

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

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

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

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 (www.csc.gov/nip/acip), the American Academy of Pediatrics (www.aap.org), the American Academy of Family Physicians (www.aafp.org), and the Canadian Paediatric Society (www.cps.ca) 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) which 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". It is also generally acknowledged that pain is a highly personal and multifaceted experience comprised of physiological, behavioral, emotional, developmental, and sociocultural components (Kazak 2001). 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, particu-

larly 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. 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 aimed primarily at changing faulty cognitions and behavioral interventions are aimed mainly at altering problematic overt behaviors, however the two are often delivered in combination (Barlow 1999). CBT interventions for pain management are aimed to assist the child 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 2000; 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; Pow-

ers 1999; Chen 2000; Christophersen 2001; Kazak 2001; Blount 2003; Devine 2004). 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., Luebbert 2001; Kleiber 1999; Broome 1989; 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 review of non-pharmacological interventions for preparing children and adolescents for hospital care (Pictor 2003) is in progress and this will address issues of psychosocial and physical health, behaviour, 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.

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 will be included in this review. No language restriction will be used during the search.

Types of participants

Studies involving children and adolescents aged 3-18 years undergoing needle-related medical procedures will be included. For the purposes of this review, a needle-related medical procedure will be defined as any procedure performed as part of a medical diagnosis, prevention, or treatment. This will include dental procedures (excluding dental surgery) but will not include procedures such as body piercings or tattoos which do involve needles but are not for medical purposes. The search will be 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 three 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. A maximum age of 17 years was chosen to ensure that our search was limited to children and adolescents only. It is acknowledged that this cut-off is somewhat arbitrary, however, the age of 18 years is often regarded as the beginning of adulthood.

After reviewing the literature and consulting with clinicians and experts in the area of pediatric health, the following comprehensive list of common medical procedures involving needles was derived. Definitions were derived from online medical dictionaries (e.g., MedLine Plus Medical Encyclopedia: www.nlm.nih.gov/medlineplus/medlineplusdictionary.html; On-Line Medical Dictionary: www.cancerweb.ncl.ac.uk/omd) and by consulting with medical professionals in the area of pediatric pain.

- **Vaccinations involving needles/Immunization (also known as immunisation)** = the creation of immunity usually against a particular disease or treatment of an organism for the purpose of making it immune to subsequent attack by a particular pathogen; the introduction into humans or domestic animals of microorganisms that have previously been treated to make them harmless for the purpose of inducing the development of immunity
- **Venipuncture (also known as venepuncture)** = surgical puncture of a vein especially for the withdrawal of blood or for intravenous medication
- **Finger prick/pick** = obtaining blood by pricking the tip of the finger
- **Injection:** The act of forcing a liquid into tissue, the vascular tree, or an organ
- **Subcutaneous injection** = being, living, used, or made under the skin
- **Intramuscular injection** = situated within, occurring within, or administered by entering a muscle
- **Lumbar punctures (LP) (also known as Spinal Tap)** = puncture of the subarachnoid space in the lumbar region of the spinal cord to withdraw cerebrospinal fluid or inject anesthetic drugs
- **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 (as of the arm) 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 known as laceration repair)** = a stitch made with a suture; a strand or fiber used to sew parts of the living body
- **Accessing a portacath (also known as a port)** = Inserting a needle into an implanted access device (portacath) which allows the drawing of blood and makes intravenous (or intra-arterial) injections into a patient in an easier way without 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
- **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 (as of the abdomen) with a trocar, aspirator, or other instrument usually to draw off an abnormal effusion for diagnostic or therapeutic purposes

Participants will include healthy children and children with chronic or transitory illnesses from both inpatient and outpatient settings. Studies including patients with known needle-phobias will not be included. Furthermore, children undergoing surgery will not be 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.

Types of intervention

The reviews cited in the Background section of this protocol (e.g., Chen 2000; Blount 2003; 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, we will classify these interventions as subtypes of the following three main well-defined categories: (1) cognitive, (2) behavioral, and (3) cognitive-behavioral. Cognitive interventions will be 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 will be 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 will include those mainly targeting central mechanisms such as thoughts and feelings, while behavioral interventions will include those mainly targeting overt behaviors. Cognitive-behavioral interventions will include at least one cognitive interventions combined with at least one behavioral intervention. Sensitivity analyses can then be conducted on the broad categories as well as the subtypes within them. Any study with at least one condition involving one of the following interventions will be included:

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 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 will rely on author definitions to distinguish between the two.
- **Preparation/Education/Information:** Explaining the steps of the procedures and/or providing sensory information associated with the procedure. 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
- **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 can help decrease the child's distress and/or pain.

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 and/or tangible rewards 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 can help decrease the child's distress and/or pain.
- **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 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)

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

The above three categories are considered "well-defined" interventions given that they are based on psychological theories with well-established treatment principles spanning both cognitive and behavioral frameworks. Psychological interventions that do not meet the criteria for any of the above definitions will fall into a fourth category of interventions which will be labeled as 'less-well

defined' interventions. The exact nature of these 'less-well defined' interventions will be identified by contacting the study authors.

Control or comparison groups can include any one of the following provided that the intervention group receives 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 can be administered by any qualified health-care professional (i.e., MD, nurse, psychologist, technician), family member, caregiver, or by the child him/herself after being trained by a parent and/or professional.

Types of outcome measures

The two measured outcomes will be 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 will be broadly defined 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 Analog Scales (VAS)
- Numerical Rating Scales (NRS)
- Verbal Rating Scales (VRS)
- Faces Pain Scales or Faces Scales designed to assess level of distress (e.g., anxiety and/or fear)

(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) will also be 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. Provided there is sufficient information available, sensitivity analyses will be conducted to determine if there are any effects attributed to the type of observer and the age of the child (see below under Sensitivity Analyses).

(3) Behavioral Measures

Any scale with established reliability and validity as defined by prior publication in at least one scientific paper from a peer-reviewed journal. These 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 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 (increases with pain)
- Respiratory rate (may increase or decrease with pain/distress)
- Blood pressure (increases with pain/distress)
- Oxygen saturation (decreases with pain/distress)
- Cortisol levels (increase with pain/distress)
- Transcutaneous oxygen tension (tcPO₂) (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, as well as a lack of data supporting the specificity of these measures to pain and distress, they are commonly used in studies of responses to medical procedures, and will therefore be 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.

SEARCH METHODS FOR IDENTIFICATION OF STUDIES

See: methods used in reviews.

Published studies will be identified by conducting electronic searches. Unpublished studies and PhD dissertations for possible inclusion in this review will be obtained from electronic databases, by contacting researchers using various E-mail list-

erves (e.g., Pain in Child Health (PICH) list-serve, Pediatric Pain list-serve, Society of Pediatric Psychology list-serve) and by contacting experts and trialists through email and direct communication to locate any additional studies. Finally, reference and citation lists from papers identified as reviews, meta-analyses, or randomized controlled trials meeting inclusion criteria for this review will be searched.

A: Electronic Search (Published Studies)

- Cochrane Central Register of Controlled Trials (CENTRAL)
- MEDLINE (1966-present)
- PsychINFO (1887-present)
- EMBASE (1974-present)
- Cumulative Index to Nursing and Allied Health Literature (1982-present)
- Web of Science (1980-present)

B. Electronic Search (Unpublished Studies)

- Dissertation-Abstracts International (1980-present)

CENTRAL Search:

- #1 NEEDLES (single term MeSH)
- #2 (needle* or inject*)
- #3 (immun* 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*) (immun* 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 stimulat*))
- #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)

A similar set of key words will be used in the searches for the other databases. Other related key words and mesh terms will be included as appropriate depending on the terms used in each of the specific databases.

METHODS OF THE REVIEW

1. Selection of trials

Two reviewers (LU & CC) will independently screen titles and abstracts of trials from literature searches for inclusion in the review. Reviewers will not be blind to authors, institutions, journals, or results. A third reviewer (PM) will be brought in if any disagreements regarding which studies to include cannot be resolved.

2. Data extraction

Data extraction will be conducted by two reviewers (LU & CC) using a data extraction form designed for this specific review. If necessary, a third reviewer (PM) will be brought in to resolve any disagreements. The following information will be extracted if available: (1) number of subjects, (2) gender, age, and race of subjects, (3) study design (e.g., parallel design, cross-over design), (4) the procedure they are undergoing (e.g., immunization), (5) the type of intervention (e.g., distraction), (6) who administered intervention (e.g., parent, nurse, doctor), (7) when intervention was administered (i.e., pre-procedure, during procedure, following procedure), (8) type(s) of outcome measures (e.g., faces pain scale, anxiety scale), (9) who completed outcome measures (i.e., self- or other-report), (10) results from outcome measures (i.e., means, standard deviations, number of subjects), (11) subject withdrawals from the study, and (12) reasons for withdrawal. Attempts will be made to obtain missing data from the authors whenever feasible. All data will first be recorded onto paper data extraction forms by one reviewer (LU) and another reviewer (CC) will independently re-record the data from 20% of the studies to establish inter-rater reliability using Kappa coefficients. Once all forms are completed they will be entered into a computer spreadsheet by (LU) and once again, 20% will be independently verified for accuracy by a second reviewer (CC).

3. Losses to follow-up

The papers should provide adequate descriptions of the number of participants who withdrew, the reasons for withdrawal, and any other protocol deviations with justification for them. If more than 20% of the originally randomized participants have withdrawn, the data will not be presented in this review.

4. Addressing publication bias

The data from all the identified and selected trials will be entered into a funnel plot with 'sample size' plotted on the Y axis and 'effect size' plotted on the X axis, in an attempt to detect the possibility of publication bias. When a large number of studies are compared, the absence of publication bias is depicted by a distribution of studies resembling a sideways funnel with the wider end down. Publication bias is detected when either end of the base of the funnel appears truncated.

5. Study quality

Each study included in the review will be scored for quality by two reviewers (LU & CC) using the scale created by Jadad et al (Jadad 1996). The scale is comprised of five questions for a maximum score of five points. Each of the following questions can be allotted either 0 or 1 point:

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

It should be noted that it is often not feasible for studies employing psychological management of pain and distress to be double-blind. Thus for the majority of the studies included, it is expected that the people administering and receiving the therapy will not be blind. However, despite the limitations of this scale for studies of psychological interventions, it is the accepted international standard and will therefore be used to assess study quality in this review.

6. Statistical analyses

Heterogeneity

Differences between the results of each included trial will be analyzed using a test of heterogeneity in order to determine whether the results are statistically similar enough to combine. Given that these tests often have low statistical power, a type 1 error level of 0.10 will be employed for rejecting the null hypothesis of homogeneity as opposed to the more traditional 0.05. If statistically significant heterogeneity is detected, the data cannot be pooled and therefore will be analyzed separately. Results will be analyzed using both the fixed and random effects models, however if significant heterogeneity is detected, only a random effects model will be used. An attempt to explore reasons for heterogeneity will be employed using post hoc analyses.

Dichotomous data

When appropriate, continuous measures will be converted to dichotomous data (e.g., 'improved' versus 'not improved'), provided that rationalized cut-offs are provided by the authors. For dichotomous data a Mantel-Haenszel odds ratio with a 95% confidence interval (CI) will be calculated using a random effects model. The number needed to treat (NNT) statistic will also be computed as a summary measure of effectiveness if sufficient data is available.

Continuous data

For continuous data (e.g., rating scales), we will compute a standardized mean difference (SMD) with 95% confidence interval (CI) which will allow us to combine the results from different scales measuring the same construct (e.g., pain). If sufficient data are available from various studies using the same measurement instruments, a weighted mean difference (WMD) with 95% CI will also be conducted. Means and standard deviations (SDs) will be reported. When SDs are not reported, attempts will be 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 will be investigated using sensitivity analyses. This review will investigate

- 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

Sub group analyses are planned, where data permits, to compare treatments, treatment settings and patient populations. It is likely that many of the sensitivity analyses may not be viable because of missing, incomplete, or poor quality data or treatment descriptions. Therefore, we will attempt to analyze the efficacy of each intervention separately if feasible. If there are insufficient data to do so, we will attempt to analyze the efficacy of intervention types (i.e., cognitive, behavioural, and cognitive behavioural). If significant heterogeneity exists, we will still compute summary statistics (i.e., weighted mean differences) however, we will notify the reader that the results need to be interpreted cautiously. We will also attempt to discuss possible reasons for the heterogeneity. Even if there are insufficient data to conduct all of the sensitivity analyses, this review will still provide valuable information regarding: (1) what psychological interventions exists for managing acute pain and distress in children, (2) the efficacy of those interventions for which there are RCTs meeting our inclusion criteria, and (3) recommendations to improve the quality of future studies assessing the efficacy of these interventions.

Statistical analyses will be conducted using RevMan Analyses 1.0.2 in RevMan 4.2 software.

POTENTIAL CONFLICT OF INTEREST

None known.

SOURCES OF SUPPORT

External sources of support

- No sources of support supplied

Internal sources of support

- No sources of support supplied

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