Psychological interventions for needle-related procedural pain and distress in children and adolescents (Review)

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ABSTRACT

Background
Needle-related procedures are a common source of pain and distress for children. Several psychological (cognitive-behavioral) interventions to help manage or reduce pain and distress are available; however, a previous comprehensive systematic review of the efficacy of these interventions has not been conducted.

Objectives
To assess the efficacy of cognitive-behavioral psychological interventions for needle-related procedural pain and distress in children and adolescents.

Search strategy
We searched the Cochrane Central Register of Controlled Trials (CENTRAL) on *The Cochrane Library* (Issue 4, 2005), MEDLINE (1966 to 2005), PsycINFO (1887 to 2005), EMBASE (1974 to 2005), the Cumulative Index to Nursing and Allied Health Literature (1982 to 2005), Web of Science (1980 to 2005), and Dissertation-Abstracts International (1980 to 2005). We also searched citation lists and contacted researchers via various electronic list-servers and via email requests.

Selection criteria
Participants included children and adolescents aged two to 19 years undergoing needle-related procedures. Only randomized controlled trials (RCTs) with at least five participants in each study arm comparing a psychological intervention group with a control or comparison group were eligible for inclusion.

Data collection and analysis
Two review authors independently extracted data and assessed trial quality. Included studies were coded for quality using the Oxford Quality Scale devised by Jadad and colleagues. Standardized mean differences with 95% confidence intervals were computed for all analyses using RevMan 4.0 software.

Main results
Twenty-eight trials with 1951 participants were included. Together, these studies included 1039 participants in treatment conditions and 951 in control conditions. The most commonly studied needle-procedures were immunizations and injections. The largest effect sizes for treatment improvement over control conditions exist for distraction (self-reported pain: SMD = -0.24, 95% CI = -0.45 to -0.04), hypnosis (self-reported pain: SMD = -1.47, 95% CI = -2.67 to -0.27; self-reported distress: SMD = -2.20, 95% CI = -3.69 to -0.71; and behavioral measures of distress: SMD = -1.07, 95% CI = -1.79 to -0.35), and combined cognitive-behavioral interventions (other-reported distress: SMD = -0.88, 95% CI = -1.65 to -0.12; and behavioral measures of distress: SMD = -0.67, 95% CI = -0.95 to -0.38). Promising but limited evidence exists for the efficacy of numerous other psychological interventions including: information/preparation, nurse coaching plus distraction, parent positioning plus distraction, and distraction plus suggestion.

Authors' conclusions

Overall, there is preliminary evidence that a variety of cognitive-behavioral interventions can be used with children and adolescents to successfully manage or reduce pain and distress associated with needle-related procedures. However, many of the included studies received lower quality scores because they failed to describe the randomization procedure and participant withdrawals or drop-outs from the study. Further RCTs need to be conducted, particularly for the many interventions for which we could not locate any trials.

PLAIN LANGUAGE SUMMARY

Psychological interventions for needle-related procedural pain and distress in children and adolescents

Many psychological interventions are available for managing procedural pain and distress, the majority being cognitive, behavioral, or a combination of the two. Twenty eight trials with 1951 participants were included. There is evidence that certain psychological interventions are effective in reducing needle-related pain and distress in children and adolescents. The largest effect sizes in favor of intervention exist for the efficacy of distraction, combined cognitive-behavioral interventions, and hypnosis, in reducing pain and distress in children. There are insufficient data available to adequately assess the efficacy of several other psychological interventions.

BACKGROUND

Medical procedures are a common source of pain and distress for children. Healthy children undergo immunizations repeatedly throughout their childhood. In fact, the Advisory Committee on Immunization Practices (ACIP 2004), the American Academy of Pediatrics (AAP 2004), the American Academy of Family Physicians (AAFP 2004), and the Canadian Paediatric Society (CPS 2004) all currently recommend over 20 various immunizations before age 18. Children with chronic illness experience an even greater number of painful procedures as part of the diagnosis, treatment, and monitoring of their condition. In a hospital setting, children often experience unpredictable and severe procedure-related pain (Cummings 1996) that can be associated with negative emotional and psychological implications (Kazak 2001). The most widely accepted definition of pain is one proposed by the International Association for the Study of Pain (IASP) in which pain is defined as: "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (IASP 2004). It is also generally acknowledged that pain is a highly personal and multifaceted experience comprised of physiological, behavioral, emotional, developmental, and sociocultural components (McGrath 1993). In addition to the pain associated with these medical procedures, they are often a source of anxiety, fear, and behavioral distress for children and their families, which can further intensify their pain and interfere with the procedure (Broome 1990). Medical procedures, particularly needles, are among the most feared experiences of children (Broome 1990).

A number of psychological interventions for managing pain and distress in children are available, and the majority of these interventions are cognitive-behavioral. Although there are also non-pharmacological interventions for pain that are not cognitive-behavioral (for example, acupuncture), these interventions were not included in the present review. Given the already broad scope of this review, we limited the focus to cognitive-behavioral psychological interventions; however, it would be valuable to assess non-cognitive-behavioral interventions in another review.

Cognitive-behavioral therapy (CBT) can be defined as: "a group of treatment procedures aimed at identifying and modifying faulty thought processes, attitudes, attributions, and problem behaviors" (Barlow 1999). Cognitive interventions are defined as interventions which involve identifying and altering negative thinking styles related to anxiety about the medical procedure, and replacing them with more positive beliefs and attitudes, leading to more adaptive behavior and coping styles (Barlow 1999). Behavioral interventions are defined as interventions based on principles of behavioral science as well as learning principles by targeting specific behaviors (Barlow 1999). CBT interventions for pain management are aimed at assisting the child to develop and apply coping skills in order to manage the pain and distress, and when developmentally appropriate, to help the child comprehend how thoughts and behaviors can alter their experience of pain (Keefe 1992). Distraction, relaxation training, imagery, breathing exercises, desensitization, preparation, hypnosis, modeling, rehearsal, reinforcement, making positive coping statements, and coaching a child to engage in such strategies are all examples of some of the psychological interventions that are frequently used to help decrease pain and distress in children during medical procedures (Chen 2000a; Christophersen 2001).

Several narrative, non-systematic reviews and book chapters on psychological interventions for the management of procedural pain and distress in children are available (e.g., Alvarez 1997; Blount 2003; Chen 2000a; Christophersen 2001; Devine 2004; Kazak 2001; Powers 1999; Young 2005). While these reviews typically conclude that psychological interventions are beneficial, the

lack of a systematic and pooled approach to integrating the literature is problematic and limits conclusions regarding the efficacy of these interventions. While there have been a few more systematic approaches to integrating this literature (e.g., Broome 1989; Kleiber 1999; Luebbert 2001; Saile 1988), these reviews are limited in that they tend to have a narrow focus (e.g., examining the effects of only one type of intervention such as distraction) and, at this point in time, are out of date given the rapid growth in research in this area in recent years.

A Cochrane protocol of non-pharmacological interventions for preparing children and adolescents for hospital care has been published (Prictor 2004) and the review is currently in progress. Their review will address issues of psychosocial and physical health, behavior, knowledge, understanding and satisfaction, as well as the effects of those interventions on parents, staff and health services. However, to our knowledge, there has been no comprehensive, systematic review of the efficacy of different psychological interventions for managing procedure-related pain and distress in children. Therefore, the present review is an important and necessary step towards an improved and current understanding of the efficacy of psychological interventions for reducing pain and distress in children during medical procedures and to highlight directions for future research.

OBJECTIVES

To assess the efficacy of cognitive-behavioral psychological interventions for needle-related procedural pain and distress in children and adolescents.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

Only randomized controlled trials (RCTs) with at least five participants in each study arm were included in this review. No language restrictions were used during the search.

Types of participants

Studies involving children and adolescents aged two to 19 years undergoing needle-related medical procedures were included. For the purposes of this review, a needle-related medical procedure was defined as any procedure performed as part of a medical diagnosis, prevention, or treatment. This includes dental procedures (excluding dental surgery) but does not include procedures such as body piercings or tattoos which do involve needles but are not for medical purposes. The search was limited to needle-related pain because receiving needles is among the most commonly occurring and feared procedures for both healthy and chronically-ill children (Broome 1990).

Our justification for not including children less than two years of age is that the majority of psychological interventions being examined in this review are either not appropriate for use with infants or are qualitatively different when applied to infants. The efficacy of psychological interventions for pain and distress in infants will be important to address in an independent review. We extended the age range initially proposed in our protocol from three to 18 years to two to 19 years after conducting our search strategy and finding that many relevant studies included children as young as two years and adolescents as old as 19 years. A maximum age of 19 years was chosen to ensure our search was limited to children and adolescents only. It is acknowledged that this cut-off is somewhat arbitrary; however, the age of 19 years is often regarded as the beginning of adulthood. The age range was kept broad so as not to exclude any relevant studies; however, studies that included any participants falling outside of this age range were excluded unless authors were able to provide data for only the age range set for this review.

After reviewing the literature and consulting with clinicians and experts in the area of pediatric health, a comprehensive list of common medical procedures involving needles was derived (please *see* Additional Table 01 for the list of medical procedures and their definitions). Definitions were derived from online medical dictionaries (e.g., MedLine Plus Medical Encyclopedia, MedLine 2004; On-Line Medical Dictionary, OLMD 2004) and by consulting with medical professionals in the area of pediatric pain.

Participants included healthy children and children with chronic or transitory illnesses from both inpatient and outpatient settings. Studies including patients with known needle-phobias were not included. While it is typical for many children to have some degree of needle apprehension, children with needle-phobias represent a distinct and smaller subset with more debilitating fear and anxiety. Furthermore, children undergoing surgery were not included because numerous factors specific to surgery can complicate and interfere with the accuracy of self-reported accounts of pain and distress. These factors may include: sedation, more intensive pharmacological interventions, long-term hospital stays, inability or difficulty attributing pain or distress to one specific medical procedure, and difficulty distinguishing between the pain and distress caused by the procedure versus that caused by the medical condition requiring the surgery. The exception to this rule was for studies that assessed the efficacy of a psychological intervention for a pre-surgical needle procedure such as an Intra-venous (IV) insertion. The outcome measures of interest had to be completed prior to surgery in order for the study to be included in this review.

Types of intervention

The reviews cited in the 'Background' of this review (e.g., Blount 2003; Chen 2000a; Christophersen 2001) were used to derive the comprehensive list of psychological interventions listed below. It is difficult to operationally define these interventions into mutually

exclusive categories, particularly because no standard definitions are used consistently in the literature.

For the purpose of this review, cognitive and behavioral interventions are defined using Barlow's definitions stated in the 'Background' section of this review. Thus, cognitive interventions are defined as interventions which involve identifying and altering negative thinking styles related to anxiety about the medical procedure, and replacing them with more positive beliefs and attitudes, leading to more adaptive behavior and coping styles (Barlow 1999). Behavioral interventions are defined as interventions based on principles of behavioral science as well as learning principles by targeting specific behaviors (Barlow 1999). Based on these definitions, cognitive interventions included those mainly targeting central mechanisms such as thoughts and feelings, while behavioral interventions included those mainly targeting overt behaviors. For this review, cognitive-behavioral interventions are defined as those including at least one cognitive intervention combined with at least one behavioral intervention.

We classified interventions as subtypes of the following three main well-defined categories (cognitive, behavioral, or combined). Any study with at least one condition involving one of the following interventions was included.

1) Cognitive interventions

- *Cognitive Distraction:* cognitive techniques to shift attention away from procedure-related pain or specific counter activities (e.g., counting, listening to music, non procedure-related talk).
- *Imagery:* cognitive technique used to encourage the child to cope with the pain and distress of the procedure by having him/her imagine a pleasant object or experience (e.g., enchanted forest).
- *Hypnosis:* dissociation from painful experience and distress via hypnotic induction, suggestions, and imagined fantasy; similar to but more involved than imagery. Given the overlap between imagery and hypnosis, when in doubt, we relied on author definitions to distinguish between the two.
- *Preparation/Education/Information:* explaining the steps of the procedures or providing sensory information associated with the procedure, or both. This may include providing instructions about what the child will need to do during the procedure. The intention is to provide information to help the child know what to expect during the procedure.
- *Thought-stopping:* child repeats "stop" or a similar type of statement during times of distress or pain.
- *Suggestion:* Providing verbal or nonverbal cues to the child suggesting that the administered intervention will or can reduce pain and/or distress.
- *Coping self-statements:* child repeats a set of positive thoughts (e.g., "I can do this"; "This will be over soon").
- *Memory change:* helping child to reframe negative memories of the procedure into positive ones.
- *Parent training:* training the parent (not the child) to engage in one of the above cognitive strategies. The goal is to decrease the parent's distress which in turn may decrease the child's distress or pain, or both.

2) Behavioral interventions

- *Behavioral Distraction*: behavioral techniques to shift attention away from procedure-related pain or specific counter activities (e.g., videotapes, games, interactive books).
- *Progressive Muscle Relaxation (PMR) Training:* progressive tensing and relaxing of muscles groups one at a time.
- *Breathing Exercises:* focus on deep breathing or breathing from the diaphragm rather than the chest (e.g., using party blowers, blowing bubbles, pretending to inflate or deflate a tire through inhaling / exhaling).
- *Modeling:* demonstration of positive coping behaviors during a mock procedure by another child or adult (often using filmed modeling).
- *Rehearsal:* practice using positive coping behaviors demonstrated during modeling.
- *Desensitization:* gradual systematic exposure to the feared stimuli. May involve developing a hierarchy of tasks related to the feared stimuli and successfully overcoming easier tasks before moving on to more difficult ones.
- *Positive reinforcement:* providing positive statements or tangible rewards, or both, to the child following the painful procedure (e.g., stickers, toys, games, small trophies).
- *Parent training:* training the parent (not the child) to engage in one of the above behavioral strategies. The goal is to decrease the parent's distress which in turn may decrease the child's distress or pain, or both.
- *Parent coaching:* training the parent to actively coach the child to use one of the above strategies (e.g., parent verbally encouraging child to use a strategy).
- *Medical staff coaching:* training a qualified health-care professional (often a nurse) to coach the child to use one of the above strategies.
- *Virtual reality:* using virtual reality technology and equipment to absorb the child's attention. Often involving goggles and earpieces to provided simultaneous visual and auditory stimuli. More involved than distraction (see above definition).

3) Cognitive-behavioral (combined) interventions.

Any intervention using at least one of the above cognitive interventions in combination with at least one of the above behavioral interventions.

Control or comparison groups included any one of the following provided that the intervention group received the intervention above and beyond any care provided to the control or comparison group:

- *nonspecific-treatment or "attention-placebo" control group:* Includes a group that engages in all of the accouterments of the intervention (e.g., meeting with a therapist, receiving an explanation for the problem) but not the key components of the intervention; used to determine if the effects of the intervention are due to nonspecific treatment components (Kazdin 2003).
- *routine or standard care:* Consists of the usual intervention or treatment that is provided for the procedure (Kazdin 2003).

Interventions administered by any qualified health-care professional (i.e., doctor, nurse, psychologist, technician), family member, caregiver, or by the child him/herself after being trained by a parent or professional, or both were included.

Types of outcome measures

The two measured outcomes of interest were pain and distress, assessed using scales or measures with established reliability and validity (i.e., as evidenced in at least one prior published study in a peer-reviewed journal). For the purpose of this review, distress was broadly defined as any type of negative affect associated with the procedure (e.g., anxiety, stress, fear).

1) Self-report

Measures of pain and distress may include various versions of the following (Champion 1998):

- Visual Analogue Scales (VAS);
- Numerical Rating Scales (NRS);
- Verbal Rating Scales (VRS);
- Faces Scales designed to assess level of pain or distress (e.g., anxiety or fear, or both).

2) Observer Global Reports

Observer versions of the self-report measures for pain and distress listed above (completed by parents, caregivers, nurses, doctors, or other hospital staff present) were also included. It is important to note that there are various factors affecting the degree to which observer reports are positively correlated with self-reports of pain and distress, such as the person completing the report (i.e., mother, nurse, or doctor) and the age of the child (Champion 1998). Despite these caveats, observer reports of pain and distress can provide valuable information, particularly for younger children.

3) Behavioral Measures

These include behavioral observation measures, typically completed by trained researchers or medical staff. They may include but are not limited to the following commonly-used scales (McGrath 1998):

Pain Scales

- The Children's Hospital of Eastern Ontario Pain Scales (CHEOPS, McGrath 1985)
- The Faces Legs Activity Cry Consolability Scale (FLACC, Merkel 1997)

Distress Scales

- The Observational Scale of Behavioral Distress (OSBD) (Jay 1983)
- The Child-Adult Medical Procedure Interaction Scale (CAMPIS) (Blount 1989); The CAMPIS-revised (Blount 1990; Blount 1997), and the CAMPIS-short form (Blount 2001)

4) Physiological Measures

Measures of pain and distress that are practical to quantify in a clinical setting may include (Sweet 1998):

- heart rate (generally increases with pain);
- respiratory rate (may increase or decrease with pain/distress);
- blood pressure (generally increases with pain/distress);
- oxygen saturation (generally decreases with pain/distress);
- cortisol levels (generally increases with pain/distress);
- transcutaneous oxygen tension (tcPO2) (generally decreases with pain/distress);
- transcutaneous carbon dioxide tension (tcPCO2) (may increase or decrease with pain/distress).

Despite concerns regarding the tendency of physiological measures to habituate in response to pain and distress, as well as a lack of data supporting the specificity of these measures to pain, they are commonly used in pediatric studies of responses to medical procedures, and are therefore included as an outcome measure in this review. However, given the subjective nature of pain, it is important to note that all measures of pain, including self-report, can be considered indirect when used with children.

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: Cochrane Pain, Palliative and Supportive Care Group methods used in reviews.

Published studies were identified by conducting electronic searches. Unpublished studies and doctoral dissertations for possible inclusion in this review were obtained from electronic databases, by contacting researchers using various electronic mailing lists/list-servers (Pain in Child Health (PICH), Pediatric Pain, the American Psychological Association's Society of Pediatric Psychology Division 54, and the American Psychological Association's Health Psychology Division 38) and by contacting experts through email and direct communication

to locate any additional studies. We also consulted the list of empirically-supported treatments for procedural pain, published by the American Psychological Association's Society of Pediatric Psychology Division 54 (APA-Division54 2004) as an addendum to the review by Powers 1999. Finally, reference and citation lists from papers identified as reviews, meta-analyses, or randomized controlled trials meeting inclusion criteria for this review were searched.

The following databases were searched from their inception to February 2005:

A: Electronic Search (Published Studies)

- Cochrane Central Register of Controlled Trials (CENTRAL)
- MEDLINE
- PsychINFO
- EMBASE
- Cumulative Index to Nursing and Allied Health Literature (CINAHL)
- Web of Science

B. Electronic Search (Unpublished Studies)

- Dissertation-Abstracts International

CENTRAL Search:
#1 NEEDLES (single term MeSH)
#2 (needle* or inject*)
#3 (immuni* or vaccin* or inject* or (finger next prick*) or (heel next prick*))
#4 ((lumbar next puncture*) or (spinal next tap*))
#5 ((bone next marrow next aspiration) or (bone next marrow next biops*))
#6 (intravenous or intra-venous or venepuncture* or (venous next cannulation*))
#7 (catheter near insert*)
#8 ((central next line) near insert*)
#9 ((central next venous next catheter) near insert*)
#10 ((local next analges*) or (local next anaesthe*) or (local next anesthe*))
#11 ((arterial next puncture) or (artery near puncture))
#12 (arterial next line*)
#13 (thoracocentesis or paracentesis)
#14 (#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13)
#15 PAIN (single term MeSH)
#16 ((needle* near pain*) or (needle* near distress*) or (needle* near discomfort) or (needle* near fear*) or (needle* near fright*) or (needle* near anxious) or (needle* near anxiet*) or (procedure* near pain*) or (intervention* near pain*) or (intervention* near distress*) or (procedure near distress*) or (procedure* near discomfort*) (immuni* near pain) or (vaccin* near pain*) or (inject* near pain*) or (procedure-related near pain))
#17 (#15 or #16)
#18 (rehears* or coping or (verbal* next encourage*) or (positiv* next reinforce*) or reward* or token* or (self next talk*) or selftalk* or (stop next signal*) or (structured next attention))
#19 ((cognitive* near intervention) OR (cognitive* near therapy) or (cognitive* near distract*) or (behaviour* near therap*) or (behaviour* near intervention) or (behavior* near therap*) or (behavior near intervention))
#20 (((audiovisual or (audio next visual) or visual*) and distract*) or movie* or television or tv:ti or tv:ab or game*:ti or game*:ab or toy*:ti or toy*:ab or (virtual next reality) or (tactile next stimulat*) or (behaviour* near distract*) or (behavior* near distract*))
#21 (cognitive next behavioural next intervention*)
#22 ((multisensory next stimulation) or (multi-sensory next stimulation))
#23 COGNITIVE THERAPY (single term MeSH)
#24 DESENSITIZATION PSYCHOLOGIC (single term MeSH)
#25 RELAXATION TECHNIQUES (single term MeSH)
#26 THERAPEUTIC TOUCH (single term MeSH)
#27 RELAXATION (single term MeSH)
#28 BREATHING EXERCISES (single term MeSH)
#29 HYPNOSIS (explode all trees MeSH)
#30 IMAGERY (PSYCHOTHERAPY) (single term MeSH)
#31 LAUGHTER THERAPY (single term MeSH)
#32 PSYCHOTHERAPY (explode all trees MeSH)
#33 (desensiti* or relax* or (theraputic next touch*) or (breathing next exercise*) or hypnosis or hypnoti* or hypnotherapy or image* or psychotherap* or (tactile next stimul*))
#34 ((autogenic next training) or (auto next suggestion*))
#35 ((colour* or color* or music* or play) and (therap* or distract*))
#36 BEHAVIOR THERAPY (single term MeSH)
#37 (#18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36)
#38 CHILD (explode all trees MeSH)
#39 INFANT (explode all trees MeSH)
#40 ADOLESCENT (single term MeSH)
#41 (child* or infant* or adolescent* or adolescence)
#42 (#38 or #39 or #40 or #41)
#43 (#14 and #17 and #37 and #42)

This search strategy was adapted for other databases. Other related key words and mesh terms were included as appropriate depending on the terms used in each of the specific databases.

METHODS OF THE REVIEW

1. Selection of trials

Two review authors (LU & CC) independently screened titles and abstracts of trials from literature searches for inclusion in the review. The lead review author (LU) read through every abstract retrieved from the search strategy. For all abstracts that were relevant, potentially relevant, or where relevance to the current review was unclear, the full articles were obtained and read by the lead review author. Using the full articles, two review authors (LU & CC) decided which studies met the inclusion criteria and which did not. Review authors were not blind to authors, institutions, journals, or results. A third review author (PM) was brought in to help resolve any issues or selection discrepancies that arose.

2. Data extraction

Two review authors (LU & CC) extracted data using a data extraction form designed for this specific review. A third review author (PM) was available to help resolve any coding discrepancies. Data from the studies were extracted and compiled into an electronic spreadsheet which was reviewed by all review authors. Attempts were made to obtain missing data from the authors whenever feasible. All data for the included studies were first recorded onto paper data extraction forms by one review author (LU) and another review author independently re-recorded 50% of the data. Inter-rater reliability assessed using a Kappa coefficient was 0.91.

3. Losses to follow up

The trial papers were checked to determine whether the following information was provided: adequate descriptions of the number of participants who withdrew, the reasons for withdrawal, and any other protocol deviations with justification for them. In the protocol for this review it was stated the data would not be presented for studies if more than 20% of the originally randomized participants withdrew; however, this was not the case for any of the retrieved studies.

4. Addressing publication bias

Although we had planned to conduct funnel plots, this is a method open to debate with regards to its usefulness and thus we decided not to conduct them. In addition, the small number of studies for each intervention also limited the appropriateness of using this technique. However, in order to help overcome publication bias, we (1) imposed no language barriers in our search, (2) contacted several list-serves and researchers in the field of pediatric health and pain to request any published, unpublished, and in-progress studies, and (3) contacted the authors of all the studies with missing means or standard deviations, or both.

Of note, many studies included several outcome measures; however, it was common practice for authors to report means and standard deviations when the group differences with respect to the intervention were significant, but not when group differences were non-significant. Given that these omissions in the literature contribute to reporting bias, attempts were made to contact all of the authors of studies with unreported data, in order to retrieve means and standard deviations for all outcome measures assessed. As such, we were able to retrieve unreported data for several studies (n = 6; Cavender 2004; Cohen 2002; French 1994; Kleiber 2001; Liossi 1999; Wint 2002), often for outcomes where no significant differences were found between treatment and control groups.

5. Study quality

Each study included in the review was scored for quality independently by two review authors using the Oxford Quality Scale created by Jadad 1996. The scale is comprised of five questions for a maximum score of five points. Each of the following questions can be allotted or substracted one point:

1) Is the study randomized? If 'yes', give one point.
2) Is the randomization procedure reported and appropriate? If 'yes', give one point. If 'no', deduct one point.
3) Is the study double blind? If 'yes', add one point.
4) Is the blinding procedure appropriate and adequate? If 'yes', add one point. If 'no' deduct one point.
5) Are withdrawals and dropouts described? If 'yes', add one point.

It should be noted that it is often not feasible for studies examining psychological management of pain and distress to be double-blinded. Despite the limitations of this scale for studies of psychological interventions, it is the accepted international standard and was therefore used to assess study quality in this review. In addition, all included studies were also coded to assess whether:
1) study coders were blind to the interventions (e.g., researchers coding child reactions from videotapes where the intervention is not visible); and
2) whether participants actually adhered to the treatment they were assigned to (i.e., treatment fidelity).

6. Statistical analyses

Heterogeneity

Differences between the results of each included trial were analyzed using a test of heterogeneity in order to determine whether the results were statistically similar enough to combine. Given that these tests often have low statistical power, a type 1 error level of 0.10 was employed for rejecting the null hypothesis of homogeneity as opposed to the more traditional 0.05. In cases where statistically significant heterogeneity was detected, the data were still pooled; however, these results should be interpreted with caution. Given that there was significant heterogeneity for several of the analyses, results were analyzed using a random-effects model. Although attempts to explore reasons for heterogeneity using post hoc analyses were proposed, there were insufficient data available to do so.

Dichotomous data

Given the nature of the outcome measures in this review, none of the data were dichotomous.

Continuous data

All of the outcome data for the included studies were continuous (for example, rating scales). We computed standardized mean

differences (SMD) with 95% confidence intervals (CI) which allowed us to combine the results from different scales measuring the same construct (for example, pain). We proposed that when sufficient data were available from various studies using the same measurement instruments, a weighted mean difference (WMD) with 95% CI would also be conducted. However, given the wide range of different assessment measures used, this was not feasible. Thus, all mean differences presented in the tables and plots of the results section represent SMDs. When means or standard deviations, or both, were not reported, attempts were made to obtain them from the authors or to calculate them using other reported measures of variation.

Sensitivity analyses

Factors that may affect the results from individual studies were investigated using sensitivity analyses. This review proposed to investigate the following if sufficient information was provided:

- differences between self-report measures and other-report measures of pain and distress;
- differences between the person administering the intervention (e.g., nurse versus parent versus doctor);
- differences between subtypes of psychological interventions and types of controls;
- differences between types of medical procedures;
- differences between analyses involving all studies and excluding trials of low methodological quality.

Some of the proposed sensitivity analyses could not be analyzed because of missing, incomplete, and poor quality data or treatment descriptions. We analyzed the efficacy of each intervention separately given that there was considerable variability in the types of cognitive-behavioral interventions used, and we decided that it would not be appropriate to combine them all into one overall analysis. When significant heterogeneity was found, we still pooled the trials; however, these results need to be interpreted cautiously. Possible reasons for the heterogeneity are addressed in the discussion section. Although there were insufficient data to conduct all of the sensitivity analyses proposed, this review can still provide valuable information regarding:
1) what psychological interventions exist for managing procedural pain and distress in children,
2) the efficacy of these interventions, and
3) recommendations to improve the quality of future studies assessing the efficacy of these interventions.

Statistical analyses were conducted using RevMan 4.2 software.

DESCRIPTION OF STUDIES

Excluded Studies

One hundred and eighty-eight papers were retrieved using the search strategy described above. These papers were read by two review authors to determine whether they met criteria for inclusion in this review. For most of these papers, it was clear from the abstract whether they failed to meet some or all of the inclusion criteria, and therefore should be excluded. However, fifty-one of these studies required further examination to confirm that they did not meet all of the inclusion criteria (please *see* 'Characteristics of excluded studies' table for reasons for exclusion). Disagreements were resolved by a third review author when necessary. Primary reasons for exclusion fell into the following categories:

- met inclusion criteria but missing means or standard deviations, or both (n = 21; Arts 1994; Bengston 2002; Carlson 2000; Chen 2000b; Dalhquist 2002; Fassler 1985; Gilbert 1982; Goymour 2000; Jay 1987; Kazak 1996; Kazak 1998; Kuttner 1988; Malone 1996; Megel 1998; O'Laughlin 1995; Peretz 1999; Reeb 1997; Santos 1999; Vernon 1974; Young 1988; Zeltzer 1982)
- not a randomized controlled trial (n = 4; Olsen 1991; Powers 1993; Schur 1986; Wood 2002)
- no control/comparison group (n = 6; Broome 1998; Hawkins 1998; Jay 1995; Smith 1989; Smith 1996; Wall 1989)
- surgical procedure (n = 5; Hatava 2000; Klorman 1980; Lustman 1983; Melamed 1974; Winborn 1989)
- inappropriate randomization procedure (e.g., alternation) (n = 6; Christiano 1996; MacLaren 2005; Manimala 2000; Manne 1990; Manne 1994; Sparks 2001)
- failed randomization (n = 2; Bowen 1999; McCarthy 1998)
- inappropriate outcome measures (n = 2; Bruck 1995; Jay 1990)
- exceeded age range (n = 1; Kwekkeboom 2003)
- inappropriate intervention (n = 1; Jay 1991)
- inappropriate control/comparison group (n = 1; Kolk 2000)
- no needle procedure (n = 1; Weinstein 2003)
- fewer than five participants per condition (n = 1; Pederson 1996)

Our search retrieved one study in another language (Portuguese), which was translated into English (Santos 1999). We attempted to contact the study authors to retrieve missing information; however, we were not able to retrieve the information necessary to include this study in our review.

Included Studies

Twenty-nine papers representing 28 separate studies were included (n = 1951). These studies met all inclusion criteria and provided the data necessary (i.e., means and standard deviations) for pooling. These papers were read by two review authors, and a consensus on the suitability of the study for inclusion in this review was attained.

In the time span between when this review was first completed and when it was revised for publication, two additional studies published during this period were found (Liossi 2006; Tak 2005). These studies met our inclusion criteria and were thus added to our review. The Liossi 2006 study was identified in our original search strategy but was still in preparation at the time. The Tak 2005 study was identified from a literature search we performed to locate any newly published trials during this period. Given that this literature search was not as extensive as the original one we conducted for this review, the possibility of bias is introduced in that not all trials published in the past year may have been identified. However, given that these two trials met our inclusion criteria and have been brought to our attention, we felt it would be equally biased not include them in this version of our review and thus opted for this decision.

The 28 included studies involved investigators from eight countries (United States of America, Canada, Australia, United Kingdom, Greece, Kuwait, Israel, and the Netherlands). Of the total 1951 participants entered in all of the trials, 1039 were in treatment conditions and 951 were in control conditions. One study used a randomly assigned within-participant design (Cohen 1999) with three treatment arms (Nurse coaching + Movie Distraction, EMLA, and Typical Care Control). Given that EMLA is not a psychological intervention, only the other two treatment arms were considered in calculating the number of participants in each condition. This accounts for why the total number of participants is 39 less than the addition of all the treatment and control participants together.

Sixteen trials used two treatment arms (Blount 1992; Cassidy 2002; Cavender 2004; Chen 1999; Cohen 1999; Cohen 2002; Fanurik 2000; Harrison 1991; Katz 1987; Kleiber 2001; Krauss 1996; Posner 1998; Press 2003; Tyc 1997; Vessey 1994; Wint 2002), seven trials used three arms (Cohen 1997; Gonzalez 1993; Goodenough 1997; Kuttner 1987; Liossi 1999; Liossi 2006, Zabin 1982), three trials used four arms (Eland 1981; French 1994; Liossi 2003), one trial used five treatment arms (Fowler-Kerry 1987), and one trial used six treatment arms (Tak 2005).

Participants

The following needle procedures were used in the 28 included studies:

- immunizations (n = 9; Blount 1992; Cassidy 2002; Cohen 1997; Cohen 1999; Cohen 2002; Fowler-Kerry 1987; French 1994; Gonzalez 1993; Krauss 1996);
- venipuncture/blood draws or sampling (n = 8; Cavender 2004; Goodenough 1997; Harrison 1991; Posner 1998; Press 2003; Tak 2005; Vessey 1994; Zabin 1982);
- lumbar punctures (n = 5; Chen 1999; Katz 1987; Liossi 2003; Liossi 2006; Wint 2002);
- IV insertions (n = 4; Cavender 2004; Fanurik 2000; Kleiber 2001; Tyc 1997);
- bone marrow aspirations (n = 3; Katz 1987; Kuttner 1987; Liossi 1999);
- intramuscular injections (n = 1; Eland 1981).

The diagnostic status of the children in the included studies was the following:

- healthy children (n = 15; Blount 1992; Cassidy 2002; Cohen 1997; Cohen 1999; Cohen 2002; Eland 1981; Fowler-Kerry 1987; French 1994; Gonzalez 1993; Harrison 1991; Krauss 1996; Liossi 2003; Tak 2005; Vessey 1994; Zabin 1982);
- oncology patients with Leukemia / Lymphoma (n = 9; Chen 1999; Katz 1987; Kuttner 1987; Liossi 1999; Liossi 2003; Liossi 2006; Posner 1998; Tyc 1997; Wint 2002);
- children without a current diagnosis who were being evaluated for various medical conditions (n = 4; Goodenough 1997; Fanurik 2000; Kleiber 2001; Zabin 1982);
- children being treated for a variety of other conditions (e.g., surgical referral; trauma; vomiting; chronic urinary tract infections; chronic constipation) (n = 2; Cavender 2004; Kleiber 2001).

Types of Treatment

The interventions were described by the study authors as follows:

- Distraction (n = 10; Cassidy 2002; Fanurik 2000; Fowler-Kerry 1987; Gonzalez 1993; Kleiber 2001; Kuttner 1987; Press 2003; Tak 2005; Vessey 1994; Zabin 1982)
- Distraction + Coping Skills Training + Use of a Party Blower (n = 1; Blount 1992)
- Distraction + Parent Positioning (n = 1; Cavender 2004)
- Distraction + Suggestion (n = 1; Fowler-Kerry 1987)
- Nurse Coaching + Parent/Child Training (n = 1; Cohen 1997)
- Nurse Coaching + Distraction (n = 2; Cohen 1997; Cohen 1999)
- Nurse Coaching (n = 1; Cohen 1997)
- Coping Skills Training (n = 1; Cohen 2002)
- Suggestion (n = 3; Eland 1981; Fowler-Kerry 1987; Goodenough 1997)
- Preparation/Procedural Information (n = 2; Harrison 1991; Tak 2005)
- Blowing Out Air (n = 1; French 1994)
- Virtual Reality Distraction (n = 1; Wint 2002)
- Videotape Modeling + Parent Participation (n = 1; Krauss 1996)
- Modeling (n = 1; Zabin 1982)

- Hypnosis (n = 5; Katz 1987; Kuttner 1987; Liossi 1999; Liossi 2003; Liossi 2006)
- Parent Assisted Behavioral Intervention (n = 1; Posner 1998)
- Memory Alteration (n = 1; Chen 1999)

Some of studies that used a combination of several interventions were analyzed under the "combined cognitive-behavioral intervention" category, even though this may not have been the label used by the authors.

Treatment Setting

The treatment settings were described as:

- community health center/clinic (n = 8; Cohen 1997; Fowler-Kerry 1987; Liossi 2003; Posner 1998; Tyc 1997; Vessey 1994; Wint 2002; Zabin 1982);
- hospital (n = 9; Chen 1999; Fanurik 2000; Gonzalez 1993; Goodenough 1997; Harrison 1991; Katz 1987; Kleiber 2001; Liossi 2006; Tak 2005);
- health department clinic (n = 4; Blount 1992; Cohen 2002; French 1994; Krauss 1996);
- emergency department of a pediatric medical center/hospital (n = 2; Cavender 2004; Press 2003);
- treatment/surgery room of a clinic (n = 2; Kuttner 1987; Liossi 1999);
- school health center/clinic (n = 1; Cohen 1999);
- urban pediatric practice (n = 1; Cassidy 2002);
- private pediatrician's office (n = 1; Eland 1981).

METHODOLOGICAL QUALITY

Study quality was assessed using the five-point Oxford Quality Scale by Jadad et al (Jadad 1996). Two raters (LU & CC) independently coded all of 27 included studies using this scale. Inter-rater reliability calculated using Kappa coefficients for the total scale score was 0.93. The two raters also independently coded all of the included studies to assess (a) whether coders were blind to treatment conditions, and (b) whether treatment fidelity was reported. Inter-rater reliabilities calculated using Kappa coefficients for coder blinding and treatment fidelity were 0.76 and 0.91 respectively. As expected, none of the trials were double-blind, thus the highest possible attainable score was three out of five on the Oxford Quality Scale (Jadad 1996). Only three studies achieved a score of three (Cohen 1999; Kleiber 2001; Liossi 2006), while five achieved a score of two (Cassidy 2002; Cavender 2004; Gonzalez 1993; Krauss 1996; Vessey 1994), four achieved a score of one (Chen 1999; Liossi 1999; Liossi 2003; Posner 1998), and the remaining 16 achieved scores of zero (Blount 1992; Cohen 1997; Cohen 2002; Eland 1981; Fanurik 2000; Fowler-Kerry 1987; French 1994; Goodenough 1997; Harrison 1991; Katz 1987; Kuttner 1987; Press 2003; Tak 2005; Tyc 1997; Wint 2002; Zabin 1982).

While the number of studies with low scores seems high, it should be noted that these low scores do not necessarily indicate that the studies were of poor quality. For example, although the Oxford Quality Scale considers alternating assignment as random, we did not give credit for alternating designs, given that alternation is not a truly random technique. Furthermore, the Oxford Quality Scale penalizes for not reporting the randomization technique and not describing withdrawals or dropouts. Thus, lower scores can often be reflective of poor reporting rather than poor study quality. For example, by contacting authors, we were able to determine that several of them used an appropriate randomization procedure (e.g., table of random numbers) even though this was not reported in the published study.

Randomization

The goal of this review was to include only randomized controlled trials. Although several studies claimed in the abstracts that assignment to groups was "randomized", further explanation in the body of the study revealed that assignment to groups was conducted using an alternating technique (i.e., the first person was assigned to experimental group, second person to control group, third person to experimental group, fourth to control, etc.). Although it is clear that many authors classify alternation as random assignment, this is a misnomer, as alternation is quasi-random at best. According to the Cochrane and National Library of Medicine Randomized Controlled Trial and Controlled Clinical Trial Criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Green 2004), a trial is eligible if the individuals in the trial were assigned prospectively to one of two (or more) alternative forms of health care using random allocation or some quasi-random method of allocation (such as alternation, date of birth, or case record number).

We chose *a priori* to include only fully randomized trials for several reasons. First, it is generally not feasible for trials assessing psychological interventions to be double-blind, thus introducing the possibility of experimenter bias. For example, given that there is often some subjectivity involved in deciding whether a participant is eligible for a study, when using alternating allocation, experimenters may consciously or subconsciously manipulate eligibility requirements so that participants will end up in one group over the other(s) (for example, by delaying entry into the study) (www.cmh.edu/stats). In addition, alternation is generally predictable whereas allocation concealment should prevent those who admit participants to a trial from knowing the upcoming assignments. Shultz 1996 states that larger estimates of treatment effects tend to occur with trials in which the allocation sequence was inadequately concealed, with odds ratios exaggerated on average by 30 to 40 percent. Given that psychological intervention trials are already limited in the sense that they generally cannot be double

or even single-blind designs, it was deemed important to control study quality by limiting inclusion to studies with true random assignment.

In this review, four studies that met all other inclusion criteria were excluded because they used alternating allocation (Christiano 1996; MacLaren 2005; Manne 1990; Sparks 2001). Although, our primary analysis was restricted to RCTs only, a secondary sensitivity analysis including these studies was also conducted to provide additional information. Of note, the study by MacLaren *et al* (MacLaren 2005) included one-year old children; however, the lead author was able to provide us with the statistical analyses excluding one-year olds in order to be able to include this study in our sensitivity analyses.

Description of Withdrawals / Dropouts

Only seven of the included studies provided adequate information describing how many participants withdrew after consenting to participate, and provided the reasons for withdrawals when they occurred (Chen 1999; Cohen 1999; Kleiber 2001; Liossi 1999; Liossi 2003; Liossi 2006; Posner 1998). Many of the studies reported how many people initially declined to participate and reasons for declining; however, declining to participate should not be confused with withdrawing from the study after agreeing to participate. This error seems to have been common in these studies, perhaps because they are so brief and thus may seldom have withdrawals during the study. According to the Oxford Quality Scale (Jadad 1996), studies with no withdrawals must still state that nobody withdrew in order to get a point for this item.

Blinding of Coders

This item was not part of the Jadad scale but was coded out of interest to compensate for the fact that double-blinding is generally not feasible with psychological intervention studies. To achieve credit on this item, the coders of at least one of the study measures had to be blind to the study conditions/groups (for example, coding from videotape so as not to be aware of the intervention condition). This item was coded as 1 = yes or 2 = no, regarding whether coders were blind to intervention groups. Ten of the 27 included studies, reported that coders were blind for at least one measure (Cassidy 2002; Fowler-Kerry 1987; Gonzalez 1993; Goodenough 1997; Katz 1987; Kleiber 2001; Krauss 1996; Liossi 1999; Liossi 2006; Tyc 1997).

Treatment Fidelity

Another item not on the Jadad scale, but scored out of interest, was whether the study provided a description regarding treatment fidelity (that is, whether the participants actually used the intervention they were assigned to). This item was also coded as 1 = yes or 2 = no, regarding whether treatment fidelity was addressed in the study. Treatment fidelity was addressed in eight out of the 28 included studies (Cassidy 2002; Cohen 1997; Cohen 1999; Gonzalez 1993; Kleiber 2001; Liossi 2003; Liossi 2006; Wint 2002).

RESULTS

Each psychological intervention was analyzed separately into the following categories based on the outcome measures of interest:

- self-reported pain
- observer-reported child pain (e.g., parent, nurse, researcher);
- self-reported distress;
- observer-reported child distress (e.g., parent,nurse, researcher);
- behavioral measures of pain;
- behavioral measures of distress;
- physiological measures (e.g., heart rate).

When one study provided more than one observer rating of the same construct (e.g., both parent and nurse VAS ratings of child pain) or more than one behavioral measure for the same construct (e.g., CAMPIS and OSBD measures to assess distress), these measures were pooled together using statistical formulas recommended by The Cochrane Collaboration for combining means and standard deviations. This was done in order to be able to summarize the large amount of data reported in these studies. The formula we used to pool means and SDs were the following: pooled mean = [(mean1 x N1) + (mean2 x N2) / (N1 + N2)] and pooled SD = square root of [SD12 (N1-1) + SD22 (N2-1)] / N1 + N2 -2. In addition, for studies that included outcomes for numerous time points, we restricted our analyses to the measurement occurring during the procedure, or if that was not provided, we used the first post-procedure measurement. For example, if a study included procedural and post-procedural measures, we included the former in our analyses. For studies that only included post-needle measures, we included the first measure following the needle (i.e., Post procedure - Time 1). Pre-procedural measures of pain or distress, or both were not analyzed, as the focus of this review is on pain / distress reduction during needle procedures. Standardized mean differences (SMDs) using a random effects model are provided below, with the confidence intervals included in brackets. Given the numerous sub-analyses, forest plots are provided for outcome measures with three or more studies. Interventions are considered efficacious when the SMD and both anchors of the confidence interval fall in the negative range (denoted by ** in the Tables).

All of the following analyses, with the exception of the sensitivity analyses, included only true RCTs where assignment to groups was truly random (for example, table of random numbers). The addition of quasi-randomized studies (for example, using alternating assignment) was only relevant to the sensitivity analyses where we wished to see if the addition of these studies changed the effect estimates and overall conclusions.

Distraction

The most evidence in terms of number of published RCTs exists for the efficacy of Distraction on self-reported pain, with a

SMD of -0.24 (95% CI = -0.45 to -0.04; see 'Comparison 01-01'). As explained above, SMDs and 95% CIs falling in the negative range demonstrate that the intervention was more effective than a control or comparison group. However, even this SMD falls close to the zero line, which indicates that the effect is not particularly large. Although SMDs for observer-reported distress, behavioral measures of pain, and behavioral measures of distress all fell in the negative range (-0.09, -0.15, and -0.05 respectively; *see* 'Comparisons 01-04', '01-05', and '01-06') their CIs passed into the positive range, indicating that while there may be a preliminary evidence to support the efficacy of distraction on these outcomes, the evidence is not strong enough to strongly provide full support at this time. For the outcomes of observer-reported pain and self-reported distress, the SMDs were positive (0.07 and 0.00 respectively; 'Comparison 01-02' and '01-03'), suggesting that distraction was not effective in reducing ratings using these measures. Taken together, distraction is effective in reducing self-reported pain but is less effective with the other outcomes. This is still a clinically significant finding, as self-report ratings are the most direct means of assessing pain and are weighed most heavily in patient outcomes (i.e., as long as the patient experiences reductions in pain, then the outcome can be considered effective) (please *see* 'Additional Table 02' for SMDs and CIs for all outcome measures for distraction).

Information/Preparation

Information/Preparation was effective in reducing observer-reported distress (SMD = -0.77, 95% CI = -0.17 to -0.38; *see* 'Comparison 02-02') and pulse rates (SMD = -0.47, 95% CI = -0.87 to -0.07; *see* 'Comparison 02-05'). Although SMDs for self-reported pain and observer-reported distress both fell in the negative range (-0.22 and -0.15; *see* 'Comparisons 02-01' and '02-03'), their CIs passed into the positive range, indicating that while there may be preliminary evidence to support the efficacy of information/preparation on these outcome, there is not enough evidence at this time to make strong conclusions. Information / Preparation did not appear to be effective in reducing distress as assessed by behavioral measures (SMD = 0.24, 95% CI = -0.30 to 0.78; *see* 'Comparisons 02-04'), as the SMD fell in the positive range. However, all of these results should be interpreted with caution as they are only based on one or two studies and definitive conclusions cannot be made regarding the efficacy of this intervention until further RCTs are conducted (please *see* 'Additional Table 03' for SMDs and CIs for all outcome measures for information / preparation). In addition, given that the test for heterogeneity was significant for self-reported pain and observer-reported distress, the comparability of the two combined studies may be questionable.

Hypnosis

Of all the interventions assessed in this review, there is the most positive evidence in support of hypnosis across several outcomes. SMDs and CIs fell in the negative range for self-reported pain (SMD = -1.47, 95% CI = -2.67 to -0.27; *see* 'Comparison 03-01'), self-reported distress (SMD = -2.20, 95% CI = -3.69 to -0.71; *see* 'Comparison 03-02'), and behavioral measures of distress (SMD = -1.07, 95% CI = -1.79 to -0.35; *see* 'Comparison 03-04'). In addition, these two fist outcomes were based on four studies (N = 146), while the latter outcome is based on five studies (N = 163). One study assessed observer-reported distress and although the SMD was negative (-0.39), the CI was not entirely in the negative range (-1.05 to 0.27), suggesting a possible trend in favor of hypnosis for this outcome (*see* 'Comparison 03-03'). Observer-reported pain, behavioral measures of pain, and physiological correlates were not assessed in any of these trials; however, given the effect sizes of the other outcomes, hypnosis appears to be an efficacious intervention for reducing both pain and distress during needle procedures. Given that the tests for heterogeneity were significant for these outcomes, the appropriateness of combining the studies may be questionable and should be interpreted with caution (please see 'Additional Table 04' for SMDs and CIs for all outcome measures for hypnosis).

Virtual Reality

Only one study with 30 participants provided data on the impact of virtual reality on self-reported pain. While the SMD was negative (-0.29), the CI fell into the positive range (-1.02 to 0.43; *see* 'Comparison 04-01'). Given that this outcome was based one only one small study, definitive conclusions regarding the efficacy of Virtual Reality for reducing pain and distress during needle procedures cannot be made until further trials are conducted and a broader range of outcomes are assessed (please *see* 'Additional Table 05').

Memory Alteration

Only one study provided outcome measures for the effects of memory alteration on pain and distress. The pattern of results indicates that memory alteration was not efficacious in reducing pain or distress across self-report, observer-report, and behavioral measures of pain and distress (*see* 'Comparisons 05-01', '05-02', '05-03', '05-04', '05-05', '05-06'). Although, the SMD (-0.65) and 95% CI (-1.27 to -0.02) for diastolic blood pressure fell in the negative range (*see* 'Comparison 05-08'), this is likely a chance finding given that the CI is quite close to zero and that none of the other seven assessed outcomes (including systolic blood pressure; see 'Comparison 05-07') fell in the negative range. However, these results should be interpreted with caution as they are only based on the results of one study. Further trials are necessary in order to draw more definitive conclusions about the efficacy of memory alteration (please *see* 'Additional Table 06' for SMDs and CIs for all outcome measures for memory alteration; however, please note that the memory alteration scores in Additional Table 06 represent "during lumbar puncture change scores").

Combined Cognitive Behavioral Intervention/Treatment (CBT)

The interventions in this category of cognitive behavioral interventions were heterogeneous, as they involved different combinations of cognitive and behavioral components. Taken together, the

evidence for these interventions shows that they were not effective in reducing self-reported pain (SMD = -0.87, 95% CI = -1.90 to 0.16; *see* 'Comparison 06-01'), observer-reported pain (SMD = -0.10, 95% CI = -0.54 to 0.34; *see* 'Comparison 06-02'), self-reported distress (SMD = -0.75, 95% CI = -1.75 to 0.25; *see* 'Comparison 06-03'), or heart rate (SMD = -0.62, 95% CI = -1.52 to 0.28; *see* 'Comparison 06-06'). Given that there were one to six studies included in these outcome measures, the pattern of results suggest that combined CBT was not effective at reducing pain on any of these outcome measures. However, Combined CBT was effective at reducing other-reported distress (SMD = -0.88, 95% CI = -1.65 to -0.12; *see* 'Comparison 06-04') and behavioral measures of distress (SMD = -0.67, 95% CI = -0.95 to -0.38; *see* 'Comparison 06-06'). Thus, although combined CBT was effective at reducing some measures of distress, it is important to note that it was not effective at reducing self-reported distress. Taken together, these interventions do not provide convincing evidence for their efficacy in reducing pain and distress during needle pain. However, these results need to be interpreted cautiously as they combined a heterogeneous group of interventions which is also reflected in the significant heterogeneity tests. It is important to note that the above conclusions are based on the more stringent criteria that both the SMD and CI should fall in the negative range in order to be able to strongly conclude that an intervention was efficacious. However, if we look at the pattern of outcome results, particularly for self-reported pain and distress, we see that the CI only crosses slightly over onto the positive side of the graph suggesting that combined CBT was likely to be effective at reducing self-reported pain and distress as assessed by these outcomes. Furthermore, when multiple interventions are included in a package format, it is difficult to tease apart which components are beneficial and which are not, unless these components are assessed separately. Thus, while some combinations of CBT were successful at reducing pain and distress on various outcomes, others were not, and it was not possible given the evidence to determine which components of the combined intervention were effective on their own as opposed to being effective only when administered as part of a package (please *see* 'Additional Table 07' for SMDs and CIs for all outcome measures for Combined CBT).

Nurse Coaching + Distraction

Only two studies assessed the effects of nurse coaching + distraction. The results of these trials indicate that this intervention was not effective in reducing any of the assessed measures of pain or distress (*see* 'Comparisons 07-01', '07-02', '07-03', '07-04', and '07-06'), with the exception of behavioral measures of distress (SMD = -0.53, 95% CI = -0.87 to -0.19; *see* 'Comparison 07-05'). Behavioral measures of pain were not assessed. Given this pattern of results, it appears that this intervention is not effective at reducing pain and distress. However, these findings should be interpreted with caution as they are only based on two studies conducted by the same investigator, and some tests of heterogeneity were significant. Further trials conducted across different research groups are necessary before more firm conclusions can be drawn (please *see* 'Additional Table 08' for SMDs and CIs for all outcome measures for Nurse Coaching + Distraction).

Parent Coaching + Distraction

The evidence for parent coaching + distraction is based on only one to two trials. The results indicate that this intervention was not effective at reducing any of the assessed outcome measures including: self-reported pain (SMD = 0.31, 95% CI = -0.28 to 0.91, *see* 'Comparison 08-01'), observer-reported distress (SMD = 0.22, 95% CI = -0.38 to 0.81; *see* 'Comparison 08-02'), or behavioral measures of distress (SMD = -0.58 to 1.48, 0.32; *see* 'Comparison 08-03'). Observer-reported pain, behavioral measures of pain, and physiological correlates were not assessed in this study. Given this pattern of results (particularly that self-reported pain and distress were not reduced with this intervention), parent coaching + distraction does not appear to be an effective intervention for reducing pain and distress during needle procedures based on this limited data. However, these results should be interpreted with caution as they are based on only one to two studies. In addition the test for heterogeneity was significant for behavioral measures of distress, suggesting that the two combined studies may not be similar enough to analyze together (please *see* 'Additional Table 09' for SMDs and CIs for all outcome measures for Parent Coaching + Distraction).

Parent Positioning + Distraction

The effects of parent positioning + distraction were assessed in this one study which included 43 participants. The results indicate that this intervention was effective at reducing observer-reported distress (SMD = -0.70, 95% CI = -1.32 to -0.08; *see* 'Comparison 09-03') but was not effective at reducing self-reported pain or distress (*see* 'Comparisons 09-01' and '09-02'), or behavioral measures of distress (*see* 'Comparison 09-04'). However, no firm conclusions can be made at this time since only one study was included (please *see* 'Additional Table 10').

Videotaped Modeling + Parent Coaching

Only one study (N = 50) assessed the efficacy of this intervention on observer-reported distress, and found that it was not effective (SMD = -0.54, 95% CI = -1.11 to 0.02; *see* 'Comparison 10-01'; also *see* 'Additional Table 11'). No other outcome measures were assessed in this trial. Further trials examining this intervention are required as no definitive conclusions can be based on this one finding alone.

Suggestion

Based on the results on our analysis, suggestion was not effective at reducing any of the measures assessed including self-reported pain (SMD = -0.20, 95% CI = -0.55 to 0.15; *see* 'Comparison 11-01'), observer-reported pain (SMD= -0.40, 95% CI = -0.85 to 0.05; *see* 'Comparison 11-02'), self-reported distress (SMD = -0.33, 95% CI = -0.78 to 0.12; *see* 'Comparison 11-03'), and observer-reported distress (SMD = 0.00, 95% CI = -0.62 to 0.62; *see* 'Comparison 11-04'). Self-reported pain was based on the find-

ings of three studies (N = 238), however, the other outcomes were based on the results of one study. Behavioral measures and physiological correlates were not assessed. Taken together, this pattern of findings indicates that this intervention is not effective. Further studies would help provide further evidence for the efficacy of suggestion (please *see* 'Additional Table 12' for SMDs and CIs for all outcome measures for Suggestion).

Blowing Out Air

The efficacy of blowing out air was assessed in one study with 75 participants. This study found that this intervention was not effective in reducing self-reported pain (SMD = -0.38, 95% CI = 0.84 to 0.08; *see* 'Comparison 12-01') or behavioral distress (SMD = -0.32, 95% CI = -0.77 to 0.14; *see* 'Comparison 12-02'). These findings should be interpreted cautiously as they are based on only one study and further trials are needed before making more definitive conclusions (please *see* 'Additional Table 13').

Distraction + Suggestion

One study with 120 participants assessed the impact of distraction + suggestion on self-reported pain. The results indicate that this intervention was efficacious in reducing self-reported pain (SMD: -0.64, 95% CI = -1.03 to -0.25; *see* 'Comparison 13-01'). Given that the two components of this intervention (distraction and suggestion) were delivered together, the impact of each component separately is unclear. However, from the above analyses which examined self-reported pain using distraction (SMD = -0.24, 95% CI = -0.45 to -0.04) and suggestion (SMD = -0.20, 95% CI = -0.55 to 0.15) separately, it is likely that distraction accounted for most of the improvement in pain scores. However, future trials comparing both components administered separately with both delivered together is necessary before firmer conclusions can be drawn regarding whether or not there is an added benefit to using this combined intervention (please *see* 'Additional Table 14').

Filmed Modeling

Filmed modeling was assessed in one study (N = 32) and was found not to be effective in reducing self-reported distress (SMD = -0.03, 95% CI = -0.73 to 0.66; *see* 'Comparison 14-01') and observer-reported distress (SMD = 0.10, 95% CI = -0.59 to 0.80; *see* 'Comparison 14-02'). Given that these findings are based on one study with a limited sample size, they should be interpreted with caution until further trials using filmed modeling are conducted (please *see* 'Additional Table 15').

Sensitivity analyses

We wished to assess whether the effect estimates changed when non-randomized trials were also included in the analyses. Thus, the four studies with alternating assignment were added to the analysis. Two of the studies examined the effects of distraction (MacLaren 2005; Sparks 2001), one examined the effect of a combined cognitive-behavioral intervention (Christiano 1996), one examined the effect of preparation / giving information (Christiano 1996), and one examined the effect of distraction plus breathing plus positive reinforcement (Manne 1990).

The sensitivity analyses tables referred to in the following paragraph, are the results with the new data from these four studies added to the previously conducted analyses. Outcomes accompanied by a one represent the analysis before the additional study(ies) were added, and outcomes accompanied by a two represent the results with the additional study(ies) added for comparison.

The results of the sensitivity analyses demonstrate that there are a few notable changes in the results with the addition of these studies. Behavioral distress for distraction changes when two of the studies with alternating allocation (MacLaren 2005; Sparks 2001) are added to the analysis (please *see* 'Additional Table 16'). Heterogeneity moves from being significant to non-significant while the interpretation of the SMDs and confidence intervals (CIs) stays consistent (i.e., confidence intervals fall on the positive side, indicating that the overall intervention was not effective in reducing pain or distress for that outcome). The SMD and CI move from -0.05 [-0.82 to 0.73] before the sensitivity analysis, to -0.09 [-0.56 to 0.38] with the addition of these two studies. Furthermore, the addition of the one study assessing distraction + breathing + positive reinforcement (Manne 1990), demonstrates that it was effective in reducing self-reported pain (SMD = -1.32, 95% CI = -2.25 to -0.40; please *see* 'Additional Table 18'). While the other measures change slightly with the addition of these studies, they do not alter the overall trends or interpretations of the results (please *see* 'Additional Table 17' for Information / Preparation and 'Additional Table 19 for Combined CBT sensitivity analyses).

Publication Bias

Although we attempted to locate all unpublished trials, it is likely that we were not able to locate every trial. In addition, studies with negative findings may be less likely to: a) be submitted for publication; b) be accepted for publication, or (c) be published in top-tier peer-reviewed journals. However, in order to minimize bias as much as possible, we conducted extensive searches for unpublished trials by contacting researchers in pain and pediatrics from a variety of academic email networks as well as individualized contact with experts in the area. We also broadened our search to include trials published in any language. Thus, we feel that these measures helped limit the amount of publication bias in this review.

DISCUSSION

Overall, there is sufficient evidence to support the efficacy of distraction, hypnosis, and combined CBT in reducing pain and distress in children and adolescents undergoing needle procedures. There is also preliminary evidence to support the efficacy of information / preparation, and combined interventions which use distraction as one of the components. There was insufficient evidence to provide strong evidence for or against the efficacy of the other interventions assessed in this review.

Of note, only distraction, hypnosis, and distraction plus suggestion, were effective in reducing self-reported pain or distress. This is an important finding because in many cases, pain or distress appeared to be reduced based on observer ratings or behavioral measures; however, the children themselves were not echoing this improvement. While parent and medical staff ratings of child pain and distress are very informative (particularly for non-verbal and pre-verbal children), these results highlight the importance of obtaining self-reports of pain and distress whenever possible, to be used in conjunction with other measures.

The objective of this review was to assess the efficacy of psychological (cognitive-behavioral) interventions for reducing needle-related pain and distress in children and adolescents. The goal was to conduct an extensive large-scale systematic review using a pooled analytic approach to summarize the vast literature on this topic. There are many available studies in the literature; however, the results of this review highlight the scarcity and need for more well-designed randomized-controlled trials of cognitive-behavioral interventions. The majority of the trials we retrieved focused on the effects of distraction, combined cognitive-behavioral interventions, and hypnosis. Immunizations were the most studied needle-related procedures.

The results of the analyses demonstrate variability across different outcome measures and reporters; however, we attempted to pool the data as much as possible, and collaborated with other experts in the field to determine which outcome measures were appropriate to pool and which were not. For example, given the variability associated with physiological outcomes, it was felt that it would not be appropriate to pool them.

Interventions were considered effective when both the effect size (Standardized Mean Difference) and confidence intervals favored treatment (that is, fell below zero). The results of this analysis revealed the following:

- distraction is effective in reducing self-reported pain;
- information/preparation is effective in reducing observer-reported child pain and pulse rate;
- hypnosis is effective in reducing self-reported pain, self-reported distress, and behavioral measures of distress;
- memory alteration is effective in reducing diastolic blood pressure;
- combined cognitive-behavioral interventions are effective in reducing observer-reported distress and behavioral measures of child distress;
- nurse coaching + distraction is effective in reducing behavioral measures of distress;
- parent positioning + distraction is effective in reducing observer-reported child distress;
- distraction + suggestion is effective in reducing self-reported pain.

The test for heterogeneity was significant for some of the findings, suggesting that there were important differences in the studies being combined. Pooling was conducted for these outcomes using random-effects models; however, the results should still be interpreted with caution. A possible reason for this heterogeneity could be that, as discussed above, different outcome measures were used in the studies, and these various outcomes may not have assessed the same constructs. Also, given that there was variability along several key factors including the populations being assessed, the age ranges of the children, and the medical procedures involved, any or all of these variations could account for the significant heterogeneity. Of particular relevance is the fact that the samples used in the included studies were quite heterogeneous (that is, some used clinical samples while others did not). Even within the clinical samples, there was consistent variability. Thus this heterogeneity could have likely affected the results as various sub-samples could respond differently to the intervention. Unfortunately given the small number of trials, sub-analyses based on sample type could not be conducted.

While the results of this review help summarize the large body of literature on psychological interventions for needle-related pain and distress in children, there are several limitations that must be addressed. First of all, the results of a meta-analysis are only as strong as the studies included. Given that we included only true randomized controlled trials, we excluded studies that used less stringent designs. Second, we used standardized mean differences because of the variability in outcome measures employed by the various studies. While various measures may claim to assess the same constructs, this may not always be the case as no two measures are exactly alike. Third, although attempts were made to retrieve unreported data by contacting study authors, we were not able to include 23 studies for which no means or standard deviations were provided, or both. Had data for these studies been available, the results of this review would be more powerful and informative. Fourth, although we conducted a thorough search for studies, it is possible that we did not locate all relevant studies from other countries, as well as those that were published in more remote sources or were unpublished. Given that studies with positive results favoring treatment may be more likely to be submitted for publication and ultimately published, this could introduce bias into the results. Finally, no two studies used the exact same intervention that followed the same manualized intervention. Thus, we restricted our pooling to interventions that were very similar, and could appropriately be pooled.

Overall study quality ratings assessed by the Oxford Quality Scale fell in the low range. A limitation of using the Oxford Quality Scale is that non double-blind studies are penalized; however, double blinding is generally not feasible with psychological intervention studies. Failure to describe the randomization procedure and par-

ticipant withdrawals / dropouts also accounted for the low quality scores.

Despite these limitations, this review provides a critical examination of the literature on cognitive-behavioral interventions for reducing pain and distress in children, which can be a helpful resource to both clinicians and researchers looking for non-pharmacological treatments to assist with pain management.

AUTHORS' CONCLUSIONS

Implications for practice

Although more RCTs need to be conducted, this review suggests that various psychological interventions, particularly distraction, combined cognitive-behavioral interventions, and hypnosis can help children by reducing the pain and distress that accompany needle-related procedures. The effectiveness of these interventions likely depends on numerous factors including the age of the child and the nature of the procedure. It is important that health professionals be aware of the value of incorporating psychological strategies for procedural pain and distress into practice with children. Future research will hopefully provide a clearer picture of which interventions work best for children of various ages undergoing different medical procedures. Furthermore, the results of this review also highlight the importance and utility of using self-report measures of pain and distress, as the ratings obtained via self-report were not always congruent with observer-ratings, behavioral measures, or physiological correlates.

Implications for research

Based on the results of this review, the following research recommendations are provided.

1) Report Means and Standard Deviations for All Outcome Measures

In order to conduct a systematic review or meta-analysis (statistically pooling the results from various studies together), study authors should include the means and standard deviations (or comparable measures of variability such as standard errors) for all of the outcome measures. In our review, several studies could not be included in the statistical analyses because this information was missing and could not be retrieved from the authors. In addition, many studies included outcome means and standard deviations when there were statistically significant differences between the groups; however, this information was omitted when non-significant differences were reported. We attempted to retrieve missing information from the study authors; however, we were not able to retrieve it for all studies because (a) updated contact information for the authors could not be located, (b) replies were not received from authors, or (c) authors no longer had these data available. Omissions of means and standard deviations are problematic for systematic reviews and meta-analyses because they can bias the results and conclusions by providing an overall effect estimate that is not representative of all the available data. In particular, given the tendency for authors to omit means and standard deviations when treatment and control groups do not demonstrate statistically significant differences, this can lead to a bias towards effect estimates favoring treatment rather than control conditions. Given that one of the main goals of a systematic review is to provide an accurate representation of the current state of research on a given topic, it is recommended that authors include all of the descriptive statistics for every outcome measure in their study, regardless or whether the treatment was effective.

2) Development of a Set of "Standard" Outcome Measures for Pain and Distress

One of the challenges of conducting a systematic review occurs when various studies assessing the same constructs use different outcome measures. This is a common problem, particularly for reviews assessing subjective constructs such as pain and distress. In addition, the wide variety of validated measures available to assess both pain and distress, makes it difficult to compare similar studies that employed different scales or measures. In order to overcome this obstacle for our review, we chose to use compute standardized mean differences (SMDs) which are effect estimates with the added advantage of allowing for comparisons between studies using different outcome measures. Calculating a SMD for a study involves computing the difference between mean scores for the control and treatment groups, and dividing this difference by the pooled standard deviation of both study arms. However, there are limitations associated with using this type of effect estimate. It has been argued that the use of standardized effects in a meta-analysis is problematic because (a) the standard deviation of study outcomes can vary for different studies, and (b) the size of the standardizing unit depends on the variation or spread of outcomes in the population of each study (Cummings 1996). To facilitate reviews of the many studies assessing pain and distress in children, it would be very beneficial to develop a set of recommended outcome measures for various age groups that could be used as the "gold standard" in pain studies. For example, this set of recommended measures might include those that are: the most commonly used in the literature, have the best psychometric properties, are easy or quick to administer, have been translated into other languages, are easily accessible, or a combination of these considerations. Authors could chose to include additional measures of their choice; however, the implementation of this standard set of outcome measures would facilitate comparisons between studies and reduce the bias introduced by allowing authors to selectively choose which outcomes they employ. That said, if the treatment effect is robust on a particular outcome, it should be apparent using any developmentally-appropriate measure with good psychometric properties.

3) Development of a Set of Standard Age Ranges for Studies

Another challenge of conducting a systematic review involves determining a priori what age range of children or adolescents should be included. By making the range too narrow, we would have had

to exclude many relevant studies, even if only one participant fell outside of the proposed range. On the other hand, by making the age range too broad, we likely included children of different developmental periods who may likely respond differently to a painful procedure and/or intervention (psychological or pharmacological) based on their chronological or mental age. We originally proposed to conduct sensitivity analyses to compare different age ranges if feasible; however, we were unable to do so because the age ranges were different for all of the studies. Thus, we recommend that future studies break down the analyses into various pre-determined age-ranges and report the results for each age group in addition to the results for the total group as a whole. Ideally, in addition to group means, studies should also provide means and standard deviations broken down by each year of age (e.g., in a study examining two to four year olds, means should be provided for all two years olds, all three year olds, and all four year olds separately and as a group). This would allow for the most flexibility as age groups could then be more accurately combined for comparisons with other trials and more specific generalizations could be made. At the least, broad age ranges should be broken down into smaller age ranges of no more than two to three years (e.g., 0-2, 3-5, 6-8, etc.). While standard guideline or recommendations on selection age ranges do not currently exist, developmental periods should be taken into account when deciding on the age range for a particular study. For example, standard child developmental textbooks often state that infancy/toddlerhood spans from birth to two years, early childhood from two to six years, middle childhood from six to twelve years, and adolescence from twelve to twenty years (e.g., Hetherington 2005).

4) Report the Method of Randomization

Although many of the retrieved studies reported that there was random assignment of participants to groups, few studies provided an explanation of what technique was used to achieve this (e.g., random table of numbers). Furthermore, although alternating assignment can be considered quasi-random, it should not be described as random assignment without further explanation. There are many reasons why randomization is not always feasible or appropriate; however, these should be described adequately within the body of the study.

5) Report Withdrawals/Drop-outs and Reasons for Dropouts

It is generally acknowledged that participants who drop out of studies before the study is completed, may differ on important dimensions from those participants who do not drop out. While it is customary for most studies to describe how many participants agreed to participate, it is crucial for authors to also describe how many participants withdrew/dropped-out from the study, and the reasons why they did so. For example, if may be that the participants who dropped out of the study were more anxious than those who did not, and this could alter the results and conclusions of the study if not accounted for. In addition, it is recommended that intention-to-treat analyses be conducted whenever possible to take participant withdrawals into consideration.

6) Development of Manualized Interventions

The lack of development and dissemination of treatment manuals creates heterogeneity and makes exact replication difficult. For example, although two studies may both report that distraction was used as an intervention, there may be important qualitative differences regarding the nature of the distraction including: (a) the item(s), (b) how long the children had access to these items, (c) how many item(s) were available, and (d) whether the items were developmentally appropriate. At the very least, if manuals are not provided, authors should provide detailed descriptions of the interventions with enough detail to allow for exact replication.

Overall, the results of this review outline the current status of the literature on randomized controlled trials of psychological interventions for needle pain and distress in children. While there have been many strong studies conducted in this area, many of the studies have employed multiple baseline designs or non-randomized techniques. The results of this review clearly demonstrate that there is a need for further fully randomized trials in this area, particularly for the interventions for which there are few or no randomized trials. Given the promising results to date, further studies in this area would help strengthen the evidence for the efficacy of cognitive-behavioral interventions with pediatric populations.

POTENTIAL CONFLICT OF INTEREST

None known.

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REFERENCES

References to studies included in this review

Blount 1992 *{published data only}*
Blount RL, Bachanas PJ, Powers SW, Cotter MC, Franklin A, Chaplin W, et al. Training children to cope and parents to coach them during routine immunizations: Effects on child, parent, and staff behaviors. *Behavior Therapy* 1992;**23**:689–705.

Cassidy 2002 *{published data only}*
Cassidy K-R, Reid GJ, McGrath PJ, Finley GA, Smith DJ, Morley C, et al. Watch needle, watch TV: Audiovisual distraction in preschool immunization. *American Academy of Pain Medicine* 2002;**3**(2):108–18.

Cavender 2004 *{published data only}*
Cavender K, Goff MD, Hollon EC, Guzzetta CE. Parent's positioning and distracting children during venipuncture. *Journal of Holistic Nursing* 2004;**22**(1):32–56.

Chen 1999 *{published data only}*
Chen E, Zeltzer LK, Craske MG, Katz ER. Alteration of memory in the reduction of children's distress during repeated aversive medical procedures. *Journal of Consulting and Clinical Psychology* 1999;**67**(4):481–90.

Cohen 1997 *{published data only}*
Cohen LL, Blount RL, Panopoulos G. Nurse coaching and cartoon distraction: An effective and practical intervention to reduce child, parent, and nurse distress during immunizations. *Journal of Pediatric Psychology* 1997;**22**(3):355–70.

Cohen 1999 *{published data only}*
Cohen LL, Blount RL, Jansevics Cohen R, Ball CM, McClellan CB, Bernard RS. Children's expectations and memories of acute distress: Short- and long-term efficacy of pain managment interventions. *Journal of Pediatric Psychology* 2001;**26**(6):367–74.

* Cohen LL, Blount RL, Jansevics Cohen R, Schaen ER, Zaff JF. Comparative study of distraction versus topical anesthesia for pediatric pain management during immunizations. *Health Psychology* 1999;**18**(6):591–8.

Cohen 2002 *{published data only}*
Cohen LL, Bernard RS, Greco LA, McClellan CB. A child-focused intervention for coping with procedural pain: Are parent and nurse coaches necessary?. *Journal of Pediatric Psychology* 2002;**27**(8):749–57.

Eland 1981 *{published data only}*
Eland JM. Minimizing pain associated with prekindergarten intramuscular injections. *Issues in Comprehensive Pediatric Nursing* 1981; **5**(5-6):361–72.

Fanurik 2000 *{published data only}*
Fanurik D, Koh JL, Schmitz ML. Distraction techniques combined with EMLA: Effects of IV insertion pain and distress in children. *Children's Health Care* 2000;**29**(2):87–101.

Fowler-Kerry 1987 *{published data only}*
Fowler-Kerry S, Lander JR. Management of injection pain in children. *Pain* 1987;**30**(2):169–75.

French 1994 *{published data only}*
French GM, Painter EC, Coury DL. Blowing away shot pain: A technique for pain management during immunization. *Pediatrics* 1994; **93**(3):384–8.

Gonzalez 1993 *{published data only}*
Gonzalez JC, Routh DK. Effects of maternal distraction versus reassurance on children's reactions to injections. *Journal of Pediatric Psychology* 1993;**18**(5):593–604.

Goodenough 1997 *{published data only}*
Goodenough B, Kampel L, Champion GD, Laubreaux L, Nicholas MK, Ziegler JB, et al. An investigation of the placebo effect and age-related factors in the report of needle pain from venipuncture in children. *Pain* 1997;**72**:383–91.

Harrison 1991 *{published data only}*
Harrison A. Preparing children for venous blood sampling. *Pain* 1991;**45**(3):299–306.

Katz 1987 *{published data only}*
Katz ER, Kellerman J, Ellenberg L. Hypnosis in the reduction of acute pain and distress in children with cancer. *Journal of Pediatric Psychology* 1987;**12**(3):379–94.

Kleiber 2001 *{published data only}*
Kleiber C, Craft-Rosenberg M, Harper DC. Parents as distraction coaches during IV insertion: A randomized study. *Journal of Pain and Symptom Management* 2001;**22**(4):851–61.

Krauss 1996 *{unpublished data only}*
Krauss WJ. Videotape modeling and parent participation: Effects on reducing distress behavior in children undergoing immunization procedures. Doctoral Dissertation, California School of Professional Psychology 1996.

Kuttner 1987 *{published data only}*
Kuttner L. Favorite stories: A hypnotic pain-reduction technique for children in acute pain. *American Journal of Clinical Hypnosis* 1988; **30**(4):289–95.

Liossi 1999 *{published data only}*
Liossi C, Hatira P. Clinical hypnosis versus cognitive behavioral training for pain management with pediatric cancer patients undergoing bone marrow aspirations. *The International Journal of Clinical and Experimental Hypnosis* 1999;**47**(2):104–16.

Liossi 2003 *{published data only}*
Liossi C, Hatira P. Clinical hypnosis in the alleviation of procedure-related pain in pediatric oncology patients. *The International Journal of Clinical and Experimental Hypnosis* 2003;**51**(1):4–28.

Liossi 2006 *{published data only}*
Liossi C, White P, Hatira P. Randomized clinical trial of local anesthetic versus a combination of local anesthetic with self-hypnosis in the management of pediatric procedure-related pain. *Health Psychology* 2006;**25**:307–15.

Posner 1998 *{unpublished data only}*
Posner K. A pharmacobehavioral intervention to reduce child cancer distress. Ferkauf Graduate School of Psychology, Doctoral Dissertation 1998.

Press 2003 *{published data only}*
Press J, Gidron Y, Maimon M, Gonen A, Goldman V, Buskila D. Effects of active distraction on pain of children undergoing venipuncture: Who benefits from it?. *The Pain Clinic* 2003;**15**(3):261–9.

Tak 2005 *{published data only}*
Tak JH, van Bon WHJ. Pain- and distress-reducing interventions for venepuncture in children. *Child: Care, Health, & Development* 2005; **32**(3):257–68.

Tyc 1997 *{published data only}*
Tyc VL, Leigh L, Mulhern RK, Kumar Srivastava D, Bruce D. Evaluation of a cognitive-behavioral intervention for reducing distress in pediatric cancer patients undergoing magnetic resonance imaging procedures. *International Journal of Rehabilitation and Health* 1997; **3**(4):267–79.

Vessey 1994 *{published data only}*
Vessey JA, Carlson KL, McGill J. Use of distraction with children during and acute pain experience. *Nursing Research* 1994;**43**(6):369–72.

Wint 2002 *{published data only}*
Sander Wint S, Eshelman D, Steele J, Guzzetta CE. Effects of distraction using virtual reality glasses during lumbar punctures in adolescents with cancer. *ONF* 2002;**29**(1):E8–15.

Zabin 1982 *{unpublished data only}*
Zabin MA. The modification of children's behavior during blood work procedures. Doctoral Dissertation, West Virginia University 1982.

References to studies excluded from this review

Arts 1994
Arts SE, Abu-Saad HH, Champion GD, Crawford MR, Fisher RJ, Juniper KH, et al. Age-related response to lidocaine-prilocaine (EMLA) emulsion and effect of music distraction on the pain of intravenous cannulation. *Pediatrics* 1994;**93**:797–801.

Bengston 2002
Bengston BS, Jacobson RM, Friedrich WM, Vierkant RA, Poland GA. Teaching self-hypnosis to alleviate vaccination-related distress in children: A randomized, single-blinded controlled trial. In preparation.

Bowen 1999

Bowen AM, Dammeyer MM. Reducing children's immunization distress in a primary care setting. *Journal of Pediatric Nursing* 1999;**14**: 296–303.

Broome 1998

Broome ME, Rehwaldt M, Fogg L. Relationships between cognitive behavioral techniques, temperament, observed distress, and pain reports in children and adolescents during lumbar puncture. *Journal of Pediatric Nursing* 1998;**13**(1):48–54.

Bruck 1995

Bruck M, Ceci SJ, Francoeur E, Barr R. "I hardly cried when I got my shot!" Influencing children's reports about a visit to their pediatrician. *Child Development* 1995;**66**:193–208.

Carlson 2000

Carlson KL, Broome M, Vessey JA. Using distraction to reduce reported pain, fear, behavioral distress in children and adolescents: A multisite study. *Journal of the Society of Pediatric Nurses* 2000;**5**:75–85.

Chen 2000b

Chen E, Craske MG, Katz ER, Schwartz E, Zeltzer LK. Pain-sensitive temperament: Does it predict procedural distress and response to psychological treatment among children with cancer?. *Journal of Pediatric Psychology* 2000;**25**(4):269–78.

Christiano 1996

Christiano BA. Children's coping and distress during invasive dental procedures: The effects of matching coping interventions to coping styles. Doctoral Dissertation 1996.

Dalhquist 2002

Dahlquist LM, Pendley JS, Landthrip DS, Jones CL, Steuber CP. Distraction intervention for preschoolers undergoing intramuscular injections and subcutaneous port access. *Health Psychology* 2002;**21** (1):94–9.

Fassler 1985

Fassler D. The fear of needles in children. *The American Journal of Orthopsychiatry* 1985;**55**(3):371–7.

Gilbert 1982

Gilbert BO, Bennett Johnson S, Spillar R, McCallum M, Silverstein JH, Rosenbloom A. The effect of a peer-modeling film on children learning to self-inject insulin. *Behavior Therapy* 1982;**13**:186–93.

Goymour 2000

Goymour K, Stephenson C, Goodenough B, Boulton C. Evaluating the role of play therapy in the pediatric emergency department. *AENJ* 2000;**3**(2):10–2.

Hatava 2000

Hatava P, Olsson GL, Lagerkranser M. Preoperative psychological preparation for children undergoing ENT operations: a comparison of two methods. *2000* Paediatric Anaesthesia;**10**:477–86.

Hawkins 1998

Hawkins PJ. Hypnosis in the alleviation of procedure related pain and distress in paediatric oncology patients. *Contemporary Hypnosis* 1998;**15**(4):199–207.

Jay 1987

Jay SM, Elliott CH, Katz E, Siegel SE. Cognitive-behavioral and pharmacologic interventions for childrens' distress during painful medical procedures. *Journal of Consulting and Clinical Psychology* 1987;**55**(6):860–5.

Jay 1990

Jay SM, Elliott CH. A stress inoculation program for parents whose children are undergoing painful medical procedures. *Journal of Consulting and Clinical Psychology* 1990;**58**(6):799–804.

Jay 1991

Jay SM, Elliott CH, Woody PD. An investigation of cognitive-behavior therapy combined with oral valium for children undergoing painful medical procedures. *Health Psychology* 1991;**10**(5):317–22.

Jay 1995

Jay S, Elliott CH, Fitzgibbons I, Woody P, Siegel S. A comparative study of cognitive behavior therapy versus general anesthesia for painful medical procedures in children. *Pain* 1995;**62**:3–9.

Kazak 1996

Kazak AE, Penati B, Boyer BA, Himelstein B, Brophy P, Waibel MK, et al. A randomized controlled perspective outcome study of a psychological and pharmacological intervention protocol for procedural distress in pediatric leukemia. *Journal of Pediatric Psychology* 1996;**21** (5):615–31.

Kazak 1998

Kazak AE, Penati B, Brophy P, Himelstein B. Pharmacologic and psychologic interventions for procedural pain. *Pediatrics* 1998;**102** (1):59–66.

Klorman 1980

Klorman F, Hilpert PL, Michael R, LaGana C, Sveen OB. Effects of coping and mastery modeling on experienced and inexperienced pedodontic patients' disruptiveness. *Behavior Therapy* 1980;**11**:156–68.

Kolk 2000

Kolk AM, van Hoof R, Fiedeldij Dop MJC. Preparing children for venepuncture. The effect of an integrated intervention on distress before and during venipuncture. *Child: Care, Health and Development* 2000;**26**(3):251–60.

Kuttner 1988

Kuttner L, Bowman M, Teasdale M. Psychological treatment of distress, pain, and anxiety for young children with cancer. *Developmental and Behavioral Pediatrics* 1988;**9**(6):374–81.

Kwekkeboom 2003

Kwekkeboom KL. Music versus distraction for procedural pain and anxiety in patients with cancer. *ONF* 2003;**30**(3):433–40.

Lustman 1983

Lustman NM. The effectiveness of two different components of stress inoculation, preparatory information and the teaching of coping devices aimed at mothers whose children are undergoing minor surgery. Yale University (Doctoral Dissertation) 1983.

MacLaren 2005

MacLaren JE, Cohen LL. A comparison of distraction strategies for venipuncture distress in children. *Journal of Pediatric Psychology* 2005; **30**(5):387–96.

Malone 1996

Malone AB. The effects of live music on the distress of pediatric patients receiving intravenous starts, venipunctures, injections, and heel sticks. *Journal of Music Therapy* 1996;**33**(1):19–33.

Manimala 2000
Manimala R, Blount RL, Cohen LL. The effects of parental reassurance versus distraction on child distress and coping during immunizations. *Child Health Care* 2000;**29**:161–77.

Manne 1990
Manne SL, Redd WH, Jacobsen PB, Gorfinkle K, Schorr O. Behavioral intervention to reduce child and parent distress during venipuncture. *Journal of Consulting and Clinical Psychology* 1990;**58**(5):565–72.

Manne 1994
Manne SL, Bakerman R, Jacobsen PB, Gorfinkle K, Redd WH. An analysis of a behavioral intervention for children undergoing venipuncture. *Health Psychology* 1994;**13**(6):556–66.

McCarthy 1998
McCarthy AM, Cool VA, Hanrahan K. Cognitive behavioral interventions for children during painful procedures: Research challenges and program development. *Journal of Pediatric Nursing* 1998;**13**(1):55–63.

Megel 1998
Erickson Megel M, Wagner Houser C, Simons Gleaves L. Children's responses to immunizations: Lullabies as a distraction. *Issues in Comprehensive Pediatric Nursing* 1998;**21**:129–45.

Melamed 1974
Melamed BG, Hawes RR, Heiby E, Glick J. Use of filmed modeling to reduce uncooperative behavior of children during dental treatment. *Journal of Dental Research* 1974;**54**(4):797–801.

O'Laughlin 1995
O'Laughlin E, Ridley-Johnson. Maternal presence during children's routine immunizations: The effect of mother as observer in reducing child distress. *Children's Health Care* 1995;**24**(3):175–91.

Olsen 1991
Olsen BR. Brief interventions for routine use with children in a phlebotomy laboratory. West Virginia University (Doctoral Dissertation) 1991.

Pederson 1996
Pederson C. Promoting parental use of nonpharmacologic techniques with children during lumbar punctures. *Journal of Pediatric Oncology Nursing* 1996;**13**(1):21–30.

Peretz 1999
Peretz B, Gluck GM. Assessing an active distracting technique for local anesthetic injection in pediatric dental patients: repeated deep breathing and blowing out air. *The Journal of Clinical Pediatric Dentistry* 1999;**24**(1):5–8.

Powers 1993
Powers SW, Blount RL, Bachanas PJ, Cotter MW, Swan SC. Helping preschool leukemia patients and their parents cope during injections. *Journal of Pediatric Psychology* 1993;**18**(6):681–95.

Reeb 1997
Reeb RN, Busch JP. Preprocedural psychological preparation in pediatric oncology: A process-oriented intervention study. *Children's Health Care* 1997;**25**:265–79.

Santos 1999
Santos LMCN, Borba RIH, Sabates AL. The importance of the preschool in the preparation for intramuscular injection using the play [La importancia del preparo de ninos en edad prescolar para la injeccion intramuscular con el uso del juguete]. *Acta Paul Enf* 2000;**13**(2):52–8.

Schur 1986
Schur JM. Alleviating behavioral distress with music or lamaze pant-blow breathing in children undergoing bone marrow aspirations and lumbar punctures. The University of Texas Health Science Center at Dallas (Doctoral Dissertation) 1986.

Smith 1989
Smith KE, Ackerson JD, Blotcky AD. Reducing distress during invasive medical procedures: Relating behavioral interventions to preferred coping style in pediatric cancer patients. *Journal of Pediatric Psychology* 1989;**14**(3):405–19.

Smith 1996
Smith JT, Barabasz A, Barabasz M. Comparison of hypnosis and distraction in severely ill children undergoing painful medical procedures. *Journal of Counseling Psychology* 1996;**43**(2):187–95.

Sparks 2001
Sparks L. Taking the "ouch" out of injections for children: Using distraction to decrease pain. *The American Journal of Maternal/Child Nursing* 2001;**26**(2):72–8.

Vernon 1974
Vernon DTA. Modeling and birth order in responses to painful stimuli. *Journal of Personality and Social Psychology* 1974;**29**(6):794–9.

Wall 1989
Wall VJ, Womack W. Hypnotic versus active cognitive strategies for alleviation of procedural distress in pediatric oncolgy patients. *American Journal of Clinical Hypnosis* 1989;**31**(3):181–91.

Weinstein 2003
Weinstein P, Raadal M, Naidu S, Yoshida T, Kvale G, Milgrom P. A videotaped intervention to enhance child control and reduce anxiety of the pain of dental injections. *European Journal of Paediatric Dentistry* 2003;**4**:181–5.

Winborn 1989
Winborn MD. Associative and dissociative preparatory strategies for children undergoing dental treatment. Memphis State University (Doctoral Dissertation).

Wood 2002
Wood C. Introducing a protocol for procedural pain. *Paediatric Nursing* 2002;**14**(8):30–3.

Young 1988
Young MR, Fu VR. Influence of play and temperament on the young child's response to pain. *CHC* 1988;**16**(3):209–15.

Zeltzer 1982
Zeltzer L, LeBaron S. Hypnosis and nonhypnotic techniques for reduction of pain and anxiety during painful procedures in children and adolescents with cancer. *Pediatrics* 1982;**101**(6):1032–5.

Additional references

AAFP 2004
American Academy of Family Physicians. www.aafp.org Accessed 2 January, 2004.

AAP 2004
American Academy of Pediatrics. www.aap.org Accessed 2 January, 2004.

ACIP 2004
Advisory Committee on Immunization Practices. www.csc.gov/nip/acip Accessed 2 January, 2004.

Alvarez 1997
Alvarez CB, Marcos AF. Psychological treatment of evoked pain and anxiety by invasive medical procedures in paediatric oncology. *Psychology in Spain* 1997;**1**(1):17–36.

APA-Division54 2004
American Psychological Association, Society of Pediatric Psychology (Division 54). Empirically-Supported Treatments. www.apa.org/divisions/div54 2004.

Barlow 1999
Barlow DH, Durand VM. *Abnormal Psychology: An Integrative Approach*. California: Brooks/Cole Publishing Company, 1999.

Blount 1989
Blount RL, Corbin SM, Sturges JW, Wolfe VV, Prater JM, James LD. The relationship between adults' behavior and child coping and distress during BMA/LP procedures: A sequential analysis. *Behavior Therapy* 1989;**20**:585–601.

Blount 1990
Blount RL, Sturges JW, Powers SW. Analysis of child and adult behavioral variations by phase of medical procedure. *Behavior Therapy* 1990;**21**:33–48.

Blount 1997
Blount RL, Cohen LL, Frank NC, Bachanas PJ. The Child-Adult medical procedure interaction scale-revised: an assessment of validity. *Journal of Pediatric Psychology* 1997;**22**:73–88.

Blount 2001
Blount RL, Bunke VL, Cohen LL, Forbes CJ. The Child-Adult Medical Procedure Integration Scale-Short Form (CAMPIS-SF): Validation of a rating scale for children's and adults' behaviors during painful medical procedures. *Journal of Pain and Symptom Management* 2001; **22**:591–9.

Blount 2003
Blount RL, Piira T, Cohen LL. Management of pediatric pain and distress due to medical procedures. In: MCRoberts editor(s). *Handbook of Pediatric Psychology*. Third Edition. New York: The Guilford Press, 2003.

Broome 1989
Broome ME, Lillis PP. A descriptive analysis of the pediatric pain management research. *Applied Nursing Research* 1989;**2**(2):74–81.

Broome 1990
Broome ME, Bates TA, Lillis PP, McGahee TW. Children's medical fears, coping behaviors, and pain perceptions during a lumbar puncture. *ONF* 1990;**17**(3):361–7.

Champion 1998
Champion GD, Goodenough B, vonBaeyer CL, Thomas W. Measurement of pain by self-report. *Measurement of Pain in Infants and Children*. Seattle: IASP Press, 1998:123–60.

Chen 2000a
Chen E, Joseph MH, Zeltzer LK. Acute pain in children: Behavioral and cognitive interventions in the treatment of pain in children. *Pediatric Clinics of North America* 2000;**47**(3):1–13.

Christophersen 2001
Christophersen ER, Mortweet SL. Assessment and management of pain. *Treatments that work with children: Empirically supported strategies for managing childhood problems*. Washington: American Psychological Association, 2001.

CPS 2004
Canadian Paediatric Society. www.cps.ca 2004.

Cummings 1996
Cummings EA, Reid GJ, Finley A, McGrath PJ, Ritchie JA. Prevalence and source of pain in pediatric inpatients. *Pain* 1996;**68**:25–31.

Devine 2004
Devine K, Benoit M, Simons LE, Cheng PS, Seri LG, Blount RL. Psychological interventions for acute pediatric pain. *[The Suffering Child] www.thesufferingchild.net* 19 June 2004;**6**:1–22.

Green 2004
Green S, Higgins J, editors. Cochrane Handbook for Systematic Reviews of Interventions 4.2.3 [updated November 2004]. http://www.cochrane.dk/cochrane/handbook/handbook.htm (accessed February 2005).

Hetherington 2005
Hetherington EM, Parke RD, Schmucker M. *Child Psychology: A Contemporary Viewpoint*. Canadian second. Toronto: McGraw-Hill Ryerson Limited, 2005.

IASP 2004
IASP Task Force on Taxonomy. *Classification of Chronic Pain*. Second Edition. Seattle: IASP Press, 2004.

Jadad 1996
Jadad A, Moore RA, Carroll D, et al. Assessing the quality of reports of randomized clinical trials: Is blinding necessary?. *Controlled Clin Trials* 1996;**17**:1–12.

Jay 1983
Jay SM, Ozoling M, Elliott C, Caldwell S. Assessment of children's distress during painful medical procedures. *Journal of Health Psychology* 1983;**2**:133–47.

Kazak 2001
Kazak AE, Kunin-Batson A. Psychological and integrative interventions in pediatric procedure pain. In: GAFinley, PJMcGrath editor (s). *Acute and Procedure Pain in Infants and Children*. Seattle: IASP Press, 2001:77–100.

Kazdin 2003
Kazdin AE. *Research Design in Clinical Psychology*. Fourth. Boston: A Pearson Education Company, 2003.

Keefe 1992
Keefe FJ, Dunsmore J, Burnett R. Behavioral and cogntive-behavioral approaches to chronic pain: Recent advances and future directions. Special issue: Behavioral medicine: An update for the 1990s. *Journal of Consulting and Clinical Psychology* 1992;**60**(4):528–36.

Kleiber 1999
Kleiber C, Harper DC. Effects of distraction on children's pain and distress during medical procedures: A meta-analysis. *Nursing Research* 1999;**48**(1):44–9.

Loebach 1979
Loebach S. The use of color to facilitate communication of pain in children. Thesis, University of Washington 1979.

Luebbert 2001
Luebbert K, Dahme B, Hasenbring M. The effectiveness of relaxation training in reducing treatment-related symptoms and improving emotional adjustment in acute non-surgical cancer treatment: A meta-analytic review. *Psycho-Oncology* 2001;**10**:490–502.

McGrath 1985
McGrath PJ, Johnson G, Goodman JT, et al. CHEOPS: a behavioral scale for rating postoperative pain in children. In: HLFields, RDubner, FCervero editor(s). *Advances in Pain Research and Therapy. Proceedings of the Fourth World Congress on Pain*. Vol. 9, New York: Raven Press, 1985:395–402.

McGrath 1993
McGrath PJ, McAlpine L. Psychologic perspectives on pediatric pain. *The Journal of Pediatrics* 1993;**122**:S2–8.

McGrath 1998
McGrath PJ. Behavioral measures of pain. *Measurement of Pain in Infants and Children*. Seattle: IASP Press, 1998:83–102.

MedLine 2004
MedLine Plus Medical Encyclopedia. www.nlm.nih.gov/medlineplus/mplusdictionary.html Accessed 4 February, 2004.

Merkel 1997
Merkel SI, Voepel-Lewis T, Shayevitz JR, Malviya S. The FLACC: A behavioral scale for scoring postopoerative pain in young children. *Pediatric Nursing* 1997;**23**(3):293–7.

OLMD 2004
On-Line Medical Dictionary. www.cancerweb.ncl.ac.uk/omd Accessed 4 February, 2004.

Powers 1999
Powers SW. Empirically supported treatments in pediatric psychology: Procedure-related pain. *Journal of Pediatric Psychology* 1999;**24**(2):131–45.

Prictor 2004
Prictor MJ, Hill SJ, Mackenzie A, Stoelwinder J, Harmsen M. Interventions (non-pharmacological) for preparing children and adolescents for hospital care. *Cochrane Database of Systematic Reviews* 2004, Issue 1 Art No.: CD004564. Art. No.: CD004564. DOI: 10.1002/14651858.CD004564.

Saile 1988
Saile H, Burgmeier R, Schmidt LR. A meta-analysis of studies on psychological preparation of children facing medical procedures. *Psychology and Health* 1988;**2**:107–32.

Shroeder 1979
Shroeder P. Use of Eland's color method in pain assessment of burned children. Unpublished research conducted at Shriner's Burn Hospital, Ohio 1979.

Shultz 1996
Schultz KF. Randomised trials, human nature, and reporting guidelines. *The Lancet* 1996;**348**:596–8.

Sweet 1998
Sweet SD, McGrath PJ. Physiological measures of pain. In: GAFinley, PJMcGrath editor(s). *Measurement of Pain in Infants and Children*. Seattle: IASP Press, 1998:59–81.

Young 2005
Young KD. Pediatric procedural pain. *Annals of Emergency Medicine* 2005;**45**(2):160–71.

* *Indicates the major publication for the study*

TABLES

Characteristics of included studies

Study	**Blount 1992**
Methods	Allocation: Randomized - no further details
Participants	Needle Procedure: Routine immunization Inclusion: -children attending a local county health department Exclusion: - none given N = 60 Age: three to seven years (M = 5 years, SD = 10 months) Gender: M = 32, F= 28 Diagnosis: none Setting: Local county health department
Interventions	1. Distraction + coping skills training + use of a party blower as an age appropriate version of deep breathing (n = 30)

Characteristics of included studies (*Continued*)

	2. No - treatment control (n = 30)
Outcomes	1. Child-Adult Medical Procedure Interaction Scale (CAMPIS) 2. Observational Scale of Behavioral Distress (OSBD) 3. Behavioral Approach-Avoidance and Distress Scale (BAADS) 4. Parent ratings of child fear, pain, and distress using a 10 cm VAS 5. Child self-reports of fear and pain using a 5-faces scale 6. Nurse ratings of child distress
Notes	none
Allocation concealment	B – Unclear

Study	**Cassidy 2002**
Methods	Allocation: Randomized using a standard randomization table for each cluster of ten subjects
Participants	Needle Procedure: DPTP immunization Inclusion: - five years old - due to receive standard DPTP preschool immunization - in good health - developmentally normal (i.e., the absence of developmental delays, in the expert opinion of the attending pediatrician) - subject's parent/guardian agreement to participate after initial recruitment contact Exclusion: - previously immunized with the preschool DPTP vaccine - previously hospitalized - the presence of any acute or chronic medical condition N = 62 Age: all five years old Gender: M = 28, F = 34 Diagnosis: none Setting: two urban pediatric practices in Halifax, Nova Scotia, Canada.
Interventions	1. Distraction using an age-appropriate TV musical cartoon (n = 29) 2. Blank TV screen control (n = 33)
Outcomes	1. Parent ratings of child anxiety before procedure on 10 cm VAS (1 = no anxiety, 10 = worst anxiety imaginable) 2. Child self-report of pain immediately after procedure using the Faces Pain Scale (FPS) 3. Blinded experimenter ratings of pain from videotaped procedures using the Children's Hospital of Eastern Ontario Pain Scale (CHEOPS) 4. Blinded experimenter ratings of pain from videotaped procedures using the Child Facial Coding System (CFCS) 5. Two objective distraction scores for "watch TV" (i.e., time spent watching TV screen) and "watch needle" (i.e., time spent watching needle) coded from videotaped procedures by experimenters
Notes	none
Allocation concealment	A – Adequate

Study	**Cavender 2004**
Methods	Allocation: Randomized- using a table of random numbers
Participants	Needle Procedure: venipuncture or IV insertion Inclusion: - English speaking between four and 11 years old - had medical order written for venipuncture or IV insertion

Characteristics of included studies (*Continued*)

	Exclusion: - children with chronic illness - children presenting with possible child abuse N = 43 Age: four to 11 years old (M = 7.88 years, SD = 1.74 years) Gender: M = 19, F = 24 Diagnosis: 11 = Surgical, 7 = Trauma, 9 = Vomiting, 4 = Other Setting: Emergency department of a private, 322 - bed, pediatric medical center in the Southwestern United States
Interventions	1. Parental Positioning + Distraction (n = 20) 2. Standard care comparison/control (n = 23)
Outcomes	1. Child self-reported pain during procedure using the FACES scale 2. Child self-reported fear during the procedure using the Glasses Fear Scale 3. Parent and Child Life Specialist ratings of child fear during the preprocedural and postprocedural time periods using the Glasses Fear Scale 4. Child Life Specialist ratings of child distress using the Procedural Behavior Checklist (PBCL)
Notes	none
Allocation concealment	A – Adequate

Study	**Chen 1999**
Methods	Allocation: Randomized- no further details
Participants	Needle Procedure: three consecutive lumbar punctures (LPs; baseline, post-intervention, and follow-up) Inclusion: - diagnosis of Acute Lymphoblastic Leukemia (ALL) - three to 18 years old - English or Spanish speaking Exclusion - none given N = 50 Age: three to 18 years (M = 7.3 years, SD = 3.7 years) Gender: M = 67%, F = 33% Diagnosis: Acute Lymphoblastic Leukemia (ALL) Setting: outpatient Children's Center for Cancer and Blood Diseases at the Children's Hospital Los Angeles
Interventions	1. Brief alteration of memory intervention (n = 25) 2. Attentional control (n = 25)
Outcomes	1. Child self-reports of anxiety and pain on 10 cm vertical VAS 2. Parent ratings of child anxiety & pain using 10cm vertical VAS 3. Physician assistant performing the LP ratings of child's procedural distress on the same VAS (physical assistants not blind to treatment condition) 4. Pain and anxiety questions administered to all children; however, they were not analyzed if the child was too young to understand 5. 35-item Memory interview 6. Procedure Behavior Check List (PBCL) coded by trained unblinded observers 7. Child systolic and diastolic blood pressure ratings 8. Child heart rate 9. Child salivary cortisol
Notes	none
Allocation concealment	B – Unclear

Characteristics of included studies (*Continued*)

Study	**Cohen 1997**
Methods	Allocation: Randomized (see note)
Participants	Needle Procedure: two injections consisting of Diphtheria and Tetanus Toxoids and Pertussis vaccine (DTP), and a live attenuated Measles-Mumps-Rubella vaccine (MMR) Inclusion: - children due to receive immunizations Exclusion: - none given N = 92 Age: four to six years (M = 4.4 years, SD = 0.54 years) Gender: M = 48, F = 44 Diagnosis: none Setting: health center that treats a wide range of clients from across a predominantly rural county
Interventions	1. Nurse Coaching + Parent/Child Training (= 31) 2. Nurse Coaching (n = 32) 3. Standard Medical Care (n = 29)
Outcomes	1. Child self-report of pain during the immunizations using the FACES scale 2. Parent ratings of child distress and their own distress using a 5-point Likert scale 3. Nurse ratings of child distress and their own distress using a five-point Likert scale 4. Observer ratings of child distress using the Child-Adult Medical Procedure Interaction Scale-Revised (CAMPIS-R)
Notes	In the study, it is stated that children were alternately assigned to groups. Personal communication with the author clarified that this was not an accurate description, and the technique used was actually a randomized schedule
Allocation concealment	A – Adequate

Study	**Cohen 1999**
Methods	Allocation: Randomized - using a Latin square design, each child was exposed to all three experimental conditions in one of six possible randomly assigned sequence orders for their series of three injections
Participants	Needle Procedure: three-injection vaccination series over six months Inclusion: - families with 4th graders in the school Exclusion: - none given N = 39 Age: 8.83 to 11.08 years (M = 9.90 years, SD = 0.51 years) Gender: M = 16, F = 23 Diagnosis: none Setting: school health clinic in a low-income, inner-city neighborhood in the southeastern United States
Interventions	1. Nurse Coaching + Movie Distraction (n = 39) 2. EMLA topical anesthetic (n = 39) 3. Typical Care (n = 39)
Outcomes	1. Child self-report of pre-shot and post-shot distress using an 100 mm VAS 2. Nurse ratings of child distress, child pain, and their own distress using the VAS 3. Observer ratings of child distress using the Child-Adult Medical Procedure Interaction Scale-Revised (CAMPIS-R) coded from videotapes of the immunizations 4. Child 60-second heart rate obtained via radial pulse

Characteristics of included studies (*Continued*)

	5. Child-rated satisfaction ratings of the intervention used
Notes	Within-subjects design
Allocation concealment	A – Adequate

Study	**Cohen 2002**
Methods	Allocation: Randomized (see note).
Participants	Needle Procedure: two immunizations consisting of Diphtheria and Tetanus Taxoids and Pertussis vaccine (DPTP) and a live attenuated Measles-Mumps-Rubella vaccine (MMR) Inclusion: -children presenting at the clinic to receive their school entry immunization Exclusion: -none given N = 61 Age: 3.73 to 6.94 years old (M = 5.37 years, SD = 0.63 years) Gender: M = 34, F = 27 Diagnosis: none Setting: health department in the rural Northwestern United States
Interventions	1. Coping Skills (n = 31) 2. Control (n = 30)
Outcomes	1. Child self-report of distress and fear (from one of five computer generated smiley faces from smiling to frowning) 2. Parent ratings of child procedural distress using a 100 mm horizontal VAS 3. Nurse ratings of child procedural distress using the same 100 mm VAS 4. Observer ratings of child distress using the Child-Adult Medical Procedure Interaction Scale-Short Form (CAMPIS-SF)
Notes	In the study, it is stated that children were alternately assigned to groups. Personal communication with the author clarified that this was not an accurate description, and the technique used was actually a randomized schedule
Allocation concealment	A – Adequate

Study	**Eland 1981**
Methods	Allocation: Randomized - no further details
Participants	Needle Procedure: intramuscular injection Inclusion: - children scheduled for pre-kindergarten physical examinations Exclusion: - none given N = 40 Age: 4.9 years to 5.9 years Gender: M = 20, F = 20 Diagnosis: none Setting: private pediatrician's office in a Midwestern city with a population of 60,000
Interventions	1. Frigiderm Coolant with Cognitive Information (n = 10) 2. Frigiderm Coolant with No Cognitive Information (n = 10) 3. Control Aerosol Spray with Cognitive Information (n = 10) 4. Control Aerosol Spray with No Cognitive Information (n = 10)
Outcomes	1. Child self-reports of pain using an adaptation of the tool used by Loebach 1979 & Schroeder 1979 comprised of eight 1 1/2 inch color squares placed across the bottom of a white felt board representing different events related to varying levels of pain

	2. Parent and nurse ratings of child anxiety
Notes	none
Allocation concealment	B – Unclear

Study	**Fanurik 2000**
Methods	Allocation: Randomized - children were assigned to one of four stratified age groups (two to four years, five to eight years, nine to 12 years, 13 to 16 years) and then randomized to the treatment or control group - no further details
Participants	Needle Procedure: IV insertion Inclusion: - two to 16 years - generally healthy - would have EMLA applied for at least 60 min prior to their IV insertion Exclusion: - children with chart-documented, parent-reported, or suspected developmental delay or cognitive impairment N = 160 Age: two to 16 years Gender: not reported Diagnosis: none (but undergoing elective outpatient gastrointestinal endoscopy) Setting: pediatric outpatients in the Gastroenterology Division of the Arkansas Children's Hospital
Interventions	1. Distraction (n = 80) 2. Typical Intervention Control (n = 80)
Outcomes	1. Child self-reports of pain and anxiety using 100 mm VASs obtained for children five years of older after IV was taped in place and prior to administration of medication for sedation 2. Three ratings of behavioral distress (pre-procedure, procedure, post-procedure) were recorded on a 6-point numerical scale (0 = not at all distressed, 5 = extremely distressed) by one of the GI specialty nurses (not involved in the medical procedure or intervention), or a research assistant (nurses and research assistants were not blind to experimental group) 3. Parental predictions of child anxiety during IV insertions using 100 mm VASs 4. Behaviors of the children and parents in the comparison group were recorded by observers in a brief narrative form (coded as 'distraction' or 'non-distraction' strategies)
Notes	none
Allocation concealment	B – Unclear

Study	**Fowler-Kerry 1987**
Methods	Allocation: Randomized - randomly assigned with the restriction that there be equal numbers of boys and girls in each group- no further details
Participants	Needle Procedure: immunization Inclusion: - healthy children 4.5 to seven years old Exclusion: - none given N = 200 Age: 4.6 to 6.2 years (M = 5.5 years) Gender: M = 100, F = 100 Diagnosis: none Setting: patients attending one of three community health clinics located near a large metropolitan area
Interventions	1. Distraction (n = 40)

Characteristics of included studies (*Continued*)

	2. Distraction + Suggestion (n = 40) 3. Suggestion (n = 40) 4. Control condition with headphones (n = 40) 5. Control condition without headphones (n = 40)
Outcomes	1. Child self-report of pain using four-point VAS (0 = no pain, 3 = most pain possible) where subjects were shown a card with four equal sized blocks representing the range of pain of the scale & asked to point to the block which represented their pain
Notes	none
Allocation concealment	B – Unclear

Study	**French 1994**
Methods	Allocation: Randomized; however, the control and experimental groups were enrolled on alternate days to avoid contamination of the control group, because at this setting, children receiving shots could clearly see and hear others who are receiving shots
Participants	Needle Procedure: preschool Diphtheria / Pertussis / Tetanus Immunization Inclusion: - children receiving immunizations Exclusion: - none given N = 149 Age: 4 to 7 years old Gender: M = 71, F = 79 Diagnosis: none Setting: one of two immunization clinics operated by the Columbus Public Health Department. Controls were predominant in Clinic 1 and experimental subjects were predominant in clinic 2 The same nurses worked in each clinic and the clinics were operated in the same way
Interventions	1. Blow Out Air + Taught to use VAS (n = 39) 2. Blow Out Air + Not Taught VAS (n = 38) 3. Control + Taught to use VAS (n = 36) 4. Control + Not Taught how to use VAS (n = 36)
Outcomes	1. Child self-report of pain using 100 mm horizontal VAS 2. Parent and nurse ratings of child pain using 100 mm VAS 3. A modification of the Observational Scale of Behavioral Distress (OSBD) coded by the investigators from videotapes of the procedures
Notes	none
Allocation concealment	A – Adequate

Study	**Gonzalez 1993**
Methods	Allocation: Randomized - using a block randomization procedure that took age into account - no further details
Participants	Needle Procedure: routine injections Inclusion: - none given Exclusion: - none given N = 42 Age: three to seven years Gender: M = 21, F = 21

	Diagnosis: none Setting: recruited from the general pediatric primary care clinic at a large, urban public hospital
Interventions	1. Maternal Reassurance (n = 14) 2. Distraction (n = 14) 3. Control (n = 14)
Outcomes	1. Research assistant ratings of child distress using the Modified Frankl Behavior Rating Scale 2. Child self-report of pain during the procedure using the Oucher Pain Rating Scale 3. Observers blind to group assignment ratings of child distress during the procedure, using the Observational Scale of Behavioral Distress-Revised (OSBD-R) coded from videotapes of the injection for the injection and post-injection time periods 4. Observers blind to group assignment ratings of parental adherence to the experimental manipulation using the 'nonprocedure- related talk' and 'reassuring comment' codes of the Child-Adult Medical Procedure Interaction Scale (CAMPIS)
Notes	none
Allocation concealment	B – Unclear

Study	**Goodenough 1997**
Methods	Allocation: Randomized- stratified by age- no further details
Participants	Needle Procedure: venipuncture Inclusion: - children aged three to 17 years consecutively scheduled to undergo venipuncture Exclusion: - children with a major mental handicap N = 117 Age: 3.5 to 17.7 years Gender: M = 73, F = 44 Diagnosis: none (although 36 children were undergoing venipuncture as part of ongoing investigation for chronic illness) Setting: Sydney Children's Hospital
Interventions	1. Placebo Cream + Suggestion (n = 39) 2. Placebo Cream alone (n = 39) 3. No Cream Control (n = 39)
Outcomes	1. Child self-report of pain using the Faces Pain Scale (FPS) 2. Child self-report of anxiety using the Children's Anxiety and Pain Scale (CAPS) 3. Child self-report of whether the cream had helped to reduce the needle-pain 4.Observer ratings of child behavioral reaction to pain during the needle
Notes	none
Allocation concealment	B – Unclear

Study	**Harrison 1991**
Methods	Allocation: Randomized - no further details
Participants	Needle Procedure: venous blood sampling Inclusion: - six to 12 year olds reporting to four hospital laboratories in Kuwait Exclusion: - none given N = 100 Age: six to 12 years Gender: M = 51, F = 49

Characteristics of included studies (*Continued*)

	Diagnosis: none Setting: four hospital laboratories in Kuwait
Interventions	1. Preparation (n = 50) 2. No Preparation control (n = 50)
Outcomes	1. Child self-report of pain and fear using 6-point histogram VAS 2. Radial pulse rates of children before and after the procedure 3. Parent responses to questions related to the procedure
Notes	none
Allocation concealment	B – Unclear

Study	**Katz 1987**
Methods	Allocation: Randomized - stratified by sex - no further details
Participants	Needle Procedure: bone marrow aspiration (BMA) (approximately 50% of the children also underwent a lumbar puncture immediately following their BMA) Inclusion: - baseline self-reported pain score > 50 (possible range: zero to 100) - baseline self-reported fear score > 4 (possible range: 1 to 7) - Procedural Behavior Rating Scale-revised score > 4 (possible range: zero to 33) - nurse rating of child anxiety > 3 (possible range: one to five) Exclusion: - none given N = 36 Age: six to 11 years old (M = 8.3 years, SD = 1.68 years) Gender: M = 24, F = 12 Diagnosis: Acute lymphoblastic leukemia (ALL) Setting: Hematology-Oncology clinic at the Children's Hospital of Los Angeles
Interventions	1. Hypnosis: baseline and intervention (n = 18) 2. Play control condition: baseline and intervention (n = 18)
Outcomes	1. Observer ratings of child distress during three temporal phases using the Procedural Behavior Rating Scale-Revised (PBRS-r) 2. Nurse ratings of child anxiety during the procedure using one to five Likert scale 3. Child self-report of fear during the procedure using the Fear Self-Report measure 4. Child self-report of pain during the procedure using the Pain Self-Report (comprised of a graphic rating scale patterned after a thermometer where 0 = no hurt at all, and 100 = the most hurt possible) 5. Therapist ratings of rapport with patient and child's response to hypnosis on one to five scale (1 = excellent, 5 = poor)
Notes	none
Allocation concealment	B – Unclear

Study	**Kleiber 2001**
Methods	Allocation: Randomized - permutated block randomization used to assure that a balanced number of children with histories of high distress were randomized to the control and experimental groups; randomization conducted according to the procedures outlined by Friedman et al., 1996 Randomization achieved using a table of random numbers (see note)
Participants	Needle Procedure: IV Insertion

Characteristics of included studies (*Continued*)

	Inclusion: - no neurological or sensory impairment at the IV site - child able to distinguish between biggest and smallest in order to Oucher pain scale - parent with legal custody agreed to be with the child during the procedure - parent able to speak and read English Exclusion: - none given N = 44 Age: four to seven years Gender: M = 11, F = 33 Diagnosis: children being treated or evaluated for non-life threatening conditions such as chronic urinary tract infections, urinary incontinence, chronic constipation, growth failure, and reactive airway disease Setting: large Midwestern tertiary care hospital that serves as the primary specialty referral site for a population of approximately three million people. It is located in a state in which the population is predominantly Caucasian, with other races accounting for 5% of the population
Interventions	1. Distraction (n = 22) 2. Control condition (n = 22)
Outcomes	1. Parent ratings of child's previous distress during medical procedures using a seven-point scale 2. Child self-report of pain during the IV insertion using the Oucher Scale 3. Parent ratings of child distress using the Perception of Procedures Questionnaire- Revised (PPQ-R) 4. Observer ratings of child distress using the Observer Scale of Behavioral Distress- Revised (OSBD-R) 5. Observer ratings of parent distraction behavior coded from videotapes (each ten-second interval of the procedure coded for the presence/absence of parental distraction)
Notes	Although it was not stated in the paper, personal communication with the author confirmed that randomization was achieved via a random table of numbers
Allocation concealment	A – Adequate

Study	**Krauss 1996**
Methods	Allocation: Randomized - 25 pieces of paper assigned with the numeral 1 (control) and 25 pieces with the numeral two (experimental) were placed in a container and drawn by the experimenter. The numbers one through 50 were written out on a sheet of paper and as the numbers (one or two) were drawn, they were assigned successively to each of the 50 subjects
Participants	Needle Procedure: immunization (series of three or a combination of immunizations) Inclusion: - children undergoing immunization procedures Exclusion: - none given N = 50 Age: four to seven years (mean = 4.86, SD = 0.78 years) Gender: M = 23, F = 27 Diagnosis: none Setting: Fresno Country Health Department
Interventions	1. Videotape Modeling + Parent Participation (n = 25) 2. Routine Procedure Control condition (n = 25)
Outcomes	1. Experimenter, parent, and nurse ratings of child distress using the Child Medical Distress Scale
Notes	none
Allocation concealment	A – Adequate

Study	**Kuttner 1987**
Methods	Allocation: Randomized- no further details

Characteristics of included studies (*Continued*)

Participants	Needle Procedure: bone marrow aspiration (BMA) Inclusion - leukemia patients who had expressed difficulty in coping with the recurrent BMAs and Lumbar Punctures (LPs) that constituted an essential part of their treatment for cancer - children six years old and younger Exclusion - none given N = 25 Age: three to 6.11 years (larger study compared three to six year olds with seven to ten year olds but this paper reports results of younger group only) Gender: not reported Diagnosis: Leukemia Setting: treatment / surgery room - no further details
Interventions	1. Hypnosis (n = 9) 2. Distraction (n = 8) 3. Standard Medical Care (n = 8)
Outcomes	1. Observer ratings of child distress using the Procedure Behavior Rating Scale- Revised (PBRS-R) 2. Observer, physician, nurse, and parents ratings of child's pain and anxiety on five-point rating scales 3. Child self-report of pain and anxiety using an interval picture five-point scale
Notes	none
Allocation concealment	B – Unclear

Study	**Liossi 1999**
Methods	Allocation: Randomized- table of random numbers (see note)
Participants	Needle Procedure: bone marrow aspirations (BMAs; baseline and intervention) Inclusion: - Leukemia patients between five and 15 years old whose medical protocol required at least two BMAs within 2.5 months Exclusion: - previous therapy with hypnosis and/or cognitive behavioral (CB) coping - concurrent treatment during the project with analgesic or psychotropic medication - a major affective disorder or other psychiatric diagnosis N = 30 Age: five to 15 years (mean = eight years, SD = 2.5 years Gender: M = 17, F = 13 Diagnosis: Leukemia Setting: treatment room of clinic - no further details
Interventions	1. Cognitive Behavioral (CB) intervention (n = 10) 2. Hypnosis (n = 10) 3. Standard Treatment control (n = 10)
Outcomes	1. Child self-report of pain and pain-related anxiety during one BMA at baseline (time 1) using a six-point faces rating scale (0 = no pain/anxiety, 5 = as much pain/anxiety child can imagine) 2. Nurse ratings of child distress during one BMA at baseline (time 1) using the Procedure Behavior Checklist (PBCL) 3. Child's hypnotic ability assessed using a Greek translation of the Stanford Hypnotic Clinical Scale for Children (SHCS-Children)
Notes	Although it was not stated in the paper, personal communication with author confirmed that randomization was achieved via a random table of numbers
Allocation concealment	A – Adequate

Characteristics of included studies (*Continued*)

Study	**Liossi 2003**
Methods	Allocation: Randomized- no further details
Participants	Needle Procedure: series of lumbar punctures (LPs; baselines and using intervention) Inclusion: - children with leukemia or non-Hodgkin's lymphoma - 6 to 16 years old - undergoing regular lumbar punctures over a 4-year period Exclusion: -previous hypnosis treatment -concurrent treatment during the project with analgesic or psychotropic medication -a major affective disorder or other psychiatric diagnosis N = 80 Age: 6 to 16 years (mean = 8.63 years, SD = 2.86 years) Gender: not reported Diagnosis: Leukemia or Non-Hodgkin's Lymphoma Setting: Hematology/Oncology Department of the Children's Hospital Aglaia Kyriakou, Athens, Greece
Interventions	1. Direct Hypnosis with Standard Medical Treatment (n = 20) 2. Indirect Hypnosis with Standard Medical Treatment (n = 20) 3. Attentional Control condition with Standard Medical Treatment (n = 20) 4. Standard Medical Treatment (n = 20)
Outcomes	1. Child self-report of pain and anxiety during three consecutive LPs at baseline and for two consecutive LPs with the intervention, using the six-point Wong & Baker faces rating scale 2. Nurse ratings of child pain during three consecutive LPs at baseline and during two consecutive LPs with the intervention, using the Procedure Behavior Checklist (PBCL) 3. Child self-reports of pain and anxiety during the first, third, and sixth LPs in which self-hypnosis was used 4. Hypnotic ability assessed within two weeks after the last LP using a Greek-translation of the Stanford Hypnotic Scale for Children (SHCS-Children)
Notes	none
Allocation concealment	B – Unclear

Study	**Liossi 2006**
Methods	Allocation: Randomized- table of random numbers
Participants	Needle Procedure: series of lumbar punctures (LPs; baselines and using intervention) Inclusion: Greek-speaking patients with leukemia or non-Hodgkin's lymphoma - between 6 and 16 years - undergoing regular LPs Exclusion: - previous hypnosis treatment - concurrent treatment during the project with analgesia or psychotropic medication - major affective disorder or other psychiatric diagnosis N = 45 Age: 6 to 16 years Gender: M = 23, F = 22 Diagnosis: leukemia or non-Hodgkin's lymphoma Setting: Hematology/Oncology Department of the Children's Hopsital Aglaia Kyriakou, Athens, Greece
Interventions	1. EMLA + Hypnosis (n = 15) 2. EMLA + Attention (n = 15) 3. EMLA only (n = 15)
Outcomes	1. Child self-reported pain using the Wong-Baker FACES Pain Rating Scale 2. Observer ratings of child distress and discomfort using the Procedure Behavior Checklist (PBCL)

	3. Hypnotic ability assessed using a Greek-translation of the Stanford Hypnotic Scale for Children (SHCS-Children)
Notes	none
Allocation concealment	A – Adequate

Study	**Posner 1998**
Methods	Allocation: Randomized - no further details
Participants	Needle Procedure: venipuncture Inclusion: - English speaking (parents and children conversant in English) - three to ten year old oncology patients scheduled for venipuncture - accompanied by parents to the hospital and remained with parents in the treatment room Exclusion: - not previously on high doses of narcotic medication - not having received EMLA cream or any behavioral intervention during a venipuncture in the past N = 20 Age: 3.3 to 10.5 years (mean age = 6.6 years) Gender: M = 15, F = 5 Diagnosis: Oncology patients - no further details Setting: Memorial Sloan-Ketting Cancer Center Pediatric Day Hospital
Interventions	1. Topical Anesthesia (EMLA) + Parent-Assisted Behavioral Intervention (n =10) 2. Topical Anesthetic (EMLA) alone (n = 10)
Outcomes	1. Child self-report of anxiety and pain 2. Parent and nurse ratings of child distress 3. Behavioral child distress scores 4. Child heart rate
Notes	none
Allocation concealment	B – Unclear

Study	**Press 2003**
Methods	Allocation: Randomized- no further details
Participants	Needle Procedure: venipuncture Inclusion: -ages six to 16 years undergoing venipuncture -conscious -Hebrew speaking -no hearing problems Exclusion: -none given N = 94 Age: six to 16 years Gender: M = 57, F = 37 Diagnosis: none Setting: Pediatric Emergency Department of the Saroka University Medical Center, Israel
Interventions	1. Distraction (n = 48) 2. Usual Care control (n = 46)
Outcomes	1. Child self-report of pain during venipuncture using a 10 cm VAS combined with a faces pain scale

	2. Parent and nurse ratings of child pain using the same 10 cm VAS and faces pain scale 3. Physician measured pressure/pain threshold of children using a dolorimeter positioned on 13 points throughout the body
Notes	none
Allocation concealment	B – Unclear

Study	**Tak 2005**
Methods	Allocation: Randomized - no further details
Participants	Needle Procedure: venepuncture Inclusion: Dutch patients receiving a venepuncture Exclusion: children of non-Dutch parentage N = 136 Age: three to twelve years (mean = 6.4, SD = 2.5) Gender: M = 73, F = 63 Diagnosis: none Setting: outpatient centre of the St Antonius Ziekenhuis in Nieuwegein (the Netherlands)
Interventions	1. Placebo, distraction, information (n = 20) 2. EMLA, distraction, information (n = 21) 3. Placebo, information (n = 20) 4. EMLA information (n = 21) 5. Information (n = 26) 6. Non-treatment control (n = 28)
Outcomes	1. Child self-reported pain using the Oucher scale for children younger than six years, and the VAS which children of six and over- a research assistant administered these scales immediately after the venepuncture 2. Research assistant ratings of child distress using the Groningen Distress Scale (GDS), a 5-point categorical behavioral observation scale of distress based on three categories: breathing, crying, and muscle tone- scored at three time points (when child entered room, just before venepuncture, and during venepuncture)
Notes	none
Allocation concealment	B – Unclear

Study	**Tyc 1997**
Methods	Allocation: Randomized - no further details
Participants	Needle Procedure: IV insertion prior to MRI Inclusion: - ages six to 18 years old and English speaking - scheduled to receive a magnetic resonance imaging (MRI) procedure of the brain or spine - had received at least one prior MRI procedure at St. Jude's Children's Hospital within the last 12 months -in remission or had stable disease, or both. Exclusion: - patients who had relapsed or had evidence of progressive disease or had severe cognitive deficits, or both (IQ < 70) based on medical chart review, psychosocial histories, or available psychological assessment data N = 55 Age: 6.3 to 18.6 years (mean = 12.5 years) Gender: M = 50.9%, F = 49.1% Diagnosis: Approximately 27% = medulloblastoma, 24% = CNS glioma, and 49% = variety of malignant CNS neoplasms Setting: St Jude's Children's Hospital, Tennessee
Interventions	1. Cognitive- Behavioral Treatment (CBT) (n = 28)

Characteristics of included studies (*Continued*)

	2. Standard Care Control (SCC) (n = 27)
Outcomes	1. Child self-report of anxiety using the State-Trait Anxiety Inventory for Children (STAI-C) 2. Child and Parent ratings of MRI Distress Ratings 3. Staff MRI Distress Ratings 4. MRI Behavior Checklist
Notes	none
Allocation concealment	B – Unclear

Study	**Vessey 1994**
Methods	Allocation: Randomized- using table of random numbers
Participants	Needle Procedure: routine blood draws Inclusion: - must have had two or fewer blood draws in the six months preceding the procedure - free of chronic conditions - fluent in English Exclusion: - none given N = 100 Age: 3.6 to 12.11 years (mean = 7.4 years, SD = 3.3 months) Gender: M = 62%, F = 38% Diagnosis: none Setting: Ambulatory Care Clinics of a children's hospital in the south central United States
Interventions	1. Distraction (n = 50) 2. Standard Care Control (n = 50)
Outcomes	1. Child self-report of pain using the Wong-Baker FACES Pain Rating Scale (FACES) 2. Investigator ratings of child pain using the Children's Hospital of Eastern Ontario Pain Scale (CHEOPS)
Notes	none
Allocation concealment	A – Adequate

Study	**Wint 2002**
Methods	Allocation: Randomized - no further details
Participants	Needle Procedure: lumbar Puncture Inclusion: - between the ages of ten to 19 years being treated for cancer - receiving LPs as part of therapy and undergoing at least a second LP - all ethnicities, and able to understand and communicate in English - able to hear and see Exclusion: - none given N = 30 Age: ten to 19 years Gender: M = 16, F = 14 Diagnosis: Acute Lymphoblastic Leukemia = 20, B-cell Lymphoma = 1, Lymphoma = 1, T-cell = 2, T-cell ALL = 4, T-cell Lymphoma = 2 Setting: private, in-hospital clinic treatment room within a 322-bed pediatric teaching hospital in the south-west United States
Interventions	1. Virtual Reality Distraction (n = 17) 2. Standard Care Comparison (n = 13)
Outcomes	1. Child/Adolescent self-report of pain using 100 mm vertical VAS

	2. Nurse ratings of child's sedation level following the LP using the Sedation Assessment Scale 3. Investigator developed ten-item questionnaire completed by the children/adolescents to determine their experiences during the LP in both groups, and the subjective experience of the VR glasses by those in the experimental group
Notes	none
Allocation concealment	B – Unclear

Study	**Zabin 1982**
Methods	Allocation: Randomized - no further details
Participants	Needle Procedure: Blood Work (finger capillary puncture) Inclusion: - children with referral for blood work Exclusion: - child in pain at the time of their appearance in the lab - if reason for referral was admission to the hospital - hospitalized children - mentally handicapped and physically disabled children N = 48 Age: six to 11 years Gender: M = 26, F = 22 Diagnosis: none (although common reasons for referral were possible heart murmur, possible seizure activity, and abnormal blood counts) Setting: referral for blood work was made from the Cardiology, Neurology, and Hematology pediatric clinics at West Virginia University Medical Center. The study was conducted in the Blood Laboratory, located in the outpatient clinic area of the hospital
Interventions	1. Distraction (n = 16) 2. Modeling (n = 16) 3. Control condition (n = 16)
Outcomes	1. Child self-reported anxiety on eight-item picture test (higher scores represent greater anxiety) 2. Direct observations of child distress during the procedures by trained observers 3. Technician ratings of child behavioral distress on four-point scale (1 = definitely negative, 4 = definitely positive)
Notes	none
Allocation concealment	B – Unclear

Characteristics of excluded studies

Study	**Reason for exclusion**
Arts 1994	Means or Standard Deviations, or both, not available
Bengston 2002	Means or Standard Deviations, or both, not available
Bowen 1999	Absolute random assignment of participants not achieved
Broome 1998	Multiple baseline design with no control / comparison group
Bruck 1995	Inappropriate outcome measures (assessed memory for pain, not experienced pain)
Carlson 2000	Means or Standard Deviations, or both, not available
Chen 2000b	Means or Standard Deviations, or both, not available
Christiano 1996	Alternating participant assignment to groups.

Dalhquist 2002	Means or Standard Deviations, or both, not available
Fassler 1985	Means or Standard Deviations, or both, not available
Gilbert 1982	Means or Standard Deviations, or both, not available
Goymour 2000	Means or Standard Deviations, or both, not available
Hatava 2000	Surgery
Hawkins 1998	Compared two variations of the same intervention (hypnosis) No control / comparison group
Jay 1987	Means or Standard Deviations, or both, not available
Jay 1990	Inappropriate outcome measures (assessed parent distress, not child distress)
Jay 1991	Compared CBT + Valium versus CBT. Thus assessed the efficacy of Valium, not CBT
Jay 1995	Compared two interventions. No control / comparison group
Kazak 1996	Means or Standard Deviations, or both, not available
Kazak 1998	Means or Standard Deviations, or both, not available
Klorman 1980	Participant assignment to groups not described. More invasive dental procedures
Kolk 2000	Inappropriate control/comparison group (Treatment group received Preparation + EMLA; Control group did not receive EMLA)
Kuttner 1988	Means or Standard Deviations, or both, not available
Kwekkeboom 2003	Adult participants
Lustman 1983	Surgery
MacLaren 2005	Alternating participant assignment to groups
Malone 1996	Means or Standard Deviations, or both, not available
Manimala 2000	Alternating participant assignment to groups Means or Standard Deviations, or both, not available
Manne 1990	Alternating participant assignment to groups
Manne 1994	Alternating participant assignment to groups Means or Standard Deviations, or both, not available
McCarthy 1998	Control/comparison group contaminated
Megel 1998	Means or Standard Deviations, or both, not available
Melamed 1974	More invasive dental procedures: No specific needle procedure identified
O'Laughlin 1995	Means or Standard Deviations, or both, not available
Olsen 1991	Non-random participant assignment to groups
Pederson 1996	Number under ten (n = 4 per group) Participant assignment to groups not described Means or Standard Deviations, or both, not available
Peretz 1999	Means or Standard Deviations, or both, not available
Powers 1993	Not a randomized controlled trial (N = 4)
Reeb 1997	Means or Standard Deviations, or both, not available
Santos 1999	Participant assignment to groups not described Means or Standard Deviations, or both, not available
Schur 1986	Non-random participant assignment to conditions (all children received the control condition first)
Smith 1989	Compared two interventions. No control / comparison group
Smith 1996	Compared two interventions. No control / comparison group
Sparks 2001	Alternating participant assignment to groups

Characteristics of excluded studies (*Continued*)

Vernon 1974	Means and/or Standard Deviations not available
Wall 1989	Compared two interventions No control/comparison group
Weinstein 2003	Participants didn't undergo the needle procedures themselves; they watched them occur on a video
Winborn 1989	Dental procedures included minor surgery
Wood 2002	Not a randomized controlled trial (quasi-experimental design)
Young 1988	Means or Standard Deviations, or both, not available
Zeltzer 1982	Means or Standard Deviations, or both, not available

ADDITIONAL TABLES

Table 01. Definitions of Medical Procedures

Procedure	Definition
Immunization (also known as immunisation)	Protection against a particular disease or treatment of an organism by protecting against certain pathogen attacks; the introduction of microorganisms that have previously been treated to make them harmless.
Venipuncture (also known as venepuncture)	The surgical puncture of a vein typically for withdrawing blood or administering intravenous medication.
Finger prick/pin	Obtaining blood by puncturing the tip of the finger.
Injection	The act of forcing a liquid into tissue, the vascular tree, or an organ.
Subcutaneous injection	Injection administered under the skin.
Intramuscular injection	Injection administered by entering a muscle.
Lumbar punctures (LP) (also know as spinal tap)	The withdrawal of cerebrospinal fluid or the injection of anesthesia by puncturing the subarachnoid space located in the lumbar region of the spinal cord.
Bone marrow aspiration (BMA)	The bone marrow is the tissue that manufactures the blood cells and is in the hollow part of most bones. This test is done by suctioning some of the bone marrow for examination.
Bone marrow biopsy (BMB)	The removal and examination of tissue, cells, or fluids from the bone marrow of a living body; usually performed at the same time as a BMA.
IV/Catheter insertion	A narrow short, flexible, synthetic (usually plastic) tube known as a catheter, that is inserted approximately one inch into a vein to provide temporary intravenous access for the administration of fluid, medication, or nutrients.
Central line (also known as central venous catheter)	Insertion of a catheter into the large vein above the heart, usually the subclavian vein, through which access to the blood stream can be made. This allows drugs and blood products to be given and blood samples withdrawn.
Suture (also know as laceration repair)	A stitch made with a strand or fiber used to sew parts of the living body.
Accessing a portacath (also known as a port)	Insertion of a needle into an implanted access device (portacath) which facilitates the drawing of blood and intravenous (or intra-arterial) injections by not having to locate and insert a canula into a new vessel. Some ports are connected for intrathecal, intraperitoneal or intracavitary injections.
Arterial puncture	A hole, wound, or perforation of an artery made by puncturing.

Table 01. Definitions of Medical Procedures (*Continued*)

Procedure	Definition
Arterial blood gas (ABG)	A test which analyses arterial blood for oxygen, carbon dioxide and bicarbonate content in addition to blood pH. Used to test the effectiveness of respiration.
Arterial line (also known as intra-arterial catheter)	Insertion of a catheter into an artery.
Thoracocentesis (also called thoracentesis)	Aspiration of fluid from the chest.
Paracentesis	A surgical puncture of a bodily cavity (e.g., abdomen) with a trocar, aspirator, or other instrument usually to draw off an abnormal effusion for diagnostic or therapeutic purposes.

Table 02. Distraction

Outcome	Studies	N	Heterogeneity	SMD-random
Self-reported pain**	9	634	P = 0.12, n.sig.	-0.24 [-0.45 to -0.04]
Observer-reported pain	1	94	n/a	0.07 [-0.33 to 0.48]
Self-reported distress	3	190	P = 0.34, n.sig.	0.00 [-0.30 to 0.31]
Observer-reported distress	4	144	P = 0.26, n.sig.	-0.09 [-0.47 to 0.29]
Behavioral pain	2	152	P = 0.10, n.sig.	-0.15 [-0.69 to 0.40]
Behavioral distress	3	88	P = 0.05, sig.*	-0.05 [-0.82 to 0.73]
Physiological measures	---	---	---	---

Table 03. Information / Preparation

Outcome	Studies	N	Heterogeneity	SMD-random
Self-reported pain	2	154	P= 0.003, sig.*	-0.22 [-1.20 to 0.76]
Observer-reported pain **	1	100	n/a	-0.77 [-1.17 to -0.36]
Self-reported distress	---	---	---	---
Observer-reported distress	2	154	P= 0.03, sig.*	-0.15 [-0.88 to 0.57]
Behavioral pain	---	---	---	---
Behavioral distress	1	54	n/a	0.24 [-0.30 to 0.78]
Physiological measures (Pulse Rate) **	1	100	n/a	-0.47 [-0.87 to -0.07]

Table 04. Hypnosis

Outcome	Studies	N	Heterogeneity	SMD-random
Self-reported pain **	4	146	P < 0.00001, sig.*	-1.47 [-2.67 to -0.27]
Observer-reported pain	---	---	---	---

Table 04. Hypnosis (*Continued*)

Outcome	Studies	N	Heterogeneity	SMD-random
Self-reported distress **	4	146	P < 0.00001, sig.*	-2.20 [-3.69 to -0.71]
Observer-reported distress	1	36	n/a	-0.39 [-1.05 to 0.27]
Behavioral pain	---	---	---	---
Behavioral distress **	5	163	P = 0.003, sig.*	-1.07 [-1.79 to -0.35]
Physiological measures	---	---	---	---

Table 05. Virtual Reality

Outcome	Studies	N	Heterogeneity	SMD-random
Self-reported pain	1	30	n/a	-0.29 [-1.02 to 0.43]
Observer-reported pain	---	---	---	---
Self-reported distress	---	---	---	---
Observer-reported distress	---	---	---	---
Behavioral pain	---	---	---	---
Behavioral distress	---	---	---	---
Physiological measures	---	---	---	---

Table 06. Memory Alteration

Outcome	Studies	N	Heterogeneity	SMD-random
Self-reported pain	1	24	n/a	-0.01 [-0.84 to 0.82]
Observer-reported pain	1	42	n/a	0.20 [-0.41 to 0.80]
Self-reported distress	---	---	---	---
Observer-reported distress	1	50	n/a	0.13 [-0.43 to 0.68]
Behavioral pain	---	---	---	---
Behavioral distress	1	50	n/a	-0.05 [-0.60 to 0.51]
Physiological measures (Heart rate)	1	44	n/a	-0.20 [-0.40 to 0.79]
Physiological measures (Cortisol)	1	44	n/a	0.00 [-0.59 to 0.59]
Physiological measures (Systolic BP)	1	42	n/a	0.47 [-0.15 to 1.09]
Physiological measures (Diastolic BP) **	1	42	n/a	-0.65 [-1.27 to -0.02]

Table 07. Combined Cognitive-Behavioural Intervention

Outcome	Studies	N	Heterogeneity	SMD-random
Self-reported pain	5	217	P < 0.00001, sig.*	-0.87 [-1.90 to 0.16]
Observer-reported pain	2	81	P = 0.40, n.sig.	-0.10 [-0.54 to 0.34]
Self-reported distress	4	156	P < 0.0001, sig.*	-0.75 [-1.75 to 0.25]
Observer-reported distress **	4	197	P = 0.004, sig.*	-0.88 [-1.65 to -0.12]
Behavioral pain	---	---	---	---
Behavioral distress **	6	277	P = 0.25, n.sig.	-0.67 [-0.95 to -0.38]
Physiological measures (Heart Rate)	1	20	n/a	-0.62 [-1.52 to 0.28]

Table 08. Nurse Coaching + Distraction

Outcome	Studies	N	Heterogeneity	SMD-random
Self-reported pain	2	138	P < 0.00001, sig.*	-1.13 [-3.52 to 1.25]
Observer-reported pain	1	78	n/a	0.07 [-0.38 to 0.51]
Self-reported distress	1	78	n/a	0.08 [-0.36 to 0.53]
Observer-reported distress	2	138	P < 0.00001, sig.*	-0.79 [-2.73 to 1.14]
Behavioral pain	---	---	---	---
Behavioral distress **	2	138	P = 0.83, n.sig.	-0.53 [-0.87 to -0.19]
Physiological measures (Heart Rate)	1	78	n/a	-0.15 [-0.59 to 0.29]

Table 09. Parent Coaching + Distraction

Outcome	Studies	N	Heterogeneity	SMD-random
Self-reported pain	1	44	n/a	0.31 [-0.28 to 0.91]
Observer-reported pain	---	---	---	---
Self-reported distress	---	---	---	---
Observer-reported distress	1	44	n/a	0.22 [-0.38 to 0.81]
Behavioral pain	---	---	---	---
Behavioral distress	2	104	P = 0.02, sig.*	-0.58 [-1.48 to 0.32]
Physiological measures	---	---	---	---

Table 10. Parent Positioning + Distraction

Outcome	Studies	N	Heterogeneity	SMD-random
Self-reported pain	1	43	n/a	-0.25 [-0.85 to 0.35]
Observer-reported pain	---	---	---	---
Self-reported distress	1	43	n/a	-0.32 [-0.92 to 0.29]
Observer-reported distress **	1	43	n/a	-0.70 [-1.32 to -0.08]
Behavioral pain	---	---	---	---
Behavioral distress	1	43	n/a	-0.32 [-0.92 to 0.29]
Physiological measures	---	---	---	---

Table 11. Videotape Modeling + Parent Coaching

Outcome	Studies	N	Heterogeneity	SMD-random
Self-reported pain	---	---	---	---
Observer-reported pain	---	---	---	---
Self-reported distress	---	---	---	---
Observer-reported distress	1	50	n/a	-0.54 [-1.11 to 0.02]
Behavioral pain	---	---	---	---
Behavioral distress	---	---	---	---
Physiological measures	---	---	---	---

Table 12. Suggestion

Outcome	Studies	N	Heterogeneity	SMD-random
Self-reported pain	3	238	P = 0.19, n.sig.	-0.20 [-0.55 to 0.15]
Observer-reported pain	1	78	n/a	-0.40 [-0.85 to 0.05]
Self-reported distress	1	78	n/a	-0.33 [-0.78 to 0.12]
Observer-reported distress	1	40	n/a	0.00 [-0.62 to 0.62]
Behavioral pain	---	---	---	---
Behavioral distress	---	---	---	---
Physiological measures	---	---	---	---

Table 13. Blowing Out Air

Outcome	Studies	N	Heterogeneity	SMD-random
Self-reported pain	1	75	n/a	-0.38 [-0.84 to 0.08]
Observer-reported pain	---	---	---	---
Self-reported distress	---	---	---	---
Observer-reported distress	---	---	---	---
Behavioral pain	---	---	---	---
Behavioral distress	1	75	n/a	-0.32 [-0.77 to 0.14]
Physiological measures	---	---	---	---

Table 14. Distraction + Suggestion

Outcome	Studies	N	Heterogeneity	SMD-random
Self-reported pain **	1	120	n/a	-0.64 [-1.03 to -0.25]
Observer-reported pain	---	---	---	---
Self-reported distress	---	---	---	---
Observer-reported distress	---	---	---	---
Behavioral pain	---	---	---	---
Behavioral distress	---	---	---	---
Physiological measures	---	---	---	---

Table 15. Filmed Modeling

Outcome	Studies	N	Heterogeneity	SMD-random
Self-reported pain	---	---	---	---
Observer-reported pain	---	---	---	---
Self-reported distress	1	32	n/a	-0.03 [-0.73 to 0.66]
Observer-reported distress	1	32	n/a	0.10 [-0.59 to 0.80]
Behavioral pain	---	---	---	---
Behavioral distress	---	---	---	---
Physiological measures	---	---	---	---

Table 16. Sensitivity Analyses - Distraction

Outcome	Studies	N	Heterogeneity	SMD-random
Self-reported pain 1 **	9	634	P= 0.12, n.sig.	-0.24 [-0.45 to -0.04]
Self-reported pain 2 **	10	733	P= 0.12 , n.sig.	-0.28 [-0.47 to -0.09]
Observer-reported pain 1	1	94	n/a	0.07 [-0.33 to 0.48]
Observer-reported pain 2	---	---	---	---
Self-reported distress 1	3	190	P= 0.34, n.sig. P= 0.34, n.sig. P= 0.34, n.sig.	0.00 [-0.30 to 0.31]
Self-reported distress 2	5	348	P= 0.27, n.sig.	-0.08 [-0.33 to 0.17]
Observer-reported distress 1	4	144	P= 0.26, n.sig.	-0.09 [-0.47 to 0.29]
Observer-reported distress 2	5	226	P= 0.40 , n.sig.	-0.11 [-0.38 to 0.16]
Behavioral pain 1	2	152	P= 0.10, n.sig.	-0.15 [-0.69 to 0.40] - 0.05 [-0.82, 0.73] - 0.05 [-0.82, 0.73]
Behavioral pain 2	---	---	---	---
Behavioral distress 1	3	88	P= 0.05, sig.*	-0.05 [-0.82 to 0.73]
Behavioral distress 2	4	166	P= 0.12, n.sig.	-0.09 [-0.56 to 0.38]
Physiological measures 1	---	---	---	---
Physiological measures 2	---	---	---	---

Table 17. Sensitivity Analyse s- Information / Preparation

Outcome	Studies	N	Heterogeneity	SMD-random
Self-reported pain 1	2	154	P= 0.003, sig.*	-0.22 [-1.20 to 0.76]
Self-reported pain 2	---	---	---	---
Observer-reported pain 1 **	1	100	n/a	-0.77 [-1.17 to -0.36]
Observer-reported pain 2	---	---	---	---
Self-reported distress 1	---	---	---	---
Self-reported distress 2	1	41	n/a	0.12 [-0.49 to 0.74]
Observer-reported distress 1	2	154	P= 0.03, sig.*	-0.15 [-0.88 to 0.57]
Observer-reported distress 2	---	---	---	---
Behavioral pain 1	---	---	---	---
Behavioral pain 2	---	---	---	---

Table 17. Sensitivity Analyse s- Information / Preparation (*Continued*)

Outcome	Studies	N	Heterogeneity	SMD-random
Behavioral distress 1	1	54	n/a	0.24 [-0.30 to 0.78]
Behavioral distress 2	---	---	---	---
Physiological measures 1 **	1	100	n/a	-0.47 [-0.87 to -0.07]
Physiological measures 2	---	---	---	---

Table 18. Sensitivity Analyses - Distraction + Breathing + Positive Reinforcement

Outcome	Studies	N	Heterogeneity	SMD-random
Self-reported pain 1	---	---	---	---
Self-reported pain 2 **	1	23	n/a	-1.32 [-2.25 to -0.40]
Observer-reported pain 1	---	---	---	---
Observer-reported pain 2	1	23	n/a	-0.66 [-1.51 to 0.19]
Self-reported distress 1	---	---	---	---
Self-reported distress 2	---	---	---	---
Observer-reported distress 1	---	---	---	---
Observer-reported distress 2	1	23	n/a	-0.75 [-1.61 to 0.11]
Behavioral pain 1	---	---	---	---
Behavioral pain 2	---	---	---	---
Behavioral distress 1	---	---	---	---
Behavioral distress 2	1	23	n/a	-0.64 [-1.48 to 0.21]
Physiological measures 1	---	---	---	---
Physiological measures 2	---	---	---	---

Table 19. Sensitivity Analyses - Combined Cognitive-Behavioral Intervention

Outcome	Studies	N	Heterogeneity	SMD-random
Self-reported pain 1	5	217	P < 0.00001, sig.*	-0.87 [-1.90 to 0.16]
Self-reported pain 2	---	---	---	---
Observer-reported pain 1	2	81	P = 0.40, n.sig.	-0.10 [-0.54 to 0.34]
Observer-reported pain 2	---	---	---	---
Self-reported distress 1	4	156	P < 0.0001, sig.*	-0.75 [-1.75 to 0.25]
Self-reported distress 2	5	196	P = 0.0001, sig.*	-0.58 [-1.33 to 0.16]
Observer-reported distress 1 **	4	197	P = 0.004, sig.*	-0.88 [-1.65 to -0.12]

Table 19. Sensitivity Analyses - Combined Cognitive-Behavioral Intervention (*Continued*)

Outcome	Studies	N	Heterogeneity	SMD-random
Observer-reported distress 2	---	---	---	---
Behavioral pain 1	---	---	---	---
Behavioral pain 2	---	---	---	---
Behavioral distress 1 **	6	277	P = 0.25, n.sig.	-0.67 [-0.95 to -0.38]
Behavioral distress 2	---	---	---	---
Physiological measures 1	1	20	n/a	-0.62 [-1.52 to 0.28]
Physiological measures 2	---	---	---	---

ANALYSES

Comparison 01. Distraction

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Self-reported pain	9	634	Standardised Mean Difference (Random) 95% CI	-0.24 [-0.45, -0.04]
02 Observer-reported pain			Standardised Mean Difference (Random) 95% CI	Totals not selected
03 Self-reported distress	3	190	Standardised Mean Difference (Random) 95% CI	0.00 [-0.30, 0.31]
04 Observer-reported distress	4	144	Standardised Mean Difference (Random) 95% CI	-0.09 [-0.47, 0.29]
05 Behavioral measures- Pain	2	152	Standardised Mean Difference (Random) 95% CI	-0.15 [-0.69, 0.40]
06 Behavioral measures- Distress	3	88	Standardised Mean Difference (Random) 95% CI	-0.05 [-0.82, 0.73]

Comparison 02. Preparation/Information

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Self-reported pain	2	154	Standardised Mean Difference (Random) 95% CI	-0.22 [-1.20, 0.76]
02 Observer-reported pain			Standardised Mean Difference (Random) 95% CI	Totals not selected
03 Observer-reported distress	2	154	Standardised Mean Difference (Random) 95% CI	-0.15 [-0.88, 0.57]
04 Behavioral measures- Distress			Standardised Mean Difference (Random) 95% CI	Totals not selected
05 Physiology- Pulse Rate			Standardised Mean Difference (Random) 95% CI	Totals not selected

Comparison 03. Hypnosis

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Self-reported pain	4	146	Standardised Mean Difference (Random) 95% CI	-1.47 [-2.67, -0.27]
02 Self-reported distress	4	146	Standardised Mean Difference (Random) 95% CI	-2.20 [-3.69, -0.71]
03 Observer-reported distress			Standardised Mean Difference (Random) 95% CI	Totals not selected
04 Behavioral measures- Distress	5	163	Standardised Mean Difference (Random) 95% CI	-1.07 [-1.79, -0.35]

Comparison 04. Virtual Reality

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Self-reported pain			Standardised Mean Difference (Random) 95% CI	Totals not selected

Comparison 05. Memory Alteration

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Self-reported pain (during procedure change score)			Standardised Mean Difference (Random) 95% CI	Totals not selected
02 Observer-reported pain (during procedure change score)			Standardised Mean Difference (Random) 95% CI	Totals not selected
03 Observer-reported distress (during procedure change score)			Standardised Mean Difference (Random) 95% CI	Totals not selected
04 Behavioral measures- Distress (during procedure change score)			Standardised Mean Difference (Random) 95% CI	Totals not selected
05 Physiology- Heart rate (during procedure change scores)			Standardised Mean Difference (Random) 95% CI	Totals not selected
06 Physiology- Cortisol (during procedure change score)			Standardised Mean Difference (Random) 95% CI	Totals not selected
07 Physiology- Systolic Blood Pressure (during procedure change score)			Standardised Mean Difference (Random) 95% CI	Totals not selected
08 Physiology- Diastolic Blood Pressure (during procedure change score)			Standardised Mean Difference (Random) 95% CI	Totals not selected

Comparison 06. CBT-Combined

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Self-reported pain	5	217	Standardised Mean Difference (Random) 95% CI	-0.87 [-1.90, 0.16]
02 Observer-reported pain	2	81	Standardised Mean Difference (Random) 95% CI	-0.10 [-0.54, 0.34]
03 Self-reported distress	4	156	Standardised Mean Difference (Random) 95% CI	-0.75 [-1.75, 0.25]
04 Observer-reported distress	4	197	Standardised Mean Difference (Random) 95% CI	-0.88 [-1.65, -0.12]
05 Behavioral measures- Distress	6	277	Standardised Mean Difference (Random) 95% CI	-0.67 [-0.95, -0.38]
06 Physiology- Heart Rate			Standardised Mean Difference (Random) 95% CI	Totals not selected

Comparison 07. Nurse Coaching + Distraction

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Self-reported pain	2	138	Standardised Mean Difference (Random) 95% CI	-1.13 [-3.52, 1.25]
02 Observer-reported pain			Standardised Mean Difference (Random) 95% CI	Totals not selected
03 Self-reported distress			Standardised Mean Difference (Random) 95% CI	Totals not selected
04 Observer-reported distress	2	138	Standardised Mean Difference (Random) 95% CI	-0.79 [-2.73, 1.14]
05 Behavioral measures- Distress	2	138	Standardised Mean Difference (Random) 95% CI	-0.53 [-0.87, -0.19]
06 Physiology- Heart Rate			Standardised Mean Difference (Random) 95% CI	Totals not selected

Comparison 08. Parent Coaching + Distraction

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Self-reported pain			Standardised Mean Difference (Random) 95% CI	Totals not selected
02 Observer-reported Distress			Standardised Mean Difference (Random) 95% CI	Totals not selected
03 Behavioral measures- Distress	2	104	Standardised Mean Difference (Random) 95% CI	-0.58 [-1.48, 0.32]

Comparison 09. Parent Positioning + Child Distraction

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Self-reported pain			Standardised Mean Difference (Random) 95% CI	Totals not selected
02 Self-reported distress			Standardised Mean Difference (Random) 95% CI	Totals not selected
03 Observer-reported distress			Standardised Mean Difference (Random) 95% CI	Totals not selected
04 Behavioral measures- Distress			Standardised Mean Difference (Random) 95% CI	Totals not selected

Comparison 10. Videotape Modeling + Parent Coaching

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Observer-reported distress			Standardised Mean Difference (Random) 95% CI	Totals not selected

Comparison 11. Suggestion

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Self-reported pain	3	238	Standardised Mean Difference (Random) 95% CI	-0.20 [-0.55, 0.15]
02 Observer-reported pain			Standardised Mean Difference (Random) 95% CI	Totals not selected
03 Self-reported distress			Standardised Mean Difference (Random) 95% CI	Totals not selected
04 Observer-reported distress			Standardised Mean Difference (Random) 95% CI	Totals not selected

Comparison 12. Blowing Out Air

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Self-reported Pain			Standardised Mean Difference (Random) 95% CI	Totals not selected
02 Behavioral measures- Distress			Standardised Mean Difference (Random) 95% CI	Totals not selected

Comparison 13. Distraction + Suggestion

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Self-reported Pain			Standardised Mean Difference (Random) 95% CI	Totals not selected

Comparison 14. Filmed Modeling

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Self-reported distress			Standardised Mean Difference (Random) 95% CI	Totals not selected
02 Observer-reported distress			Standardised Mean Difference (Random) 95% CI	Totals not selected

INDEX TERMS

Medical Subject Headings (MeSH)

Adolescent; Anxiety [*prevention & control; psychology]; Cognitive Therapy [*methods]; Hypnosis; *Needles; Pain [*prevention & control; psychology]; Punctures [*psychology]; Randomized Controlled Trials

MeSH check words

Adult; Child; Child, Preschool; Humans

COVER SHEET

Title	Psychological interventions for needle-related procedural pain and distress in children and adolescents
Authors	Uman LS, Chambers CT, McGrath PJ, Kisely S
Contribution of author(s)	Lindsay Uman undertook the administration of the review, protocol development, study searching, study retrieval, study selection, data extraction, data entry, statistical analyses, and report writing. Christine Chambers provided pediatric and pain management expertise, assisted with protocol development, study selection, interpretation of results, and report editing. Patrick McGrath provided pediatric and pain management expertise, assisted with protocol development, study selection, and report editing. Stephen Kisely provided expertise in conducting systematic reviews, statistical analyses, protocol development, reporting results, and report editing.
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Date new studies found but not yet included/excluded	Information not supplied by author
Date new studies found and included/excluded	Information not supplied by author
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GRAPHS AND OTHER TABLES

Analysis 01.01. Comparison 01 Distraction, Outcome 01 Self-reported pain

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

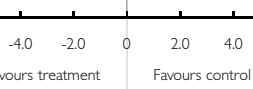
Comparison: 01 Distraction

Outcome: 01 Self-reported pain

Study	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Standardised Mean Difference (Random) 95% CI	Weight (%)	Standardised Mean Difference (Random) 95% CI
Cassidy 2002	31	1.36 (1.39)	28	2.03 (1.90)		10.6	-0.40 [-0.92, 0.12]
Cavender 2004	20	2.30 (1.87)	20	2.74 (1.63)		8.1	-0.25 [-0.87, 0.38]
Fanurik 2000	53	22.60 (24.03)	56	27.29 (29.27)		15.2	-0.17 [-0.55, 0.20]
Fowler-Kerry 1987	40	1.34 (1.14)	80	1.78 (1.14)		15.0	-0.38 [-0.77, 0.00]
Gonzalez 1993	14	2.86 (1.61)	14	3.29 (1.44)		6.2	-0.27 [-1.02, 0.47]
Kleiber 2001	22	3.24 (1.95)	22	2.70 (1.40)		8.7	0.31 [-0.28, 0.91]
Press 2003	48	2.80 (2.00)	46	3.80 (2.90)		14.0	-0.40 [-0.81, 0.01]
Tak 2005	20	2.58 (1.89)	20	1.85 (1.18)		8.0	0.45 [-0.17, 1.08]
Vessey 1994	50	2.18 (1.61)	50	3.23 (1.78)		14.2	-0.61 [-1.02, -0.21]
Total (95% CI)	298		336			100.0	-0.24 [-0.45, -0.04]

Test for heterogeneity chi-square=12.83 df=8 p=0.12 I^2 =37.6%

Test for overall effect z=2.29 p=0.02

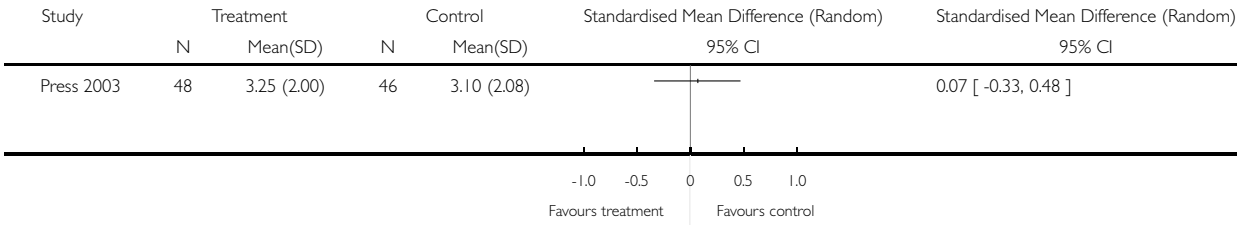


Analysis 01.02. Comparison 01 Distraction, Outcome 02 Observer-reported pain

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 01 Distraction

Outcome: 02 Observer-reported pain

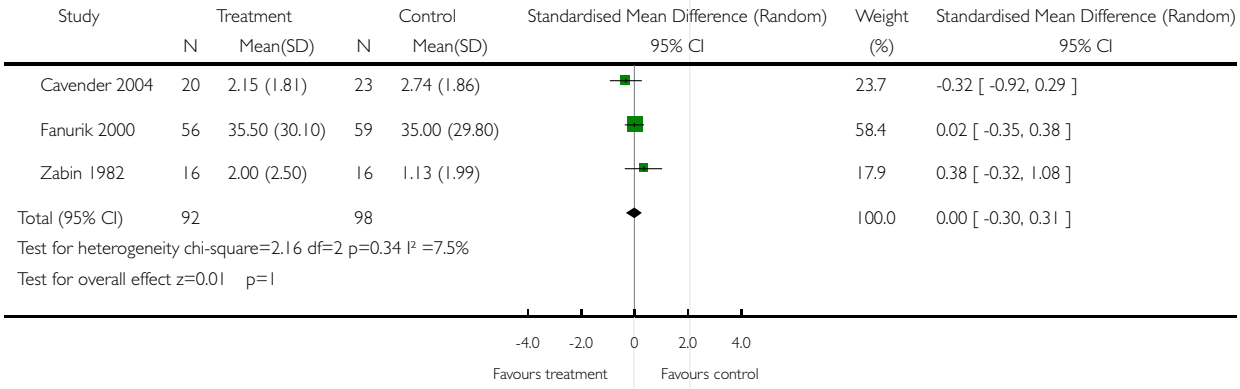


Analysis 01.03. Comparison 01 Distraction, Outcome 03 Self-reported distress

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 01 Distraction

Outcome: 03 Self-reported distress

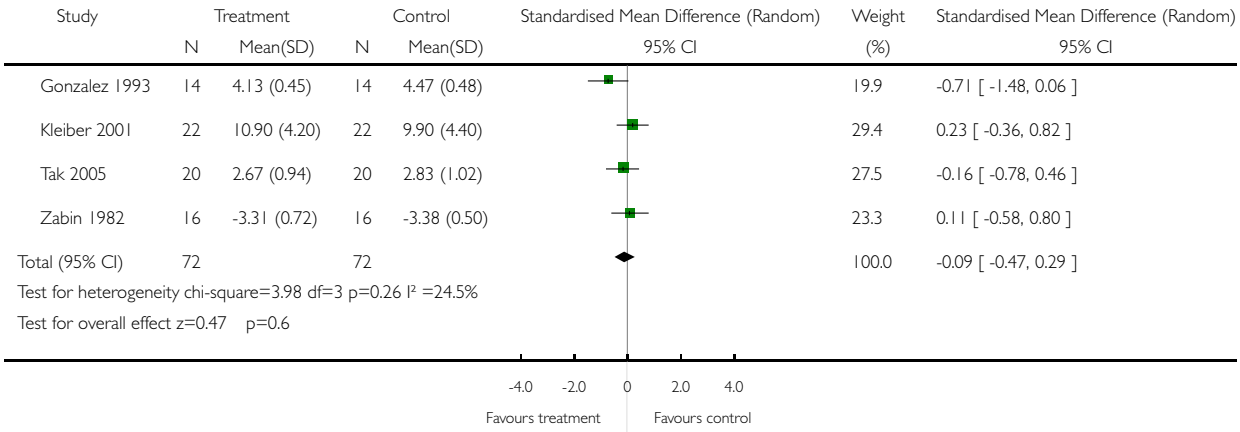


Analysis 01.04. Comparison 01 Distraction, Outcome 04 Observer-reported distress

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 01 Distraction

Outcome: 04 Observer-reported distress

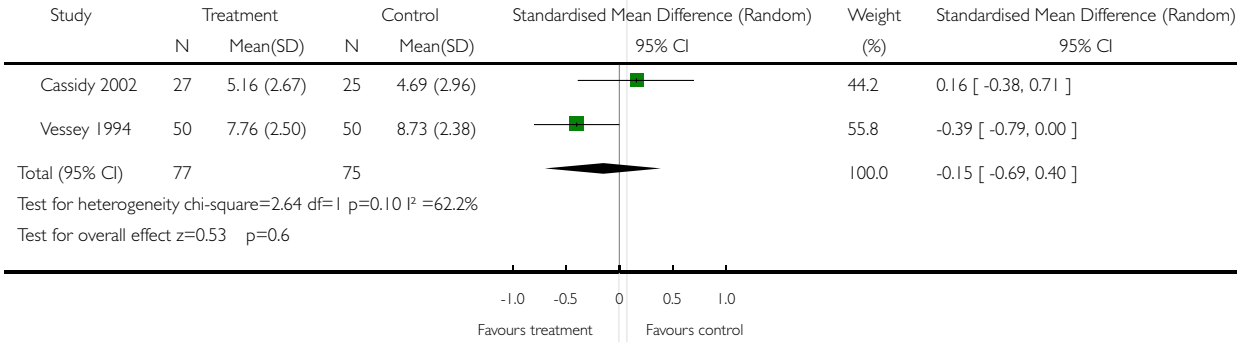


Analysis 01.05. Comparison 01 Distraction, Outcome 05 Behavioral measures- Pain

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 01 Distraction

Outcome: 05 Behavioral measures- Pain

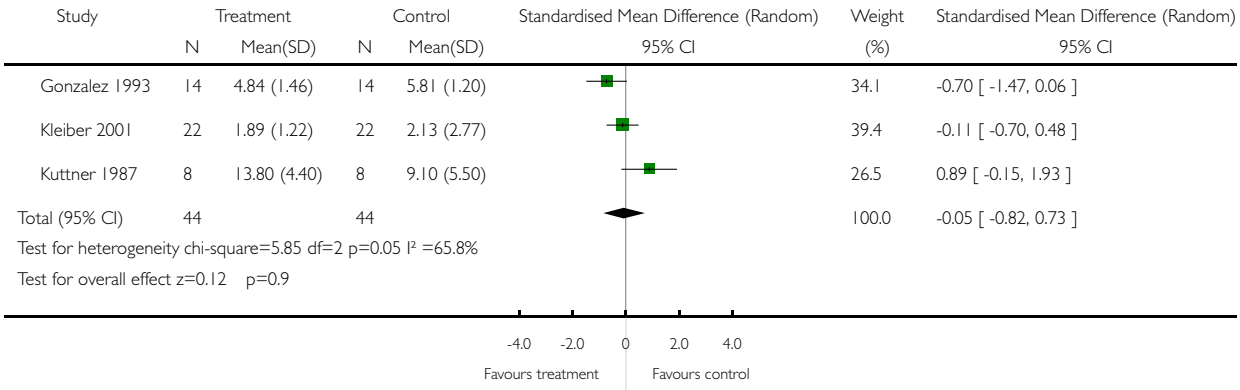


Analysis 01.06. Comparison 01 Distraction, Outcome 06 Behavioral measures- Distress

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 01 Distraction

Outcome: 06 Behavioral measures- Distress

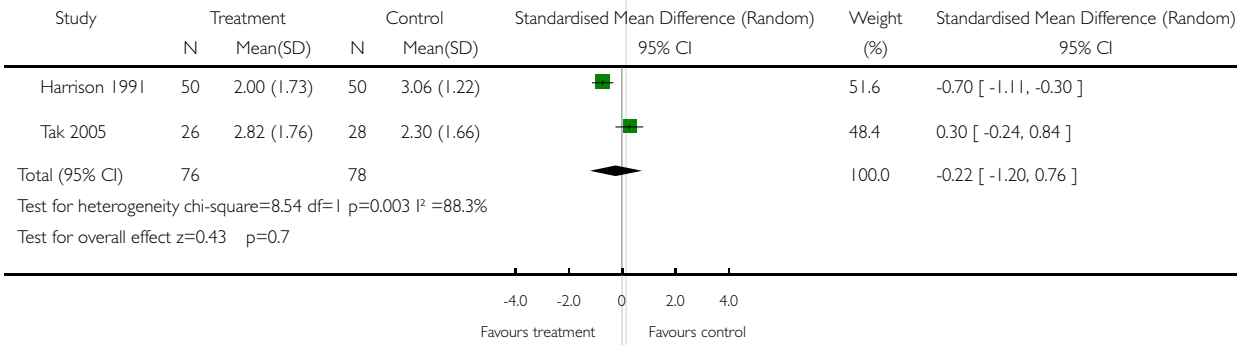


Analysis 02.01. Comparison 02 Preparation/Information, Outcome 01 Self-reported pain

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 02 Preparation/Information

Outcome: 01 Self-reported pain

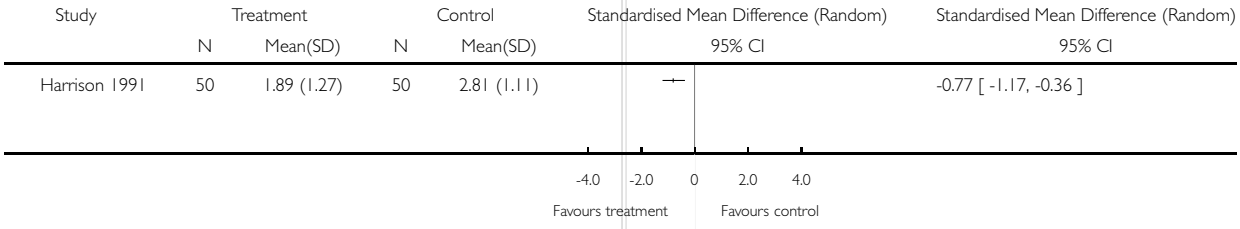


Analysis 02.02. Comparison 02 Preparation/Information, Outcome 02 Observer-reported pain

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 02 Preparation/Information

Outcome: 02 Observer-reported pain

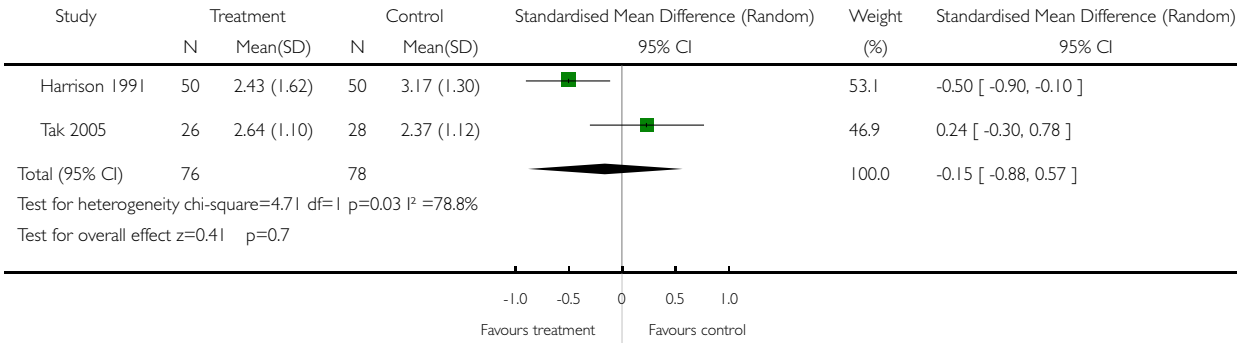


Analysis 02.03. Comparison 02 Preparation/Information, Outcome 03 Observer-reported distress

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 02 Preparation/Information

Outcome: 03 Observer-reported distress

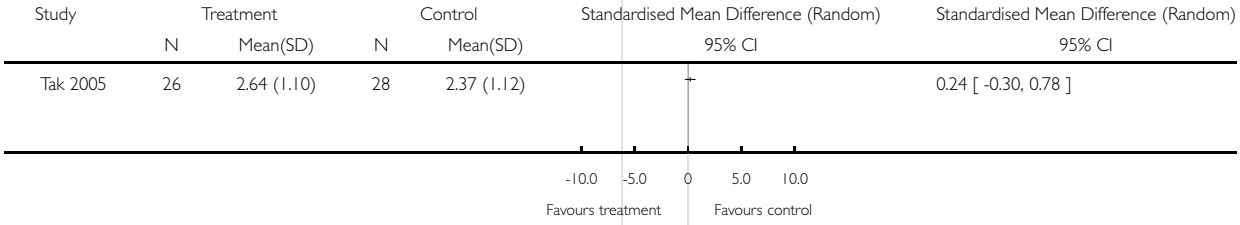


Analysis 02.04. Comparison 02 Preparation/Information, Outcome 04 Behavioral measures- Distress

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 02 Preparation/Information

Outcome: 04 Behavioral measures- Distress



Analysis 02.05. Comparison 02 Preparation/Information, Outcome 05 Physiology- Pulse Rate

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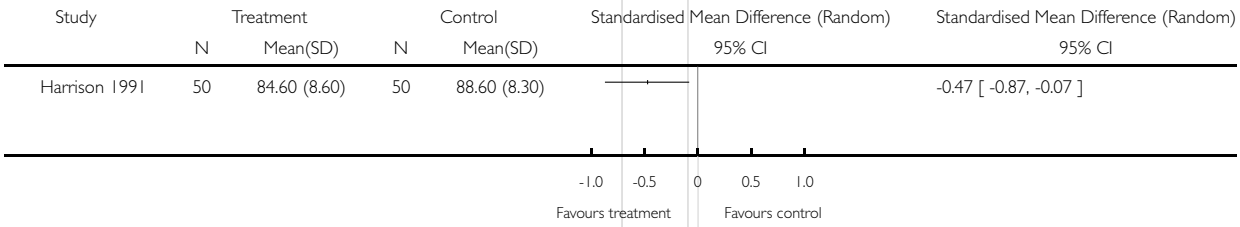
Comparison: 02 Preparation/Information

Outcome: 05 Physiology- Pulse Rate

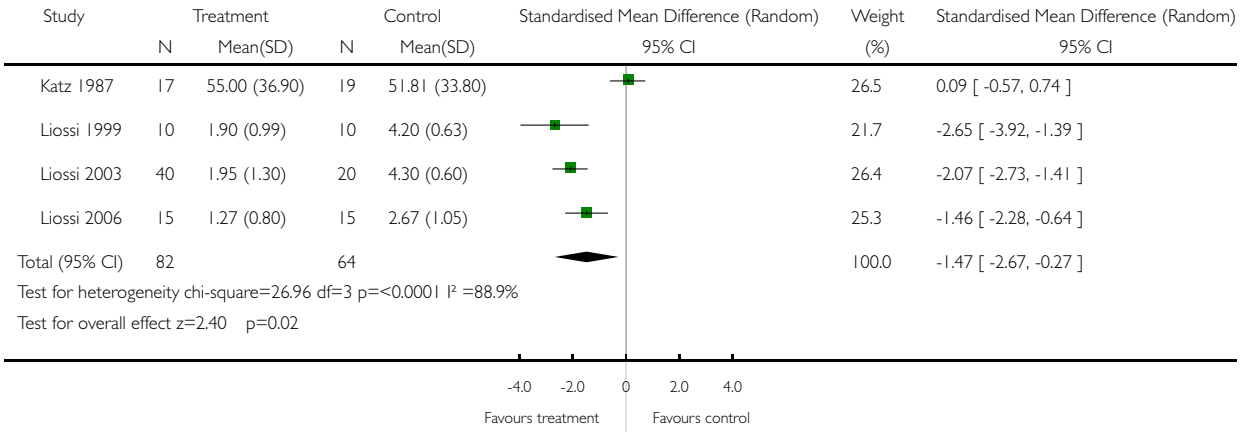


Analysis 03.01. Comparison 03 Hypnosis, Outcome 01 Self-reported pain

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 03 Hypnosis

Outcome: 01 Self-reported pain

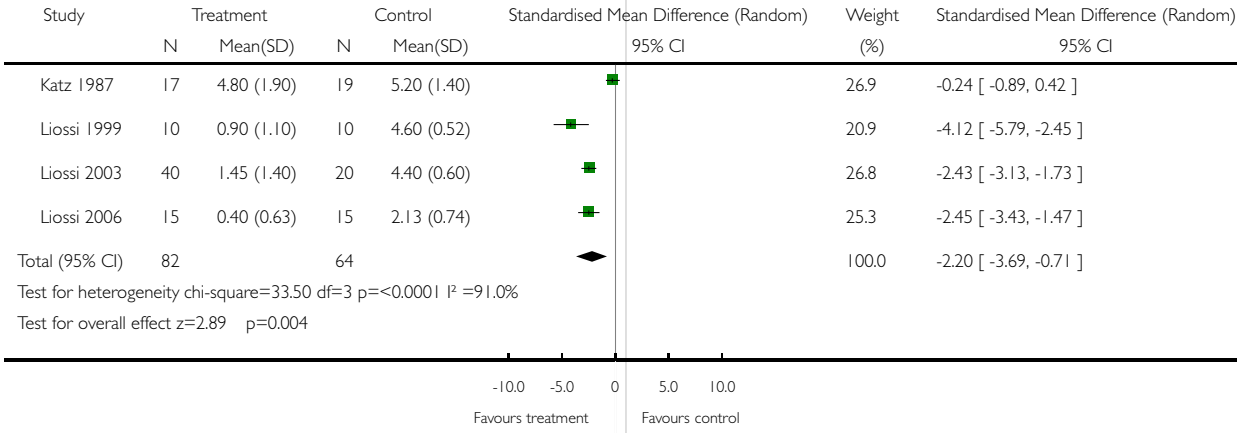


Analysis 03.02. Comparison 03 Hypnosis, Outcome 02 Self-reported distress

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 03 Hypnosis

Outcome: 02 Self-reported distress

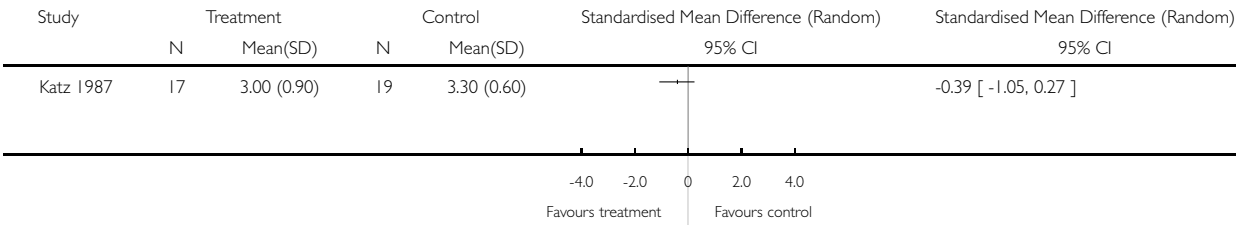


Analysis 03.03. Comparison 03 Hypnosis, Outcome 03 Observer-reported distress

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 03 Hypnosis

Outcome: 03 Observer-reported distress



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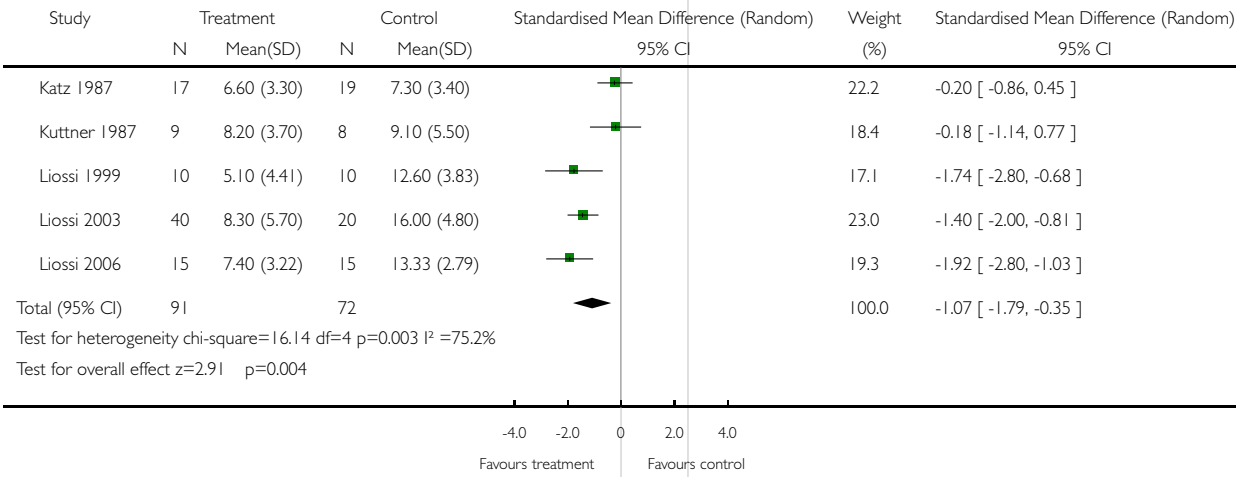
Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 03 Hypnosis

Outcome: 04 Behavioral measures- Distress

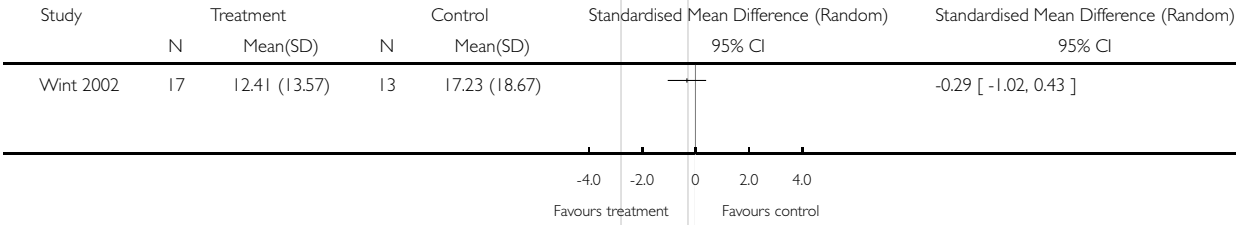


Analysis 04.01. Comparison 04 Virtual Reality, Outcome 01 Self-reported pain

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 04 Virtual Reality

Outcome: 01 Self-reported pain



Analysis 05.01. Comparison 05 Memory Alteration, Outcome 01 Self-reported pain (during procedure change score)

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 05 Memory Alteration

Outcome: 01 Self-reported pain (during procedure change score)

Study	Treatment		Control		Standardised Mean Difference (Random)	Standardised Mean Difference (Random)
	N	Mean(SD)	N	Mean(SD)	95% CI	95% CI
Chen 1999	15	-0.06 (3.90)	9	-0.02 (3.20)		-0.01 [-0.84, 0.82]

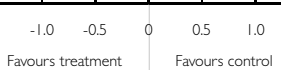
Analysis 05.02. Comparison 05 Memory Alteration, Outcome 02 Observer-reported pain (during procedure change score)

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 05 Memory Alteration

Outcome: 02 Observer-reported pain (during procedure change score)

Study	Treatment		Control		Standardised Mean Difference (Random)	Standardised Mean Difference (Random)
	N	Mean(SD)	N	Mean(SD)	95% CI	95% CI
Chen 1999	20	0.40 (3.10)	22	-0.10 (1.80)		0.20 [-0.41, 0.80]



Analysis 05.03. Comparison 05 Memory Alteration, Outcome 03 Observer-reported distress (during procedure change score)

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 05 Memory Alteration

Outcome: 03 Observer-reported distress (during procedure change score)

Study	Treatment		Control		Standardised Mean Difference (Random)	Standardised Mean Difference (Random)
	N	Mean(SD)	N	Mean(SD)	95% CI	95% CI
Chen 1999	25	-0.20 (2.60)	25	-0.50 (1.90)		0.13 [-0.43, 0.68]

Analysis 05.04. Comparison 05 Memory Alteration, Outcome 04 Behavioral measures- Distress (during procedure change score)

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 05 Memory Alteration

Outcome: 04 Behavioral measures- Distress (during procedure change score)

Study	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Standardised Mean Difference (Random) 95% CI	Standardised Mean Difference (Random) 95% CI
Chen 1999	25	-0.62 (3.70)	25	-0.48 (2.00)		-0.05 [-0.60, 0.51]

Analysis 05.05. Comparison 05 Memory Alteration, Outcome 05 Physiology- Heart rate (during procedure change scores)

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 05 Memory Alteration

Outcome: 05 Physiology- Heart rate (during procedure change scores)

Study	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Standardised Mean Difference (Random) 95% CI	Standardised Mean Difference (Random) 95% CI
Chen 1999	24	0.10 (26.90)	20	-4.90 (21.80)		0.20 [-0.40, 0.79]

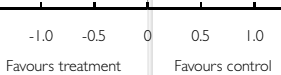
Analysis 05.06. Comparison 05 Memory Alteration, Outcome 06 Physiology- Cortisol (during procedure change score)

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 05 Memory Alteration

Outcome: 06 Physiology- Cortisol (during procedure change score)

Study	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Standardised Mean Difference (Random) 95% CI	Standardised Mean Difference (Random) 95% CI
Chen 1999	22	0.01 (0.18)	22	0.01 (0.20)		0.00 [-0.59, 0.59]



Analysis 05.07. Comparison 05 Memory Alteration, Outcome 07 Physiology- Systolic Blood Pressure (during procedure change score)

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 05 Memory Alteration

Outcome: 07 Physiology- Systolic Blood Pressure (during procedure change score)

Study	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Standardised Mean Difference (Random) 95% CI	Standardised Mean Difference (Random) 95% CI
Chen 1999	23	-0.50 (11.80)	19	-5.40 (7.90)		0.47 [-0.15, 1.09]

Analysis 05.08. Comparison 05 Memory Alteration, Outcome 08 Physiology- Diastolic Blood Pressure (during procedure change score)

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 05 Memory Alteration

Outcome: 08 Physiology- Diastolic Blood Pressure (during procedure change score)

Study	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Standardised Mean Difference (Random) 95% CI	Standardised Mean Difference (Random) 95% CI
Chen 1999	23	-4.10 (10.90)	19	2.90 (10.20)		-0.65 [-1.27, -0.02]

Analysis 06.01. Comparison 06 CBT-Combined, Outcome 01 Self-reported pain

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

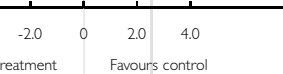
Comparison: 06 CBT-Combined

Outcome: 01 Self-reported pain

Study	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Standardised Mean Difference (Random) 95% CI	Weight (%)	Standardised Mean Difference (Random) 95% CI
Cohen 1997	32	-4.30 (1.10)	29	-1.90 (1.30)		20.8	-1.98 [-2.60, -1.36]
Cohen 2002	31	3.00 (1.67)	30	2.77 (1.59)		21.4	0.14 [-0.36, 0.64]
Liossi 1999	10	2.70 (0.67)	10	4.20 (0.63)		17.5	-2.21 [-3.37, -1.05]
Posner 1998	10	1.50 (0.85)	10	2.90 (2.00)		19.0	-0.87 [-1.80, 0.05]
Tyc 1997	28	2.70 (2.40)	27	1.90 (2.60)		21.2	0.32 [-0.22, 0.85]
Total (95% CI)	111		106			100.0	-0.87 [-1.90, 0.16]

Test for heterogeneity chi-square=45.94 df=4 p=<0.0001 I^2 =91.3%

Test for overall effect z=1.65 p=0.1



Analysis 06.02. Comparison 06 CBT-Combined, Outcome 02 Observer-reported pain

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

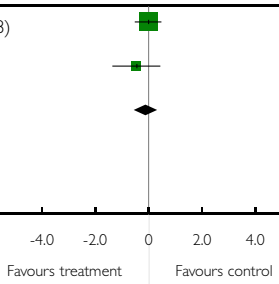
Comparison: 06 CBT-Combined

Outcome: 02 Observer-reported pain

Study	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Standardised Mean Difference (Random) 95% CI	Weight (%)	Standardised Mean Difference (Random) 95% CI
Cohen 2002	31	33.42 (26.71)	30	33.24 (25.08)		75.8	0.01 [-0.50, 0.51]
Posner 1998	10	2.20 (1.00)	10	2.70 (1.20)		24.2	-0.43 [-1.32, 0.46]
Total (95% CI)	41		40			100.0	-0.10 [-0.54, 0.34]

Test for heterogeneity chi-square=0.71 df=1 p=0.40 I^2 =0.0%

Test for overall effect z=0.45 p=0.7



Analysis 06.03. Comparison 06 CBT-Combined, Outcome 03 Self-reported distress

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

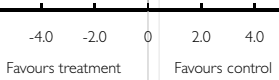
Comparison: 06 CBT-Combined

Outcome: 03 Self-reported distress

Study	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Standardised Mean Difference (Random) 95% CI	Weight (%)	Standardised Mean Difference (Random) 95% CI
Cohen 2002	31	2.77 (1.59)	30	2.20 (1.54)		28.0	0.36 [-0.15, 0.87]
Liossi 1999	10	3.50 (1.08)	10	4.60 (0.52)		23.4	-1.24 [-2.22, -0.27]
Posner 1998	10	1.30 (0.67)	10	3.70 (1.10)		20.6	-2.52 [-3.76, -1.29]
Tyc 1997	28	2.70 (2.40)	27	3.10 (3.00)		27.9	-0.15 [-0.67, 0.38]
Total (95% CI)	79		77			100.0	-0.75 [-1.75, 0.25]

Test for heterogeneity chi-square=22.65 df=3 p=<0.0001 I^2 =86.8%

Test for overall effect z=1.48 p=0.1

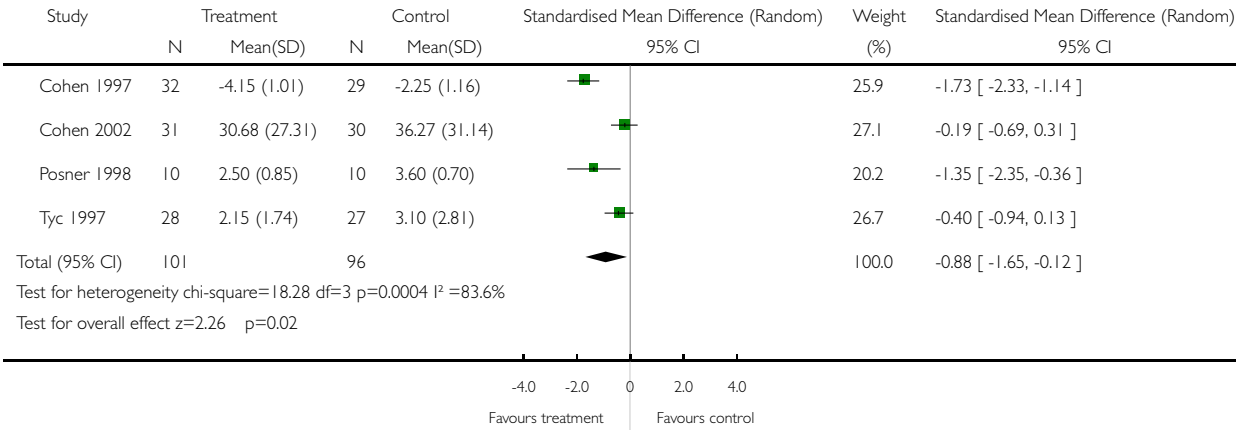


Analysis 06.04. Comparison 06 CBT-Combined, Outcome 04 Observer-reported distress

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 06 CBT-Combined

Outcome: 04 Observer-reported distress

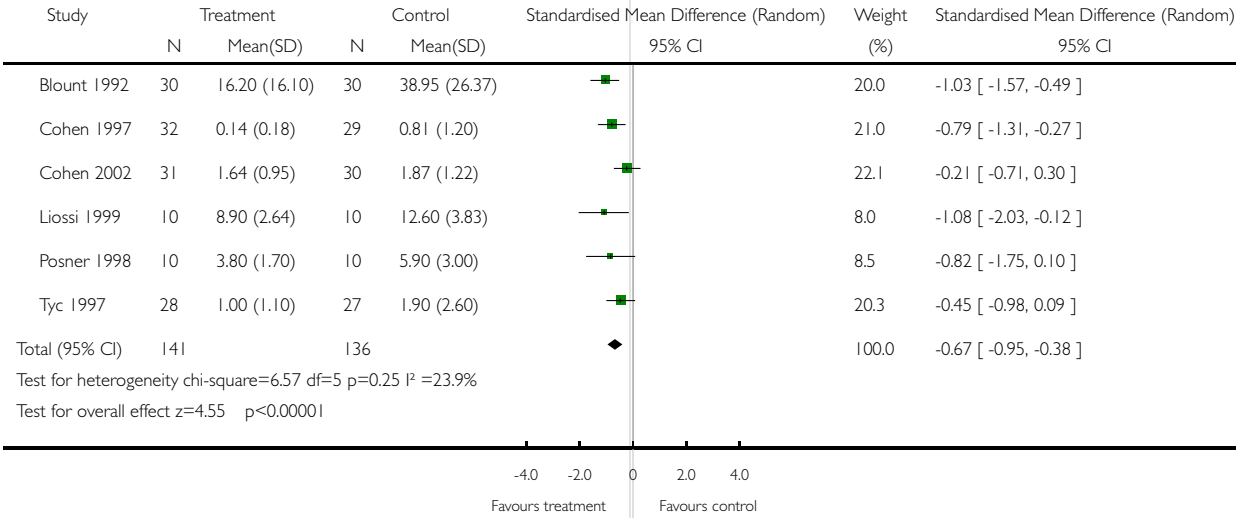


Analysis 06.05. Comparison 06 CBT-Combined, Outcome 05 Behavioral measures- Distress

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 06 CBT-Combined

Outcome: 05 Behavioral measures- Distress

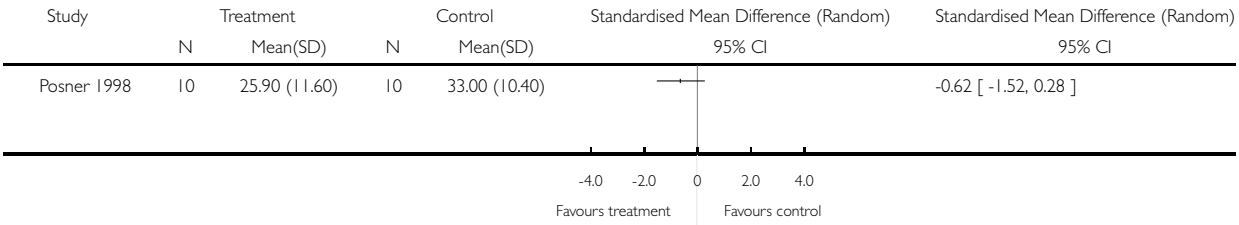


Analysis 06.06. Comparison 06 CBT-Combined, Outcome 06 Physiology- Heart Rate

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 06 CBT-Combined

Outcome: 06 Physiology- Heart Rate

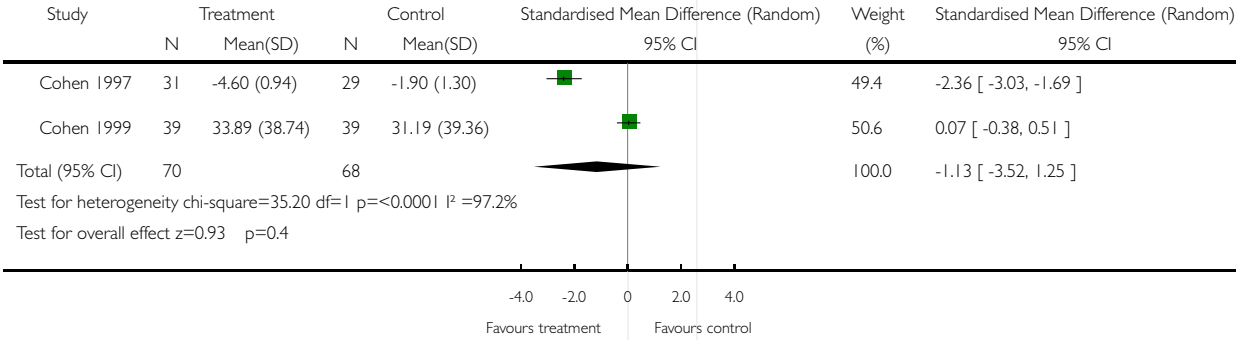


Analysis 07.01. Comparison 07 Nurse Coaching + Distraction, Outcome 01 Self-reported pain

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 07 Nurse Coaching + Distraction

Outcome: 01 Self-reported pain

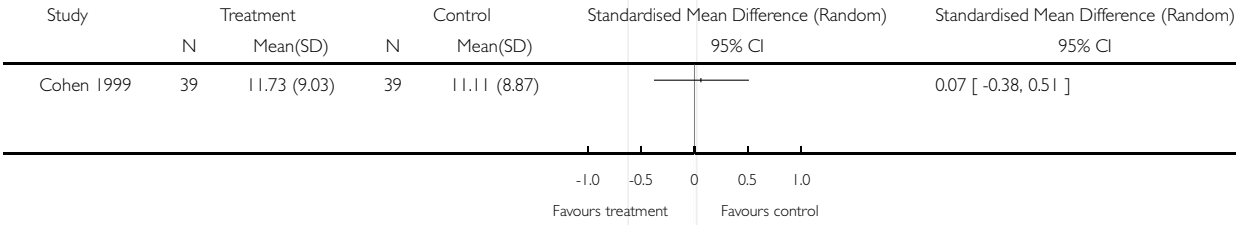


Analysis 07.02. Comparison 07 Nurse Coaching + Distraction, Outcome 02 Observer-reported pain

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 07 Nurse Coaching + Distraction

Outcome: 02 Observer-reported pain

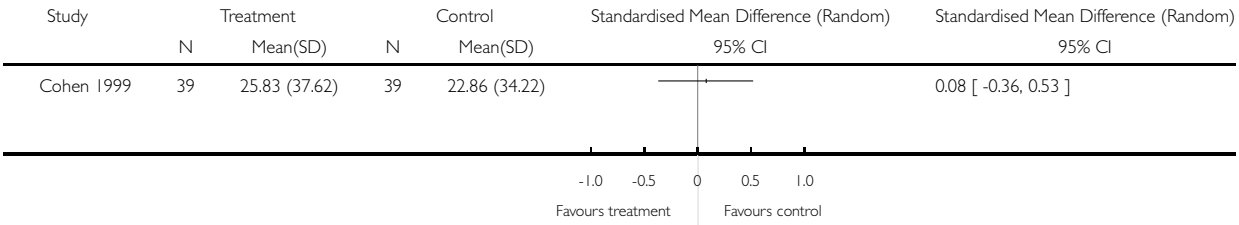


Analysis 07.03. Comparison 07 Nurse Coaching + Distraction, Outcome 03 Self-reported distress

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 07 Nurse Coaching + Distraction

Outcome: 03 Self-reported distress

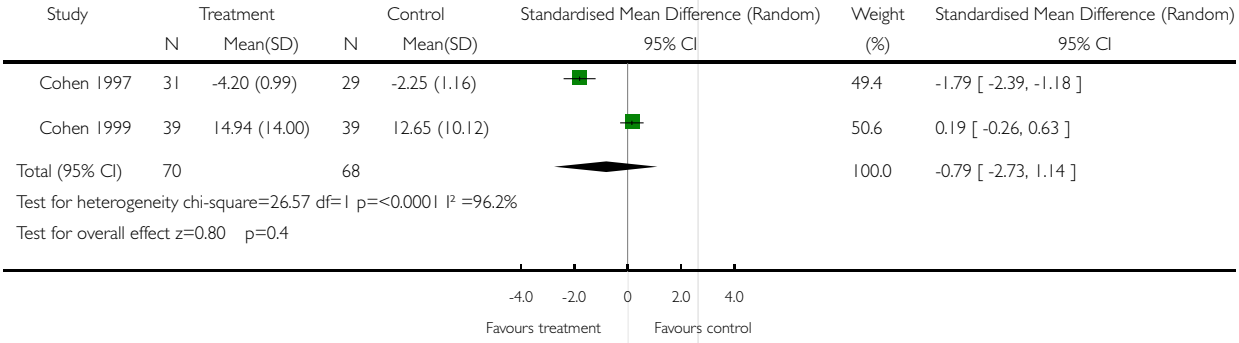


Analysis 07.04. Comparison 07 Nurse Coaching + Distraction, Outcome 04 Observer-reported distress

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 07 Nurse Coaching + Distraction

Outcome: 04 Observer-reported distress

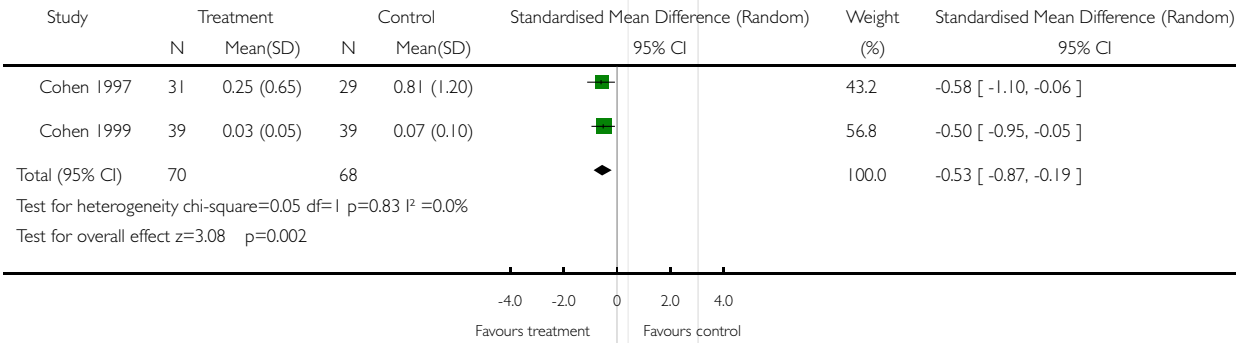


Analysis 07.05. Comparison 07 Nurse Coaching + Distraction, Outcome 05 Behavioral measures- Distress

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 07 Nurse Coaching + Distraction

Outcome: 05 Behavioral measures- Distress



Analysis 07.06. Comparison 07 Nurse Coaching + Distraction, Outcome 06 Physiology- Heart Rate

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 07 Nurse Coaching + Distraction

Outcome: 06 Physiology- Heart Rate

Study	Treatment		Control		Standardised Mean Difference (Random)	Standardised Mean Difference (Random)
	N	Mean(SD)	N	Mean(SD)	95% CI	95% CI
Cohen 1999	39	76.97 (12.06)	39	78.86 (12.83)		-0.15 [-0.59, 0.29]

Analysis 08.01. Comparison 08 Parent Coaching + Distraction, Outcome 01 Self-reported pain

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 08 Parent Coaching + Distraction

Outcome: 01 Self-reported pain

Study	Treatment		Control		Standardised Mean Difference (Random)	Standardised Mean Difference (Random)
	N	Mean(SD)	N	Mean(SD)	95% CI	95% CI
Kleiber 2001	22	3.24 (1.95)	22	2.70 (1.40)		0.31 [-0.28, 0.91]

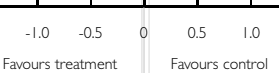
Analysis 08.02. Comparison 08 Parent Coaching + Distraction, Outcome 02 Observer-reported Distress

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 08 Parent Coaching + Distraction

Outcome: 02 Observer-reported Distress

Study	Treatment		Control		Standardised Mean Difference (Random)	Standardised Mean Difference (Random)
	N	Mean(SD)	N	Mean(SD)	95% CI	95% CI
Kleiber 2001	22	10.80 (4.20)	22	9.90 (4.00)		0.22 [-0.38, 0.81]

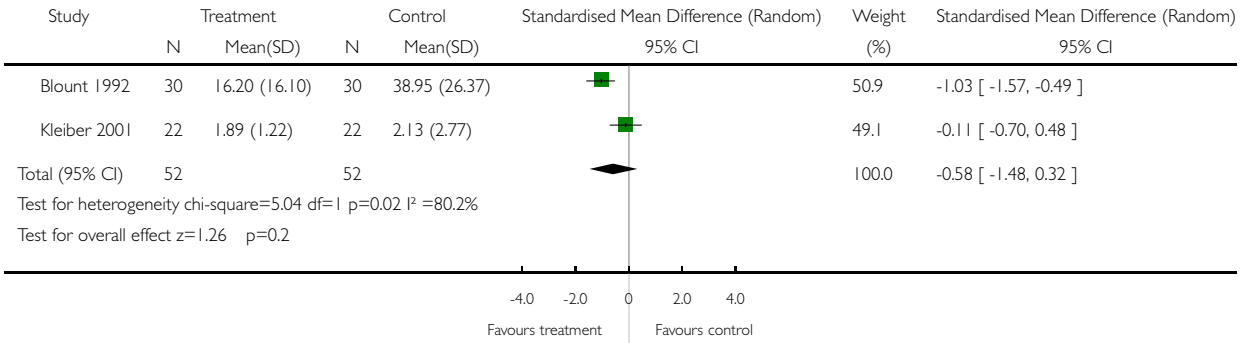


Analysis 08.03. Comparison 08 Parent Coaching + Distraction, Outcome 03 Behavioral measures- Distress

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 08 Parent Coaching + Distraction

Outcome: 03 Behavioral measures- Distress

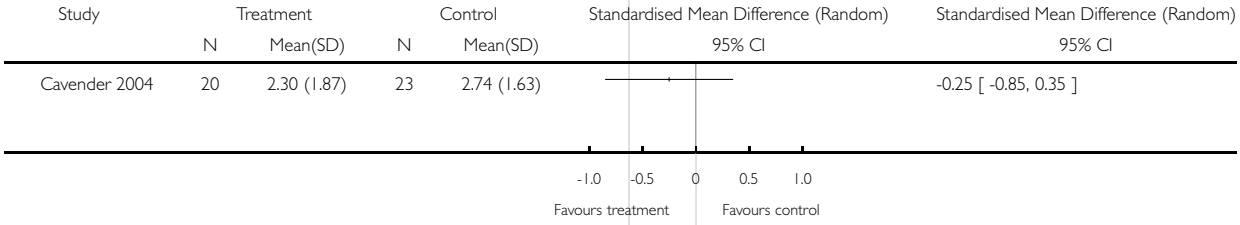


Analysis 09.01. Comparison 09 Parent Positioning + Child Distraction, Outcome 01 Self-reported pain

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 09 Parent Positioning + Child Distraction

Outcome: 01 Self-reported pain

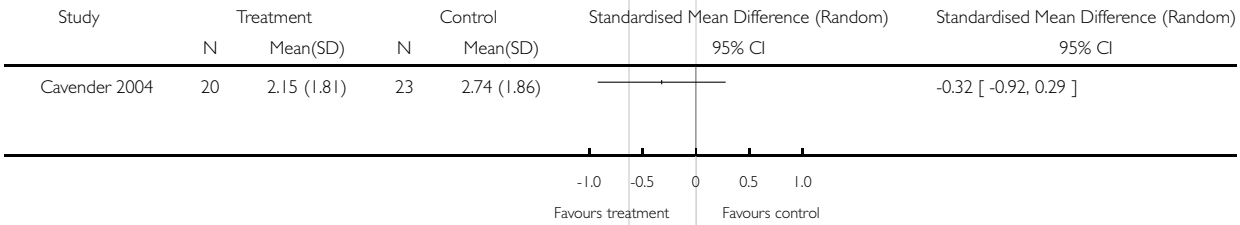


Analysis 09.02. Comparison 09 Parent Positioning + Child Distraction, Outcome 02 Self-reported distress

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 09 Parent Positioning + Child Distraction

Outcome: 02 Self-reported distress

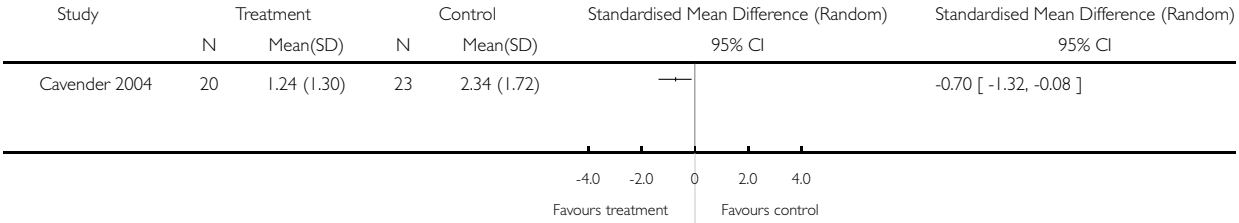


Analysis 09.03. Comparison 09 Parent Positioning + Child Distraction, Outcome 03 Observer-reported distress

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 09 Parent Positioning + Child Distraction

Outcome: 03 Observer-reported distress

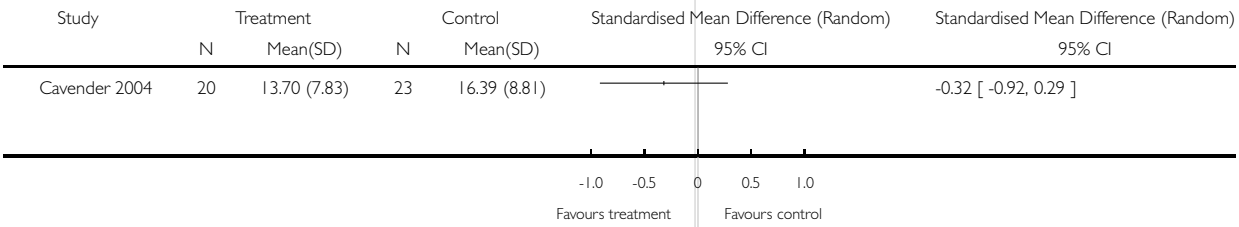


Analysis 09.04. Comparison 09 Parent Positioning + Child Distraction, Outcome 04 Behavioral measures- Distress

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 09 Parent Positioning + Child Distraction

Outcome: 04 Behavioral measures- Distress

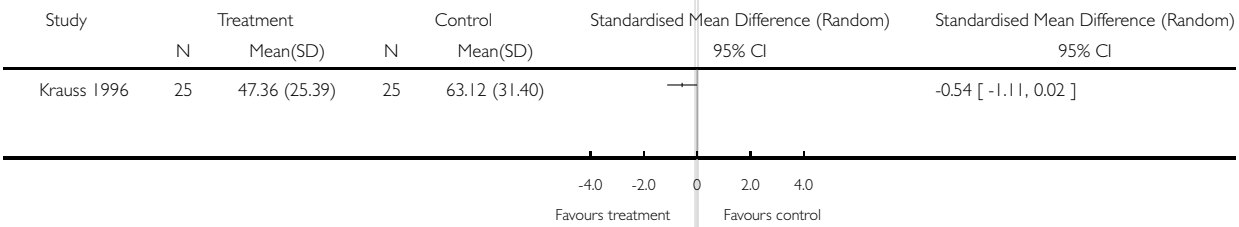


Analysis 10.01. Comparison 10 Videotape Modeling + Parent Coaching, Outcome 01 Observer-reported distress

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 10 Videotape Modeling + Parent Coaching

Outcome: 01 Observer-reported distress

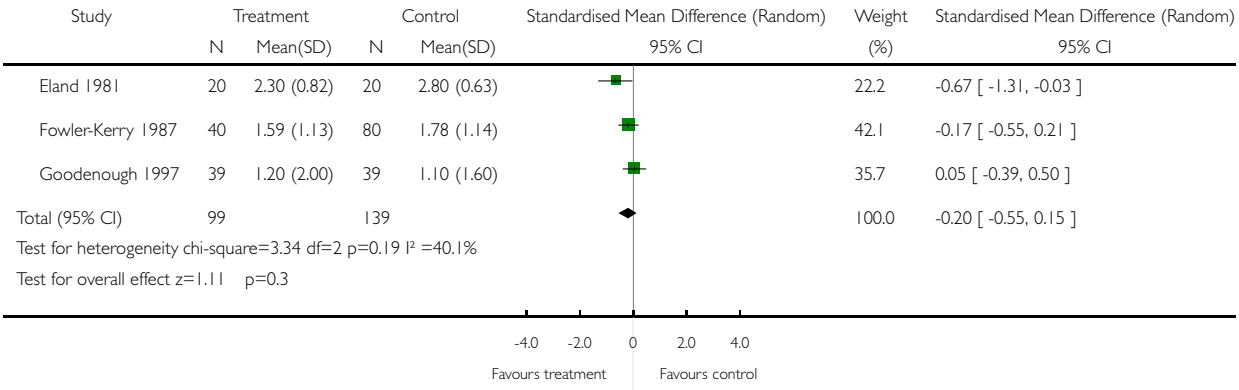


Analysis 11.01. Comparison 11 Suggestion, Outcome 01 Self-reported pain

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 11 Suggestion

Outcome: 01 Self-reported pain

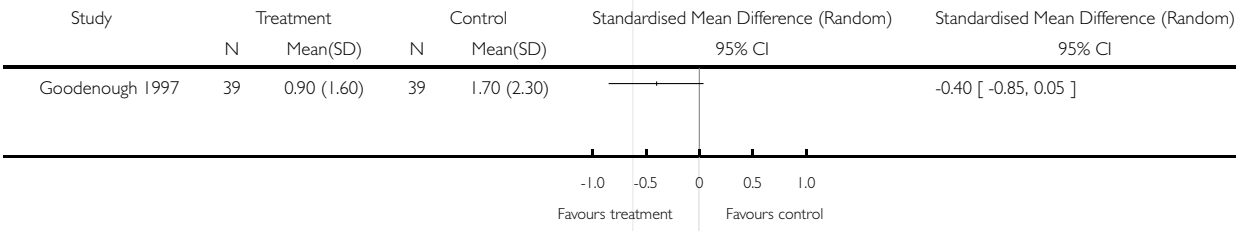


Analysis 11.02. Comparison 11 Suggestion, Outcome 02 Observer-reported pain

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 11 Suggestion

Outcome: 02 Observer-reported pain

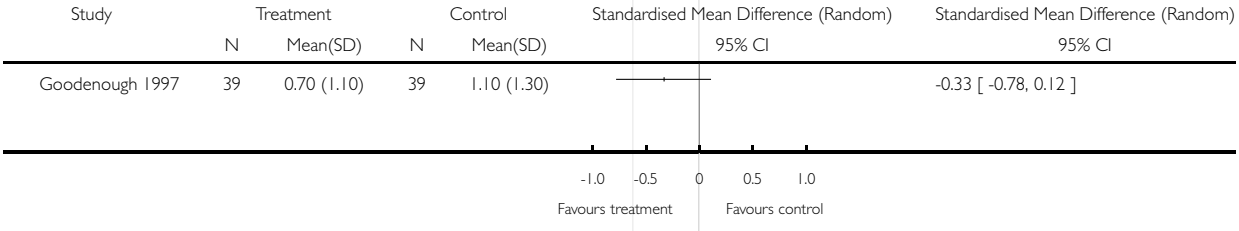


Analysis 11.03. Comparison 11 Suggestion, Outcome 03 Self-reported distress

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 11 Suggestion

Outcome: 03 Self-reported distress



Analysis 11.04. Comparison 11 Suggestion, Outcome 04 Observer-reported distress

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 11 Suggestion

Outcome: 04 Observer-reported distress

Study	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Standardised Mean Difference (Random) 95% CI	Standardised Mean Difference (Random) 95% CI
Eland 1981	20	1.80 (0.71)	20	1.80 (0.79)		0.00 [-0.62, 0.62]

Analysis 12.01. Comparison 12 Blowing Out Air, Outcome 01 Self-reported Pain

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 12 Blowing Out Air

Outcome: 01 Self-reported Pain

Study	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Standardised Mean Difference (Random) 95% CI	Standardised Mean Difference (Random) 95% CI
French 1994	39	36.00 (38.00)	36	51.00 (40.00)		-0.38 [-0.84, 0.08]

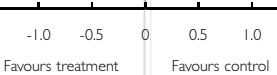
Analysis 12.02. Comparison 12 Blowing Out Air, Outcome 02 Behavioral measures- Distress

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 12 Blowing Out Air

Outcome: 02 Behavioral measures- Distress

Study	Treatment N	Treatment Mean(SD)	Control N	Control Mean(SD)	Standardised Mean Difference (Random) 95% CI	Standardised Mean Difference (Random) 95% CI
French 1994	39	0.90 (1.30)	36	1.40 (1.80)		-0.32 [-0.77, 0.14]

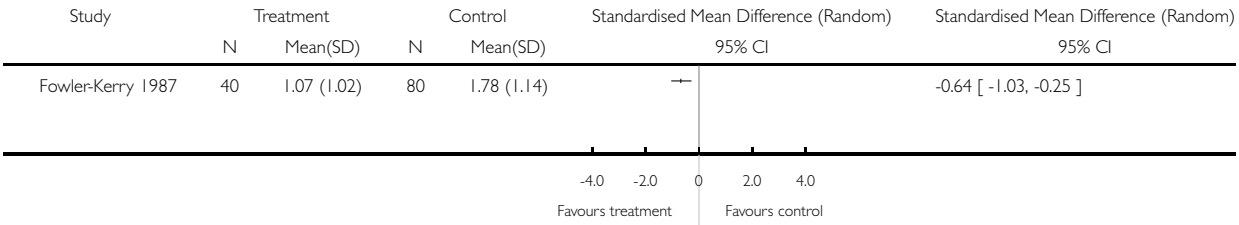


Analysis 13.01. Comparison 13 Distraction + Suggestion, Outcome 01 Self-reported Pain

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 13 Distraction + Suggestion

Outcome: 01 Self-reported Pain

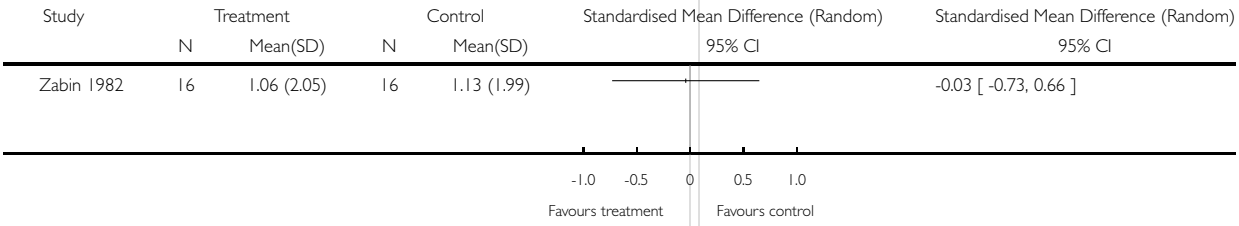


Analysis 14.01. Comparison 14 Filmed Modeling, Outcome 01 Self-reported distress

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 14 Filmed Modeling

Outcome: 01 Self-reported distress



Analysis 14.02. Comparison 14 Filmed Modeling, Outcome 02 Observer-reported distress

Review: Psychological interventions for needle-related procedural pain and distress in children and adolescents

Comparison: 14 Filmed Modeling

Outcome: 02 Observer-reported distress