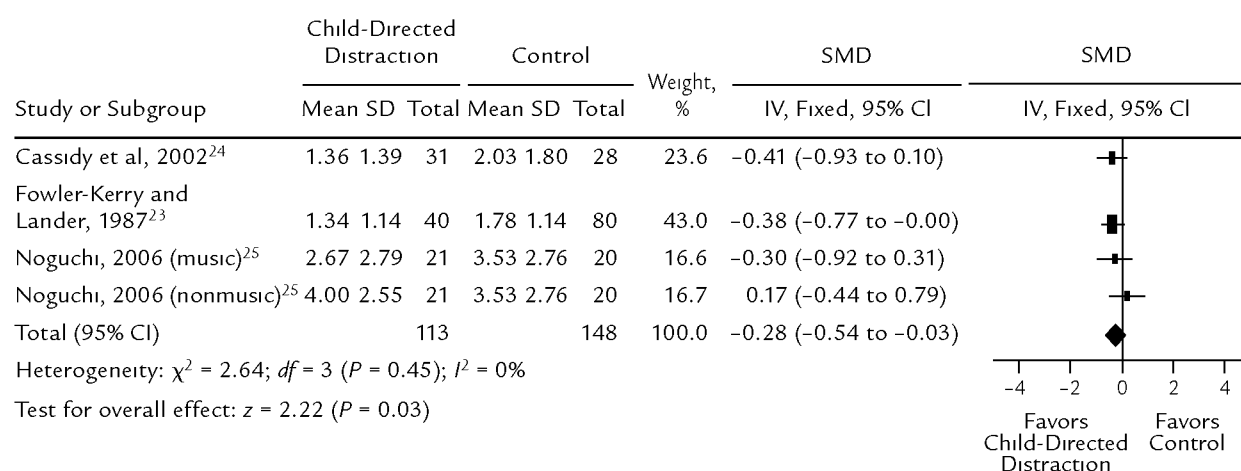


Figure 3. Effects of child-directed distraction on self-reported pain. SMD = standardized mean difference; df = degrees of freedom.

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SMD was -0.19 (95% CI, -0.50 to 0.12 ; $P = \text{NS}$). Heterogeneity was not significant for this outcome. Observer-rated distress using the Measure of Adult and Infant Soothing and Distress or OSBD-R was examined in 2 studies^{26,29}; the SMD was -0.50 (95% CI, -0.82 to -0.19 ; $P = 0.002$). Heterogeneity was not significant for this outcome.

Three studies²⁶⁻²⁸ reported parent-rated distress using a VAS; the SMD was -0.12 (95% CI, -0.35 to 0.11 ; $P = \text{NS}$). Heterogeneity was not significant for this outcome. Nurse-rated distress using a VAS or Modified Frankl Behavior Rating Scale was reported in 2 studies^{26,29}; the SMD was -0.25 (95% CI, -0.56 to 0.06 ; $P = \text{NS}$). Again, heterogeneity was not significant.

In the study by Gonzalez et al,²⁹ self-reported Oucher pain scores did not differ significantly between the parent-led distraction group and the control group (MD, -0.43 ; 95% CI, -1.56 to 0.70).

In summary, parent-led distraction was effective in reducing observer-rated distress, but not other measures of pain or distress during immunization.

Nurse-Led Distraction

Three studies³⁰⁻³² examined observer-rated distress using the CAMPIS-R or MBPS; the SMD was -0.40 (95% CI, -0.68 to -0.12 ; $P = 0.005$) (Figure 4). Heterogeneity was not significant for this outcome.

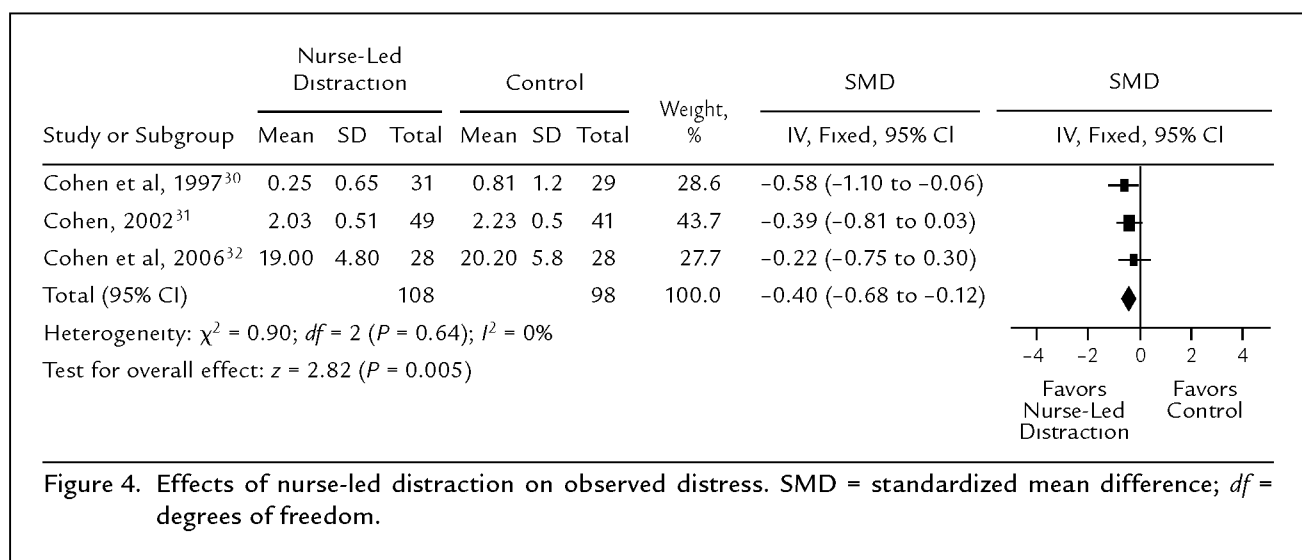
Three studies³⁰⁻³² reported parent- and nurse-rated distress using a Likert Scale or VAS; the SMDs were -0.37 (95% CI, -0.66 to -0.07 ; $P = 0.01$) and -0.42 (95% CI, -0.70 to -0.14 ; $P = 0.004$), respectively.

Heterogeneity was significant for both analyses ($\chi^2 = 38.22$; $P < 0.001$; $I^2 = 95\%$ and $\chi^2 = 17.4$; $P < 0.001$; $I^2 = 89\%$, respectively). Qualitative analyses of parent-rated distress found a significant effect in 1 study³⁰; the SMD was -2.17 (95% CI, -2.82 to -1.52 ; $P < 0.001$). No significant differences were observed in the other studies^{31,32}; the SMDs were -0.01 (95% CI, -0.43 to 0.40) and 0.26 (95% CI, -0.26 to 0.79), respectively. For nurse ratings, a significant reduction was reported in 1 study³⁰; the SMD was -1.47 (95% CI, -2.05 to -0.90 ; $P < 0.001$). No significant differences were reported in 2 studies^{31,32}; the SMDs were 0.01 (95% CI, -0.41 to 0.42) and -0.23 (95% CI, -0.76 to 0.29), respectively. In the remaining study,³⁰ self-reported pain (using an FPS) was lower in the nurse-led distraction group than in the control group (MD, -2.70 ; 95% CI, -3.28 to -2.12 ; $P < 0.001$).

In summary, nurse-led distraction was effective in reducing observer-rated distress and parent and nurse ratings of distress. Evidence from 1 study indicated a reduction in self-reported pain.

Parent Coaching

Two studies^{27,34} reported observer-rated pain using the Neonatal Facial Coding System or the MBPS; the SMD was -0.13 (95% CI, -0.47 to 0.22 ; $P = \text{NS}$). Heterogeneity was not significant for this outcome. Two studies^{27,35} reported observer-rated distress using the MBPS or the duration of distress; the SMD was -0.71 (95% CI, -1.02 to -0.39 ; $P < 0.001$). Heterogeneity



neity was not significant for this outcome. Parent-rated distress using a VAS was not significantly different in 1 study (WMD, 0.11; 95% CI, -0.91 to 1.13).²⁷ In the other study,³⁴ cry duration was significantly shorter in the parent-coaching group than in the control group (SMD, -7.20 sec; 95% CI, -13.31 to -1.09; $P = 0.02$).

In summary, parent coaching was effective in reducing observer-rated distress, but not other measures of pain or distress during immunization.

Combined Cognitive-Behavioral Interventions

Three studies^{23,30,36} examined self-reported pain using an FPS or a VAS; the SMD was -0.75 (95% CI, -1.03 to -0.48; $P < 0.001$) (Figure 5). Heterogeneity was significant for this outcome ($\chi^2 = 21.02$; $P < 0.001$; $I^2 = 90\%$). Qualitative analyses revealed significant effects in studies by Cohen et al³⁰ and Fowler-Kerry and Lander²³; the SMDs were -1.98 (95% CI, -2.60 to -1.36; $P < 0.001$) and -0.64 (95% CI, -1.03 to -0.25; $P = 0.001$), respectively. The difference in the study by Cohen et al,³⁶ however, was not statistically significant (SMD, -0.14; 95% CI, -0.65 to 0.36).

Observer-rated distress using the CAMPIS-R or a Likert Scale was reported in 3 studies^{30,36,37}; the SMD was -0.53 (95% CI, -0.83 to -0.23; $P < 0.001$). Heterogeneity was not significant for this outcome. Two studies^{30,36} reported parent-rated distress using a VAS; the SMD was -0.97 (95% CI, -1.37 to -0.57; $P < 0.001$). Heterogeneity was significant for this outcome

($\chi^2 = 26.73$; $P < 0.001$; $I^2 = 96\%$). Qualitative analysis found a positive effect in 1 study³⁰; the SMD was -2.37 (95% CI, -3.03 to -1.70; $P < 0.001$). The difference was not statistically significant in the other study³⁶ (SMD, -0.17; 95% CI, -0.67 to 0.33).

Individual analyses of self-reported distress using the FPS in 1 study by Cohen et al³⁶ found a nonsignificant difference between children in the combined cognitive-behavioral intervention group and those in the control group (SMD, -0.36; 95% CI, -0.87 to 0.15). The study by Blount et al³⁷ reported a lower risk of being restrained during the procedure for children in the intervention group than in the control group (RR, 0.53; 95% CI, 0.28 to 0.99; $P = 0.05$). The RD was -0.27 (95% CI, -0.51 to -0.03; $P = 0.03$). The NNT to prevent 1 child from being restrained was 3.7.^{2,34}

In summary, evidence suggested that combined cognitive-behavioral interventions were effective in reducing children's self-reported pain, observer-rated distress, and parent-rated distress.

DISCUSSION

The results of this systematic review provided evidence in support of several psychological interventions for reducing the pain and distress associated with immunization in children (Table III). Evidence supported breathing exercises as a method for reducing pain and distress during childhood immunization. The studies included in the review had children en-

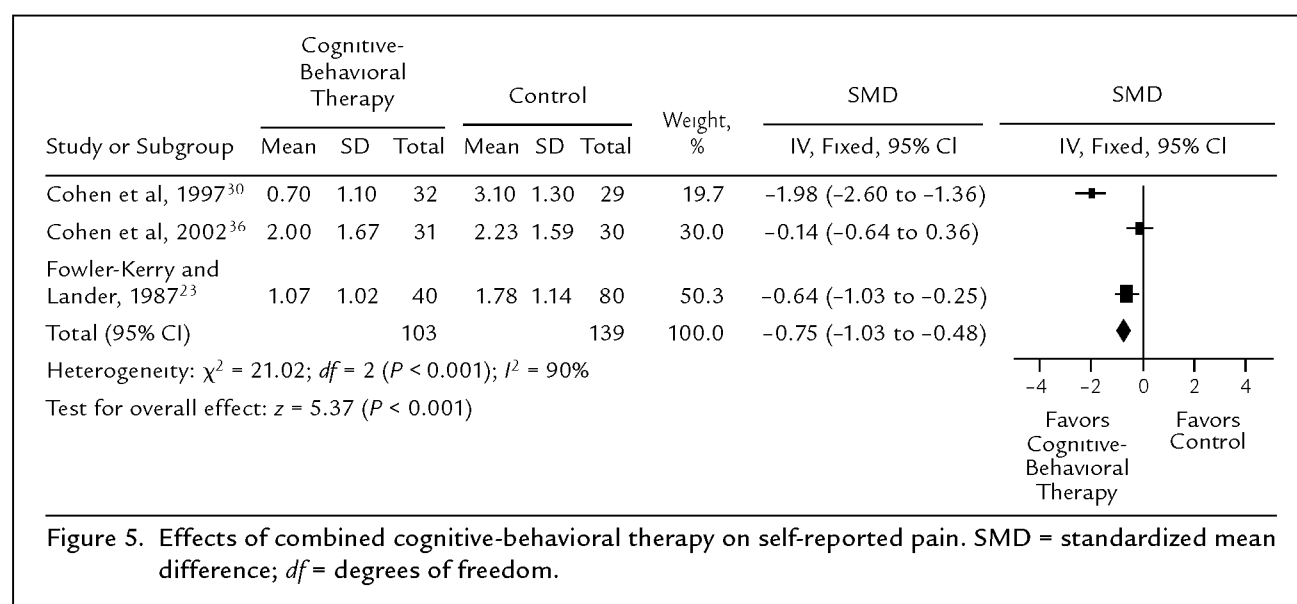


Table III. Efficacy of the psychological interventions assessed in the systematic review.

Intervention	Reduces Pain and/or Distress*
Breathing exercises	Yes
Suggestion	No
Child-directed distraction	Yes
Parent-led distraction	?
Nurse-led distraction	Yes
Parent coaching	?
Combined cognitive-behavioral interventions	Yes

Yes = evidence supports the stated intervention; No = no evidence is available to support the stated intervention at this time; ? = there is insufficient evidence to support the stated intervention at this time (ie, additional research is needed).

*See text for details.

gage in deep breathing (“blowing the hurt/pain away”) using a party blower,^{16,20} bubble blowing,²¹ or direct instruction to simply take a deep breath at the time of the injection.¹⁹ Several of these studies conceptualized breathing exercises not only as the intended intervention, but also as a distraction (eg, by focusing attention on the bubbles or party blower); in most of these studies, adults (either parents or the researchers) were also instructed to prompt or remind the child to engage in deep breathing. The finding that simple breathing exercises are effective at significantly reducing injection pain and distress during immunization is important, because these exercises can be easily and quickly taught to children as young as 3 years of age with minimal instruction. They also make use of inexpensive and accessible items (eg, bubbles, party blowers) that are easy to make available in the clinic or office.

There was no evidence to support the use of suggestion for reducing pain and distress associated with pediatric immunization at this time. Suggestion typically involves inducing the patient into a relaxed state and then using words and intonation to produce a desired effect or alternative behavior. The 2 studies in this review that examined suggestion as an intervention^{22,23} used a simple suggestion technique in which

children were told that someone (ie, the experimenter) or something (eg, a placebo aerosol spray) would make them feel less pain during the procedure. No difference in self-reported pain was observed between the children who received the suggestion intervention and those in the control group. Data from only 1 outcome measure (ie, self-reported pain) were available to include in our meta-analysis; it could be that the effects of suggestion in these studies were evident on other measures. Conversely, it could be that the suggestion interventions used in these studies were too subtle to be effective. Also, the application of the suggestion message without first ensuring that the children were in a relaxed state (a necessary precondition for effective application of suggestion) could also explain the failure of this intervention.

Child-directed distraction and nurse-led distraction were found to be effective in reducing pain and distress. The included studies used a range of age-appropriate distraction strategies meant to take children’s attention away from the procedure. The child-directed distraction studies used either videotaped cartoons²⁴ or music or stories played via a headset^{23,25} to direct the child’s attention away from the pain. For nurse-led distraction, nurses were trained to direct the child’s attention to a movie or other age-appropriate toys (eg, rattles, electric phones, dolls); several studies reported use of a 15-minute training program.^{30–33} These types of distraction strategies are relatively simple and easy to administer for immunizations, provided some basic equipment is available or brought by the child and/or family (eg, a portable, handheld device for playing favorite movies or music). In the case of nurse-led distraction, an investment of 15 minutes in a distraction training program that provides the skills to distract many children thereafter is worthwhile. Distraction with age-appropriate toys has the advantage of being the only psychological intervention examined in this review that can be used for children of all ages, from infants to adolescents.

Interestingly, evidence was insufficient to support parent-led distraction or parent coaching at this time. Although these interventions were effective in reducing observer-rated distress, no differences in other measures of pain or distress were reported. Parent-led distraction typically involves training parents on how to deliver age-appropriate distraction, whereas parent coaching involves training in distraction combined with other strategies known to be effective, such as

minimizing parental use of reassurance, empathy, and criticism.³⁸

The finding that these 2 parent-targeted interventions were ineffective is surprising. It is generally accepted that parents are an important part of children's medical procedures, and that involving them formally in the delivery of psychological interventions can be helpful in reducing child pain and distress. Perhaps parents in these studies had difficulty appropriately implementing the distraction and other procedures because they were feeling anxious about the procedure or they were unable to inhibit their more instinctive responses.

In addition, the parent interventions described in the included studies generally referred only to brief parent training or instruction using a 1-page information sheet. It could be that parents require more intensive training and practice to properly implement these interventions in a way that reliably reduces child pain and distress. Laboratory-based studies, in which parents receive verbal explanation, watch a video, engage in role playing with the trainer, and have written reminders, have been effective in altering parents' behavior when their children are in pain.³⁹ Additional research is needed to examine the extent to which parents actually adhere to distraction techniques and the best ways to train parents to support their children in reducing pain and distress during immunization. Regardless, this review did find beneficial effects of parent-led distraction and coaching on general distress; therefore, some evidence suggests that encouraging parents to engage in these strategies could be helpful.

Evidence suggested that combined cognitive-behavioral interventions were effective in reducing the pain and distress associated with immunization. Considerable heterogeneity was found with regard to the interventions included in this category, ranging from simple combined distraction and suggestion,²³ to more involved interventions that included child-directed training in coping skills³⁶ and parent and child training combined with nurse coaching.^{30,37} Given that some of the interventions were quite involved and may not be feasible in terms of time or cost, future studies will be needed to identify the critical components of combined cognitive-behavioral interventions for reducing injection-related pain and distress. These interventions are also generally only applicable for use with older children and adolescents who have the cognitive capability to learn to use them.

Limitations of the current review include its focus on trials with infants and school-aged children (age range, 1 month to 11 years) as participants; no trials of psychological interventions for reducing pain and distress associated with immunization in adolescents were identified. Adolescents must also undergo immunizations, and the value of psychological interventions for reducing their pain and distress during these procedures should be examined.

Unfortunately, the overall quality of the trials included in this systematic review was poor; 18 (90%) of the 20 trials were classified as having a high risk of bias. This is due, in part, to the difficulties inherent in completing trials of psychological interventions. In most cases, it is impossible to properly blind participants and health care professionals and to administer a credible "placebo." However, some of the included studies failed to adhere to the most basic principle of true randomization (eg, using an alternating or time-of-day assignment). Although it is recognized that the nature of clinical research often precludes the ability to properly randomize, the confidence with which conclusions can be drawn from these quasi-experimental designs is limited. Other than brief descriptions of the psychological interventions, often too little information is available regarding the specifics of the intervention to permit replication or translation of the intervention into clinical practice.

Recommendations for improving the quality and methodology of trials of psychological interventions for reducing procedural pain and distress in children have been made.¹⁰ It will be important to show greater methodologic rigor in the design, conduct, and reporting of future trials. In particular, examining the degree to which parents and nurses administer interventions accurately and quantifying the level of engagement of the child in these interventions are critical elements. In addition, this review only examined data from trials that compared psychological interventions with a control (no treatment). This does not permit conclusions to be made regarding the comparative efficacy of psychological versus pharmacologic interventions. Ideally, psychological interventions would be used in combination with pharmacologic interventions to maximize the potential to reduce pain and distress, although relevant data are limited (see the article by Shah et al⁴ in this supplement).

Future trials could examine the use of other psychological interventions not examined in the trials in

this review. For example, evidence supports the use of hypnosis for painful medical procedures other than immunizations, and evidence has been promising for other interventions (eg, providing information and preparation of the child before the scheduled day of immunization) that could be applied to reduce pain and distress during immunization.^{9,10,40} Furthermore, few studies have examined the long-term impact of psychological interventions (ie, the potential for beneficial carryover effects to future procedures). More detailed work should examine which psychological interventions work best for children of different ages and whether certain child characteristics (eg, temperament, anxiety level, cognitive ability) warrant different types of psychological interventions.

CONCLUSIONS

Evidence suggests that relatively simple psychological strategies, such as breathing exercises, child-directed distraction (using age-appropriate music or videotape), nurse-led distraction, and combined cognitive-behavioral interventions, significantly reduce immunization pain and distress in children. However, despite the evidence supporting these techniques, there is generally a poor understanding on the part of parents and health care professionals regarding the value of these interventions. Parents and health care professionals should be advised to incorporate psychological interventions during immunization to ensure that children receive evidence-based pain-relieving interventions such as those identified in this review.

ACKNOWLEDGMENTS

We wish to thank the chief librarian at The Hospital for Sick Children (Elizabeth Uleryk) for conducting the literature searches. This research was funded by a Canadian Institutes of Health Research (CIHR) Knowledge Synthesis grant awarded to Dr. Taddio and colleagues (KRS – 91783). Dr. Taddio is supported by a CIHR New Investigator Award. Dr. Chambers is funded by a Canada Research Chair. The authors are grateful to Dr. Vibhuti Shah and Dr. Patrick McGrath for their helpful comments on drafts of this manuscript and to Sandra Williams and Kelly Hayton for their organizational assistance in this project. The authors have indicated that they have no conflicts of interest regarding the content of this article and that there was no involvement of industry in the preparation of this manuscript.

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Appendix. Search strategies for MEDLINE, PsycINFO, EMBASE, CINAHL, and the Cochrane Central Register of Controlled Trials.

Set	History	Results	Comments
MEDLINE Search Strategy (1950 to October, Week 3, 2008)			
1	Pain Measurement/ or exp pain/ or Antibody Formation/ or Crying/ or anxiety/ or fear/ or panic/ or (adverse adj2 effect:).ti,ab. or (side adj2 effect:).ti,ab. or (skin adj2 reaction:).ti,ab. or (distress* or discomfort* or fright* or anxious).ti,ab.	602,516	Pain terms
2	Immunization/ or immunization, passive/ or adoptive transfer/ or immunotherapy, adoptive/ or immunization schedule/ or immunization, secondary/ or immunotherapy, active/ or vaccination/ or mass immunization/ or (simultaneous or sequential).ti,ab. or exp vaccines/	376,085	Immunization or vaccine terms
3	exp "mind-body and relaxation techniques"/ or aromatherapy/ or "biofeedback (psychology)"/ or breathing exercises/ or exp hypnosis/ or "imagery (psychotherapy)"/ or laughter therapy/ or meditation/ or mental healing/ or "mind-body relations (metaphysics)"/ or psychophysiology/ or relaxation/ or relaxation techniques/ or tai ji/ or therapeutic touch/ or yoga/ or psychotherapy/ or art therapy/ or autogenic training/ or cognitive therapy/ or desensitization, psychologic/ or music therapy/ or play therapy/ or complementary therapies/ or exp acupuncture therapy/ or exp sensory art therapies/ or recreation/ or "play and playthings"/ or video games/ or relaxation/ or audiovisual aids/ or multimedia/ or radio/ or exp television/ or (toy or toys or movie* or film or films or video or videos or distraction* or distracts or distracted or distract or distracting or laugh or laughs or laughter or colour* or color* or music or relax*).mp. or Adaptation, Psychological/ or px.fs.	1,060,605	Relaxation techniques or psychology terms
4	Guidelines as topic/ or practice guidelines as topic/ or evaluation studies as topic/ or exp clinical trials as topic/ or validation studies as topic/ or ((clinical: adj5 trial:) or random: or ((singl: or doubl: or tripl: or trebl:) adj5 (mask: or blind:)) or (control: adj5 group:) or (quasi adj5 randomiz:) or (quasi adj5 randomis:)).ti,ab. or (clinical trial, all or clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or clinical trial or controlled clinical trial or evaluation studies or guideline or meta analysis or multicenter study or practice guideline or randomized controlled trial or validation studies).pt.	1,447,055	Study design/ methodology terms
5	1 and 2 and 3 and 4	318	Base clinical set
6	Limit 5 to humans	304	Human limit
7	Limit 6 to "all child (0 to 18 years)"	99	Age group limit
8	5 and (neonat: or newborn: or infan: or child: or adolescen: or teen:).mp.	100	Age group textwords
9	7 or 8	100	Final results

(continued)

Appendix (continued).

Set	History	Results	Comments
PsycINFO Search Strategy (1967 to October, Week 3, 2008)			
1	Pain/ or pain management/ or pain measurement/ or exp pain perception/ or pain thresholds/ or suffering/ or crying/ or anxiety/ or anxiety management/ or exp fear/ or facial expressions/ or grimaces/ or smiles/ or (adverse adj2 effect:).ti,ab. or (side adj2 effect:).ti,ab. or (skin adj2 reaction:).ti,ab. or (distress* or discomfort* or fright* or anxious).ti,ab.	124,442	Pain terms
2	Immunization/ or (vaccinat* or vaccine* or immuniz* or immunis*).mp. or (simultaneous or sequential).ti,ab.	23,036	Immunization or vaccine terms
3	Relaxation therapy/ or progressive relaxation therapy/ or anxiety management/ or autogenic training/ or exp behavior modification/ or guided imagery/ or exp hypnotherapy/ or meditation/ or posthypnotic suggestions/ or exp psychotherapeutic techniques/ or systematic desensitization therapy/ or biofeedback/ or biofeedback training/ or neurofeedback/ or exp conditioning/ or autogenic training/ or relaxation/ or guided imagery/ or leisure time/ or exp recreation/ or yoga/ or laughter/ or exp humor/ or smiles/ or meditation/ or exp alternative medicine/ or breathing.mp. or hypnosis/ or (therapeutic adj2 touch).mp. or yoga/ or art therapy/ or recreation therapy/ or play therapy/ or computer games/ or games/ or simulation games/ or exp toys/ or music therapy/ or music/ or alternative medicine/ or acupuncture/ or aromatherapy/ or massage/ or radio/ or television viewing/ or television/ or music/ or films/ or distraction/ or distractibility/ or animal assisted therapy/ or psychotherapeutic techniques/ or pets/ or cognitive behavior therapy/ or exp behavior modification/ or exp behavior therapy/ or cognitive therapy/ or coping behavior/ or autogenic training/ or biofeedback training/ or exp relaxation therapy/ or massage/ or physical contact/ or (desensitization adj10 (psycholog* or psychiatr*)).ti,ab. or (toy or toys or movie* or film or films or video or videos or distraction* or distracts or distracted or distract or distracting or laugh or laughs or laughter or colour* or color* or music or relax*).mp.	248,666	Relaxation techniques or psychology terms
4	1 and 2 and 3	197	Base clinical set 1
5	Qualitative research/ or exp empirical methods/ or exp experimental design/ or exp interviews/ or observation methods/ or treatment effectiveness evaluation/ or clinical audits/ or clinical trials/ or psychotherapeutic outcomes/ or exp treatment outcomes/ or treatment guidelines/ or best practices/ or client treatment matching/ or exp professional standards/ or ((evaluat* or validat*) adj2 (study or studies)).mp. or guideline*.mp. or ((clinical: adj5 trial:) or random: or ((singl: or doubl: or tripl: or trebl:) adj5 (mask: or blind:)) or (control: adj5 group:) or (quasi adj5 randomiz:) or (quasi adj5 randomis:)).ti,ab.	236,895	Study design/ methodology terms
6	4 and 5	47	Base clinical set 2

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Appendix (continued).

Set	History	Results	Comments
7	Limit 6 to human	43	Human limit
8	Limit 7 to (childhood <birth to 12 years> or adolescence <13 to 17 years>)	21	Age group limit
9	Limit 7 to (100 childhood <birth to age 12 yrs> or 120 neonatal <birth to age 1 mo> or 140 infancy <age 2 to 23 mo> or 160 preschool age <age 2 to 5 yrs> or 180 school age <age 6 to 12 yrs> or 200 adolescence <age 13 to 17 yrs>)	21	Age group limit
10	7 and (neonat: or newborn: or infan: or child: or adolescen: or teen:). mp.	22	Age group textwords
11	8 or 9 or 10 Limit 4 to (childhood <birth to 12 years> or adolescence <13 to 17 years>)	23 67	Final results Age group limit
12	Limit 4 to (100 childhood <birth to age 12 yrs> or 120 neonatal <birth to age 1 mo> or 140 infancy <age 2 to 23 mo> or 160 preschool age <age 2 to 5 yrs> or 180 school age <age 6 to 12 yrs> or 200 adolescence <age 13 to 17 yrs>)	67	Age group limit
13	4 and (neonat: or newborn: or infan: or child: or adolescen: or teen:). mp.	67	Age group textwords
14	11 or 12 or 13	76	Final results
EMBASE Search Strategy (1980 to 2008, Week 43)			
1	Pain assessment/ or pain/ or injection pain/ or vaccination reaction/ or exp application site reaction/ or exp injection site reaction/ or antibody production/ or crying/ or facial expression/ or gesture/ or fear/ or anticipatory anxiety/ or anxiety/ or (adverse adj2 effect:).ti,ab. or (side adj2 effect:).ti,ab. or (skin adj2 reaction:).ti,ab. or (distress* or discomfort* or fright* or anxious).ti,ab.	409,491	Pain terms
2	Immunization/ or mass immunization/ or passive immunization/ or active immunization/ or immunotherapy/ or adoptive immunotherapy/ or adoptive transfer/ or vaccination/ or bcg vaccination/ or influenza vaccination/ or measles vaccination/ or revaccination/ or (simultaneous or sequential).ti,ab. or exp vaccine/	317,636	Immunization or vaccine terms

(continued)

Appendix (continued).

Set	History	Results	Comments
3	Cognitive behavioral stress management/ or cognitive rehabilitation/ or cognitive therapy/ or guided imagery/ or coping behavior/ or behavior therapy/ or Psychotherapy/ or music therapy/ or play therapy/ or relaxation training/ or therapeutic community/ or exp sensory stimulation/ or (desensitization adj10 (psycholog* or psychiatr*)).ti,ab. or recreation/ or television viewing/ or game/ or exp audiovisual equipment/ or reward/ or (toy or toys or movie* or film or films or video or videos or distraction* or distracts or distracted or distract or distracting or laugh or laughs or laughter or colour* or color* or music or relax*).mp. or alternative medicine/ or aromatherapy/ or reiki/ or exp touch/ or (therapeutic adj2 touch*).mp. or breathing exercise/ or breathing pattern/ or breathing rate/ or hypnosis/ or suggestion/ or imagery/ or psychological aspect/ or (autogenic* or auto).ti,ab.	623,112	Relaxation techniques or psychology terms
4	exp Clinical Trial/ or double blind procedure/ or single blind procedure/ or triple blind procedure/ or validation study/ or (evaluation studies or evaluation study).ti,ab. or exp practice guideline/ or ((clinical: adj5 trial:) or random: or ((singl: or doubl: or tripl: or trebl:) adj5 (mask: or blind:)) or (control: adj5 group:) or (quasi adj5 randomiz:) or (quasi adj5 randomis:)).ti,ab.		Study design/ methodology terms
5	1 and 2 and 3 and 4	298	Base clinical set
6	Limit 5 to human	287	Human limit
7	Limit 6 to (infant <to one year> or child <unspecified age> or preschool child <1 to 6 years> or school child <7 to 12 years> or adolescent <13 to 17 years>)	31	Age group limit
8	6 and (neonat: or newborn: or infan: or child: or adolescen: or teen:).mp.	46	Age group textwords
9	7 or 8	46	Final results
CINAHL Search Strategy (1982 to October, Week 3, 2008)			
1	Treatment related pain/ or Pain Measurement/ or exp pain/ or Antibody Formation/ or Crying/ or anxiety/ or fear/ or (adverse adj2 effect:).ti,ab. or (side adj2 effect:).ti,ab. or (skin adj2 reaction:).ti,ab. or (distress* or discomfort* or fright* or anxious).ti,ab.	93,714	Pain terms

(continued)

Appendix (continued).

Set	History	Results	Comments
2	Immunization/ or immunization schedule/ or Immunization Programs/ or Immunotherapy/ or (immunization: or immunisation:).mp. or (simultaneous or sequential).ti,ab. or exp vaccines/	23,657	Immunization or vaccine terms
3	Psychologic/ or relaxation techniques/ or distraction/ or guided imagery/ or meditation/ or bibliotherapy/ or color therapy/ or hypnosis/ or music therapy/ or pet therapy/ or play therapy/ or psychotherapeutic processes/ or alternative medical systems/ or aromatherapy/ or manual therapy/ or exp massage/ or reflexology/ or exp mind body techniques/ or reiki/ or therapeutic touch/ or (autogenic adj2 train*).mp. or sensory stimulation/ or acoustic stimulation/ or leisure activities/ or recreation/ or "play and playthings"/ or games/ or video games/ or singing/ or distraction/ or laughter/ or (toy or toys or movie* or film or films or video or videos or distraction* or distracts or distracted or distract or distracting or laugh or laughs or laughter or colour* or color* or music or relax*).mp. or audiovisuals/ or audiorecording/ or radio/ or television/ or exp videorecording/ or ADAPTATION, PSYCHOLOGICAL/	93,583	Relaxation techniques or psychology terms
4	exp evaluation research/ or clinical trials/ or double-blind studies/ or intervention trials/ or preventive trials/ or single-blind studies/ or therapeutic trials/ or triple-blind studies/ or ((random: adj2 control: adj2 trial:) or (random: adj2 clinic: adj2 trial:)).ti,ab. or ((clinical: adj5 trial:) or random: or ((singl: or doubl: or tripl: or trebl:) adj5 (mask: or blind:)) or (control: adj5 group:) or (quasi adj5 randomiz:) or (quasi adj5 randomis:)).ti,ab.	123,052	Study design/ methodology terms
5	1 and 2 and 3 and 4	36	Base clinical set
6	Limit 5 to (newborn infant <birth to 1 month> or infant <1 to 23 months> or preschool child <2 to 5 years> or child <6 to 12 years> or adolescence <13 to 18 years>)	29	Age group limit
7	5 and (neonat: or newborn: or infan: or child: or adolescen: or teen:).mp.	29	Age group textwords
8	6 or 7		Final results

(continued)

Appendix (continued).

Set	History	Results	Comments
Cochrane Central Register of Controlled Trials Search Strategy (4th Quarter, 2008)			
1	Treatment related pain/ or Pain Measurement/ or exp pain/ or Pain Assessment/ or injection pain/ or vaccination reaction/ or exp application site reaction/ or exp injection site reaction/ or antibody production/ or Antibody Formation/ or facial expression/ or gesture/ or fear/ or anticipatory anxiety/ or anxiety/ or Crying/ or anxiety/ or fear/ or (adverse adj2 effect:).ti,ab. or (side adj2 effect:).ti,ab. or (skin adj2 reaction:).ti,ab. or (distress* or discomfort* or fright* or anxious).ti,ab.	69,602	Pain terms
2	Immunization/ or immunization schedule/ or Immunization Programs/ or Immunotherapy/ or mass immunization/ or passive immunization/ or active immunization/ or immunotherapy/ or adoptive immunotherapy/ or adoptive transfer/ or vaccination/ or bcg vaccination/ or influenza vaccination/ or measles vaccination/ or revaccination/ or exp vaccines/ or (immunization: or immunisation:).mp. or (simultaneous or sequential).ti,ab. or exp vaccines/	13,615	Immunization or vaccine terms
3	exp "mind-body and relaxation techniques"/ or aromatherapy/ or "biofeedback (psychology)"/ or breathing exercises/ or exp hypnosis/ or "imagery (psychotherapy)"/ or laughter therapy/ or meditation/ or mental healing/ or "mind-body relations (metaphysics)"/ or psychophysiology/ or relaxation/ or relaxation techniques/ or tai ji/ or therapeutic touch/ or yoga/ or psychotherapy/ or art therapy/ or autogenic training/ or cognitive therapy/ or desensitization, psychologic/ or music therapy/ or play therapy/ or complementary therapies/ or exp acupuncture therapy/ or exp sensory art therapies/ or recreation/ or "play and playthings"/ or video games/ or audiovisual aids/ or multimedia/ or radio/ or exp television/ or (toy or toys or movie* or film or films or video or videos or distraction* or distracts or distracted or distract or distracting or laugh or laughs or laughter or colour* or color* or music or relax*).mp. or Adaptation, Psychological/ or px.fs. or behavior therapy/ or distraction/ or guided imagery/ or bibliotherapy/ or color therapy/ or pet therapy/ or psychotherapeutic processes/ or alternative medical systems/ or manual therapy/ or exp massage/ or reflexology/ or exp mind body techniques/ or (autogenic adj2 train*).mp. or sensory stimulation/ or acoustic stimulation/ or leisure activities/ or recreation/ or games/ or singing/ or distraction/ or audiovisuals/ or audiorecording/ or exp Video Recording/ or ADAPTATION, PSYCHOLOGICAL/ or cognitive behavioral stress management/ or cognitive rehabilitation/ or coping behavior/ or behavior therapy/ or relaxation training/ or therapeutic community/ or exp sensory stimulation/ or (desensitization adj10 (psycholog* or psychiatr*)).ti,ab. or recreation/ or television viewing/ or game/ or exp audiovisual equipment/ or reward/ or alternative medicine/ or reiki/ or exp touch/ or (therapeutic adj2 touch*).mp. or breathing pattern/ or breathing rate/ or suggestion/ or psychological aspect/ or (autogenic* or auto).ti,ab.	44,261	Relaxation techniques or psychology terms
4	1 and 2 and 3	132	Base clinical set
5	4 and (neonat: or newborn: or infan: or child: or adolescen: or teen:).mp. (50)	50	Age group textwords