Empirically Supported Treatments in Pediatric Psychology: Procedure-Related Pain

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Objective: To use the Chambless criteria for empirically supported treatments and determine if any interventions for procedure-related pain in children and adolescents can be designated as “well established,” “probably efficacious,” or “promising.”

Methods: The Chambless criteria were applied to 13 treatment outcome studies identified by a comprehensive literature review.

Results: A detailed summary is provided for each study, including the following information: citation, subjects, diagnostic criteria, baseline, experimental design, assessment measures, treatment protocol, outcome, and follow-up.

Conclusions: Cognitive behavioral therapy is a “well-established treatment” for procedure-related pain in children and adolescents. Treatment includes breathing exercises and other forms of relaxation and distraction, imagery and other forms of cognitive coping skills, filmed modeling, reinforcement/incentive, behavioral rehearsal, and active coaching by a psychologist, parent, and/or medical staff member. I discuss future challenges for biobehavioral research and practice in the area of procedure-related pain.

Key words: painful medical procedures; children; adolescents; cognitive behavioral therapy; empirically supported treatments.

Over 30 years ago the need for interventions to help children cope with the stress of hospitalization and illness was highlighted by Vernon, Foley, Sipowicz, and Schulman (1965). Over 20 years ago, Eland and Anderson (1977) focused attention on the paucity of research on pain in children and adolescents. These authors reviewed over 1,380 empirical articles, finding a mere 33 references that discussed pediatric pain; only 3 of those discussed the assessment and/or treatment of pain in children. During the past two decades, however, the development of treatments for children undergoing painful medical procedures has been a major focus of pediatric behavioral medicine research and care. The goal of this article is to review the research on treatments for procedure-related pain in children and adolescents and determine if any treatments meet the Chambless criteria for empirically supported treatments (Chambless et al., 1996; Task Force on Promotion and Dissemination of Psychological Procedures, 1995). First, I will discuss the Chambless criteria.

The Chambless criteria allow for classification as a “well-established treatment,” a “probably efficacious treatment,” or, for this special issue of the Journal, a “promising intervention.” The specific criteria for designation as a well-established treatment...
are as follows: (1) at least two good between-group design experiments demonstrating efficacy in one or more of the following ways: superior to pill or psychological placebo or alternative treatment, or equivalent to an already established treatment in experiments with adequate statistical power (about 30 per group, but can be smaller for chronic illness groups) or (2) a large series of single case design experiments (n ≥ 9) demonstrating efficacy that have used good experimental design and compared the intervention to another treatment (pill, psychological placebo, or alternative treatment). In addition, well-established treatments must employ a treatment manual (or at least present a well defined treatment protocol), clearly specify the characteristics of the client samples, and be shown effective by at least two different investigators or investigatory teams. The specific criteria for designation as a probably efficacious treatment are as follows: (1) two experiments showing the treatment is more effective than a waiting-list control group or (2) one or more experiments meeting the well-established treatment criteria (with the exception of the two investigators/teams criterion). For this special issue of the *Journal*, an additional designation of promising interventions was included. The specific criteria for promising interventions are as follows: (1) at least one well-controlled study and another less rigorously controlled study by a separate investigator, (2) two or more well-controlled studies with small samples, or (3) two or more well-controlled studies by the same investigator.

Using these guidelines for designating interventions, this article will review the history of treatment developments for procedure-related pain in children and adolescents, highlight a number of intervention studies, and discuss the future of treatment outcome research in this area. According to the Chambless criteria for empirically supported treatments, a treatment package often labeled “cognitive behavioral therapy” (CBT) gains empirical support as a well-established treatment.

**Historical Overview**

Early work in this area of intervention focused on preparation for hospitalization and surgery. Observations that children displayed behavioral problems during and after hospitalization led to the development of preparation programs (Harbeck-Weber & McKee, 1995). Such programs were education-focused and included providing information to children about the operation and hospital. Children were typically given specific information about events that would happen during the hospitalization and sensations many children experience. Demonstration and modeling, usually in an audiovisual fashion (e.g., slide show or videotape), were often used to provide the information. In many cases, peer models provided information about the hospitalization and common sensations. Harbeck-Weber and McKee, summarizing the research on preparation and modeling, concluded that, in general, children’s anxiety and behavioral distress were reduced after preparation. This seemed to be especially the case for children who had no prior experience with hospitalization (Melamed & Siegel, 1980) or who had had positive prior experiences (Melamed, 1992). Indeed, preparation programs for surgery were made the standard of care in many hospitals.

To further enhance the effectiveness of preparation programs, it was suggested that making the child and parent more active participants in the learning process might lead to more clinically significant outcomes (Peterson & Shigetomi, 1981). As preparation programs were applied to children who were awake and undergoing outpatient medical procedures, it became clear that children needed to learn specific coping behaviors to use before and during painful medical procedures to reduce distress. Since this observation, a package of interventions often labeled cognitive behavioral therapy has been the predominant psychological intervention examined in research on procedure-related pain in children and adolescents.

As the Appendix illustrates, there has been a high degree of consistency in the type of psychological treatments used across a variety of medical procedures. Typical components of a cognitive behavioral package have included breathing exercises and other forms of relaxation and distraction (e.g., counting aloud, blowing a party blower, playing with toys such as puzzles, progressive muscle relaxation), imagery and other cognitive coping skills (e.g., positive self statements), filmed modeling usually depicting a coping peer model, reinforcement/incentive for using coping skills and lying still, and behavioral rehearsal using modeling and role play. Active coaching (i.e., prompting the child to engage in coping skills) by either the psychologist, parent, medical staff, or some combination during the actual medical procedure has also been a consistent
aspect of the treatment programs. Medical procedures studied have included the ubiquitous immunization injections and dental treatments to the more rare bone marrow aspiration (BMA), lumbar puncture (LP), or burn debridement.

Outcome measures have most often included behavioral observations of child distress before, during, and after the medical procedures. Child reports of pain and fear have also been incorporated in most studies. Physiological measures of arousal (e.g., heart rate and blood pressure) have been used in a few studies. Parent and medical staff reports of child distress and cooperation have also been employed. More recent studies have included behavioral observations of child coping behavior (e.g., breathing, relaxation, distraction, imagery) and the coping-promoting behaviors (e.g., prompting the child to breathe or use other coping skills, distracting the child with talk or activities) of parents and medical personnel. However, the primary outcome standard has been reduction in child distress behavior before and during the medical procedure.

With this historical overview, specific studies that meet the Chambless criteria for a well-established treatment will now be highlighted. The Appendix includes complete details of many studies that support the efficacy of a CBT package for treatment of procedure-related pain in children and adolescents. Including 13 studies used to categorize treatments according to the Chambless criteria, the Appendix presents the following study characteristics: citation, subjects, diagnostic criteria, baseline, experimental design, assessment measures, treatment protocol, outcome, and follow-up.

Review of Studies

Elliott and Olson (1983) and Jay, Elliott, Ozolins, Olson, and Pruitt (1985) were some of the first scientists to describe in detail a cognitive behavioral treatment protocol in the empirical literature. Elliott and Olson worked with four children who were undergoing painful medical treatments for burn injuries. These treatments included hydrotherapy, debridement, and dressing changes—all very painful for the child who has been severely burned. Children often have to undergo one or two treatments per day for weeks to months. Child cooperation is essential for the success of these burn injury treatments. Jay et al. worked with five children who had leukemia and were undergoing painful BMA and/or LP procedures. A BMA is a diagnostic procedure that involves insertion of a needle into the bone, usually the iliac crest, and withdrawal of bone marrow fluid to assay for the presence or absence of cancer cells. An LP, similarly, is a diagnostic procedure in which a needle is inserted into the spinal column and spinal fluid is collected. Behavioral assessment research has shown that children and adolescents describe BMAs and LPs as very painful procedures (McGrath, 1990). The components of the comprehensive CBT protocol used by Jay et al. will be outlined further to illustrate an empirically supported treatment. These components include breathing exercises, imagery, filmed modeling, reinforcement/incentive, and behavioral rehearsal.

Breathing exercises were described as an active-attention diversion strategy. The goal was to help the child be active and learn a mastery over pain and anxiety rather than maintain a passive and submissive approach. A typical instruction involved having the child pretend to be a tire, breathing in to fill the tire with air, and then slowly breathing out, making a hissing sound as the air leaked out. This strategy was modeled and practiced by the child during preprocedure training. During the procedure, the psychologist and parent coached the child in use of the breathing skill.

Imagery was conceptualized as a cognitive strategy. Emotive imagery as described by Lazarus and Abramowitz (1962) was the basis for this component of the package. Children were asked about their favorite super hero or cartoon character. A story was developed that included this imaginary character and involved the character helping the child cope with the painful medical procedure. The story often focused on imagining special powers and using help from the hero character to lie still and use breathing skills. In addition, imagery incompatible with the experience of pain (e.g., a pleasant image of walking on the beach or going to an amusement park) was taught to the child. As with breathing skills, imagery was created and practiced before the procedure. During the procedure the psychologist and parent prompted the child to use the individualized imagery scene (emotive and/or incompatible).

Filmed modeling was included in the package. “Joy Gets a Bone Marrow and Spinal Tap” is a 12-minute film of a 6-year-old child with leukemia describing her thoughts and feelings about the medical procedures and demonstrating the use of coping skills. A coping model strategy was used and
included the child model discussing her fears and concerns, exhibiting some signs of distress, but, in general, coping well. The film specifically noted the reasons why the medical procedures had to be conducted and illustrated what happens during each step of the procedures. In the film, a psychologist was shown conducting an intervention session with the child model and coaching the child to engage in coping skills such as breathing and imagery.

Reinforcement/incentive involved the awarding of a trophy with the child’s name engraved on it contingent upon the child lying still and using breathing skills during the painful procedure. Children were encouraged to act bravely during these difficult medical procedures. Jay and colleagues noted that lying still allowed the medical personnel to conduct the procedures in the most time-efficient and safe manner possible, and breathing skills worked to actively distract the child and preclude severe behavioral distress.

As mentioned, breathing skills, imagery development, and discussion of how to earn the trophy occurred before the medical procedure and were practiced. This practice, “behavioral rehearsal,” followed a set protocol. First, the child was asked to pretend to be the doctor and give a doll a BMA or LP with actual medical equipment. The doll was coached to lie still and use breathing skills. Second, the child pretended to do the medical procedure on the psychologist, who modeled breathing skills. Finally, a pretend medical procedure was practiced by the child, who worked to lie still and use breathing skills. Behavioral rehearsal was conceptualized as a means of providing in vivo desensitization, provision of information, and modeling and role-playing of active coping skills.

In a series of studies over the course of 10 years, Jay and colleagues have demonstrated that this package of interventions is superior to baseline conditions (Jay et al., 1985), Valium at a dose of 0.3 mg/kg given orally 30 minutes before the medical procedure (Jay, Elliott, Katz, & Siegel, 1987), and minimal treatment/attention control of watching cartoons for the 30 minutes before the medical procedure (Jay et al., 1987). These two studies used the following experimental designs: a multiple-staggered baseline design in which each subject served as his or her own control (Jay et al., 1985) and a repeated-measures counterbalanced design across three conditions including CBT, Valium, and minimal treatment-attention control (Jay et al., 1987). In addition, the treatment package has been found to be as effective as CBT plus oral Valium (0.15 mg/kg given orally 30 minutes before the medical procedure; Jay, Elliott, Woody, & Siegel, 1991) and general anesthesia with Halothane delivered with nitrous oxide (60%–70%) via a face mask (Jay, Elliott, Fitzgibbons, Woody, & Siegel, 1995). Jay et al. (1991) used a 2 (group: CBT or CBT + Valium) × 2 (medical procedure: BMA or LP) × 2 (phase: preintervention or postintervention) repeated-measures factorial design, and Jay et al. (1995) employed a repeated-measures counterbalanced design contrasting two experimental conditions (CBT and general anesthesia). Child distress was observed to be reduced as a result of CBT in each of these studies (or at least be equivalent to the reductions achieved via another established treatment). In addition, Jay et al. (1987) demonstrated lower pain ratings and pulse rates in comparison to an attention-control condition. Jay et al. (1991) also found decreases in pulse rate and self-reported pain after CBT; CBT was as effective as CBT + Valium on these measures. Based upon the success of these and other studies, Jay et al. (1995) concluded that “administration of BMAs with no psychological or medical intervention is no longer acceptable practice given the data on distress and pain in children undergoing these procedures as well as the data on effective intervention” (p. 8).

Other investigators have used similar cognitive behavioral therapies to help children cope with BMAs and LPs. Blount, Powers, Cotter, Swan, and Free (1994) used a multiple baseline across-subjects design to further document the efficacy of a treatment that included breathing and distraction, incentive/reward, behavioral rehearsal, and parent and psychologist coaching during the BMA and/or LP. These authors added to the empirical support for a CBT package by demonstrating the child actually used the coping skills before and during the medical procedure. Distraction was used for the early, anticipatory phase of the medical procedure and active breathing using a party blower and/or counting aloud was used during the later, painful phase of the medical procedure. Parent use of coping-promoting behaviors before and during the medical procedure was also documented. Coping-promoting behaviors included nonprocedural/disturbing talk or humor directed toward the child and commands/prompts to engage in coping strategies such as breathing with the party blower and counting. Maintenance of treatment gains for two of the three subjects was studied. With no interven-
tion or psychologist coaching on the day of the medical procedure, child distress remained reduced and parent coping-promoting and child coping behaviors remained increased relative to baseline levels. Maintenance sessions were conducted 4 months postintervention for one subject and 1.5 months and 4 months postintervention for the second subject.

Kazak et al. (1996) used many of the same CBT components to test the efficacy of psychological intervention combined with conscious sedation for children undergoing BMAs and LPs. In a prospective, randomized clinical trial of 92 children, the combined treatment was found to be superior to conscious sedation alone on ratings of child distress by mothers and nurses. With this work, Kazak (along with Jay and colleagues in their earlier studies) demonstrated the utility of combining a CBT package with pharmacotherapy approaches to acute pain management in children and adolescents.

In other studies of children with cancer, a number of researchers have demonstrated the efficacy of CBTs during injection and venipuncture procedures. Dahlquist, Gil, Armstrong, Ginsberg, and Jones (1985) used a multiple baseline across-subjects design to show that child distress during venipunctures was reduced 46%-68% in the three children studied. The treatment package included information, progressive muscle relaxation, deep breathing, positive mental imagery, positive self-talk, reinforcement/incentive, and behavioral rehearsal. The psychologist coached the child during the venipuncture. For two subjects, treatment gains of reduced child distress were maintained in the absence of coaching after 6 and 13 sessions, respectively. Sessions were held at 1- to 4-week intervals, with one subject demonstrating maintenance for one session and another subject exhibiting maintenance for two sessions.

Manne et al. (1990) employed a randomized, controlled clinical trial to further support the use of a CBT package for children with cancer undergoing venipuncture. Children had to have a history of needing restraint during venipuncture to be included in the trial. Compared to an attention control condition, CBT (including attentional distraction [use of a party blower], paced breathing, reinforcement/incentive, and behavioral rehearsal) was found to decrease child distress and the need for restraint during the medical procedure. During the third (and final) treatment session (M = 142 days since baseline assessment), the psychologist briefly reviewed the CBT intervention and allowed the parent to do all of the coaching.

Powers, Blount, Bachanas, Cotter, and Swan (1993) used a similar treatment package to show, via a multiple baseline across-subjects design, that preschool children with leukemia exhibited less distress with intervention. These authors provided further support for CBT by documenting that the children and their parents used the coping skills (child) and coping-promoting skills (parents) during the injection and venipuncture procedures. The treatment was delivered with a focus upon programming maintenance of behavior change for children and parents. Intensive training sessions were followed by brief overview sessions (maintenance promoting training), and the psychologist was never present in the medical treatment room to provide active coaching. True maintenance sessions (range: 1-3 sessions) in which no therapy occurred showed that treatment gains were maintained from 1 to 6 months (typically 1-2 months) after completion of the cognitive behavioral intervention for all four subjects.

Cognitive behavioral therapy has also been used to help children who do not have a chronic illness or experience repeated painful medical procedures. Blount et al. (1992) used a similar package to what Powers et al. (1993) used with preschool children who have cancer. Children in this study received routine immunizations at a county health clinic prior to entering kindergarten. The study used a randomized, controlled clinical trial design. Measures showed a reduction in child distress, and increases in child-coping and parent-coping promoting behaviors. Gonzalez, Routh, and Armstrong (1993) also studied children between age 3 and 7 who were undergoing routine immunization injections in a primary care clinic. They used a randomized clinical trial design to investigate a specific component of the commonly used CBT package—distraction versus reassurance by the parent during the medical procedure. Blount, Powers, and colleagues had previously categorized distraction as "coping promoting" and reassurance as "distress promoting" based upon behavioral assessment studies (Blount et al., 1989; Blount, Sturges, & Powers, 1990; Blount, Davis, Powers, & Roberts, 1991; Blount, Landolf-Fritsche, Powers, & Sturges, 1991). Gonzalez et al. (1993) found that teaching parents to use distraction techniques (e.g., nonprocedural talk) led to reduced child distress behavior.

Dahlquist (1992) concluded that CBT for
procedure-related pain in children and adolescents was efficacious but noted that issues of cost-effectiveness, maintenance of treatment gains over time, and generalizability of treatment effects were the challenges of future research. While those issues remain challenges, Cohen, Blount, and Panopoulos (1997) recently addressed the issue of cost-effectiveness for young children undergoing immunizations. Three conditions were examined in a randomized clinical trial design: standard medical care (controlling for attention and time of contact with child), nurse coach and cartoon distraction (a type of CBT, with only nurse coaching to attend, but without prior child/parent behavioral rehearsal), and nurse coach, cartoon distraction, and behavioral rehearsal (using the Powers et al. [1993] and Blount et al. [1992] protocols). The two interventions were found to be superior to the control condition for measures of child distress, child coping, parent coping promoting, and nurse coping promoting. No differences were found between the two interventions. However, a cost analysis showed the nurse coach + cartoon distraction condition to be more practical and cost-effective than the nurse coach + cartoon distraction + behavioral rehearsal condition ($454 and no future costs vs. $1,654 plus annual costs of $1,200 for helping 600 children and their families). Therefore, individual training may not be necessary for all children for all painful medical procedures, provided that effective distraction and coaching procedures are used.

Conclusions and Recommendations for Future Intervention Research

Clearly, CBT has been shown in a number of studies to reduce the distress of children with cancer undergoing a variety of painful medical procedures. These studies have been conducted by a variety of investigators using a variety of experimental designs. In addition, this treatment package has led to children and parents actually using the coping skills learned in therapy during the medical procedure, adding support to the assertion that it is the use of the cognitive behavioral therapies that leads to reduced distress and pain. This type of intervention has also been used effectively with children undergoing routine immunizations (e.g., Blount et al., 1992), treatment for burn injuries (e.g., Elliott & Olson, 1983), and dental treatments (Stokes, Stark, & Allen, 1990). By the Chambless criteria, CBT is considered a well-established treatment. While subtle variations in the exact treatment package employed were found between many studies highlighted in this article, each intervention project kept to the basic principles outlined by Elliott and Olson (1983) and Jay et al. (1985).

Future directions should include the compilation of these types of treatments into published treatment manuals and further dissemination of the findings. This type of work has been initiated by the United States Department of Health and Human Services via the Agency of Health Care Policy and Research. A Clinical Practice Guideline for “Acute Pain Management: Operative or Medical Procedures and Trauma” was published in 1992 (1992b). A quick reference for clinicians that specifically focuses on acute pain in infants, children, and adolescents was also disseminated (1992a). Cognitive behavioral therapies were included in these guideline documents. The documents (AHCPR Pub. Nos. 92-0032, 92-0019, & 92-0020) can obtained by calling 1-800-358-9295 or writing: Center for Research Dissemination and Liaison, AHCPR Publications Clearinghouse, P. O. Box 8547, Silver Spring, MD 20907. Notably, since the publication of these documents, more extensive empirical support for cognitive behavioral therapies has accumulated. In future efforts to develop interdisciplinary practice guidelines, the field of pediatric psychology should take an active and collaborative approach that ensures dissemination of empirically supported treatments such as the ones highlighted in this review.

Application of empirically supported treatments in the “real-world” context of pediatric medical care will not be widespread without active, interdisciplinary collaboration. Children, families, our medical colleagues, and insurance providers want helpful interventions that work over time and in a number of situations, that are cost-effective, and that can be learned and used by a number of health care providers in a medical setting. While studies designed to isolate the effects of specific components of the therapy package should be considered, in the environment of day-to-day care, work showing the effectiveness of an individualized application of the basic cognitive behavioral package (either alone or in combination with pharmacological treatment) is the most notable area for future intervention research for procedure-related pain in children and adolescents.

Finally, further examination of the combined use of pharmacotherapy and CBT is warranted (Powers, 1995). Indeed, current practice patterns would strongly suggest that research on the optimal
combination of behavioral and medication treatments (such as EMLA and/or conscious sedation with a narcotic and an anxiolytic agent) for various medical procedures and in various settings should be a top priority. Emphasis should be placed on the potential for combined and complementary applications, as opposed to an either/or approach (Powers, 1995). This type of focus would assist in meeting the challenges of cost, practicality, and usefulness in everyday pediatric practice (Dahlquist, 1992).

In conclusion, pediatric psychologists should be resolved to ensure that all children undergoing painful medical procedures receive interventions that work. These interventions should be designed and documented to increase coping and decrease pain and distress. They should be useful in day-to-day pediatric practice and capitalize on the optimal and complementary combination of pharmacologic and behavioral techniques. These are the future challenges in the area of procedure-related pain for the field of pediatric behavioral medicine.

**Appendix. Procedure-Related Pain Intervention Studies**


Subjects. N = 8, 4 received intervention. Ages: 5–12 years. Gender: 8 males. Ethnicity unknown. Representativeness: all had second or third degree burns covering 5%–68% of their total body surface. Burn treatment included hydrotherapy, debridement, and dressing changes.

Diagnostic criteria. Treatment for second or third degree burns.

Baseline. Four subjects were observed only during baseline conditions to confirm the reliability of observational scale. The 4 subjects who received intervention had 1–5 medical procedure sessions (randomly scheduled); pre-baseline was 2–16 burn treatment procedure sessions.

Experimental design. Combined multiple-staggered baseline across subjects and reversal design. Baseline was conducted at varying points in the burn treatment process (i.e., pre-baseline involved time since first procedure until observations actually began).

Assessment measures. Burn-Treatment Distress Scale (BTDS).

Treatment protocol. 1. Cognitive-behavioral therapy package (CBT) = distraction, breathing, emotive imagery and/or reinterpretation of the context of pain, reinforcement for using coping skills during the procedure. **Psychologist present in medical treatment room and actively coached child. Standardized: yes. Manual: very detailed description, no mention of manual. One 45-minute session prior to and same day as procedure.

Outcome. M = 36.7% reduction in distress (range: 25%–50%). Treatment gains found only when psychologist was present to coach child.

Follow-up. Treatment response maintained for up to 16 sessions, but only when psychologist was present to coach the child. During reversal session the psychologist was not present, and the level of distress increased.


Subjects. N = 5. Ages: 3.5–7 years. Gender: 3 females, 2 males. Ethnicity unknown. Representativeness: number of previous procedures was 4 to 17. Range of time since diagnosis was 1–2.5 years.

Diagnostic criteria. Leukemia diagnosis; clinical referral because of prior levels of severe anxiety and/or behavioral distress during BMAs and/or LPs.

Baseline. Subjects received 1–5 medical procedure sessions (randomly scheduled); pre-baseline was 3–16 medical procedure sessions.

Experimental design. Multiple baseline across subjects staggered so that baseline was conducted at varying points in the leukemia treatment process (i.e., pre-baseline involved time since first procedure until observations actually began).

Assessment measures. Observation Scale of Behavioral Distress (OSBD).

Treatment protocol. 1. Cognitive-behavioral therapy package (CBT) = breathing exercises, reinforcement for lying still and using breathing during procedure, emotive imagery, behavioral rehearsal, filmed modeling. **Parents and psychologist accompanied child during intervention session and coached the child during the medical procedure. Standardized:
yes. Manual: very detailed description, not mention of manual. One 45-minute session prior to and same day as procedure.

**Outcome.** $M = 50.5\%$ reduction in distress (range: $41.9\%–62.5\%$). No need for restraint after intervention. Clinical significance noted in child, parent, nurse, and physician responses to success of the intervention.

**Follow-up.** Treatment response maintained in 4 of 5 subjects for 1–2 additional sessions. No further follow-up conducted.


**Subjects.** $N = 56$. Ages: $M = 6.7$ years, range: 3–14 years (71% less than age 8). Gender: 20 females, 36 males. Ethnicity: 55% White, 25% Hispanic, 13% Black, 7% Asian. Representativeness: 27% of subjects were newly diagnosed and in first six weeks of medical treatment, 62% in first remission, 11% in second or third remission. No subjects were either in relapse or terminally ill. Previous BMA procedures: 1–33. Range of time since diagnosis was 0.5–78 months.

**Diagnostic criteria.** Leukemia diagnosis, not in relapse or terminal condition; medical protocol included at least 3 BMAs; no diagnosis of mental retardation.

**Baseline.** No baseline other than time since diagnosis and number of previous BMAs.

**Experimental design.** Repeated measures counterbalanced design contrasting three interventions (CBT, Valium, minimal treatment–attention control). Subjects were grouped in stratified blocks according to age and months since diagnosis and then randomly assigned to sequence of interventions.

**Assessment measures.** Observation Scale of Behavioral Distress (OSBD); child self-report on “Pain Thermometer (1–100 scale)”; pulse rate and blood pressure pre-BMA.

**Treatment protocol.** 1. Cognitive-behavioral therapy package (CBT) as described by Jay et al. (1985) = breathing exercises, reinforcement for lying still and using breathing during procedure, emotive imagery, behavioral rehearsal, filmed modeling. 2. Valium = 0.3 mg/kg of oral Valium 30 minutes before the BMA. 3. Minimal treatment/attention control = children watched cartoons for 30 minutes prior to BMA; routine support and reassurance provided by parents and nurses. **Psychologist present in medical treatment room for each of the 3 conditions (coaching in CBT only).

**Outcome.** OSBD-rated distress, self-reported pain, and pulse rates were lower in CBT than Valium or attention control condition. Valium = control except for lower diastolic blood pressure. CBT distress 18% less than attention control and CBT self-report pain 25% less than attention control were noted as evidence of clinical significance.

**Follow-up.** No follow-up data reported. Of note, absence of sequence effects suggests that one-time CBT did not generalize to future procedure sessions.


**Subjects.** $N = 83$ (BMAs = 33; LPs = 50). Ages: $M = 6.3$ years, range: 3–12 years (75% less than age 8). Gender: 38 females, 45 males. Ethnicity: 46% White, 18% English-speaking Latino, 18% Spanish-speaking Latino, 11% Asian, 7% Black. Representativeness: 28% of subjects were newly diagnosed, 55% in first remission, 16% in second remission, 1 subject in relapse. Previous BMA procedures: 1–18; previous LP procedures: 1–30. Range of time since diagnosis was 2 weeks to 5 years. Average of 2 months between baseline session and intervention.

**Diagnostic criteria.** Leukemia or lymphoma diagnosis; medical protocol included at least 2 BMAs or 2 LPs within a 6-month period. Subjects were either English or Spanish speaking.

**Baseline.** One baseline session followed within 6 months ($M = 2$ months) by intervention.

**Experimental design.** Repeated-measures factorial design contrasting 2 interventions (CBT, CBT + Valium). Subjects were randomly assigned to an intervention.

**Assessment measures.** Observation Scale of Behavioral Distress (OSBD); child self-report of fear (pre procedure) and pain (post procedure) on 5-point Faces scales; pulse rate pre procedure.
Treatment protocol. 1. Cognitive-behavioral therapy package (CBT) as described in Jay et al. (1985) = breathing exercises, reinforcement for lying still and using breathing during procedure, emotive imagery, behavioral rehearsal, filmed modeling. 2. CBT + Valium = 0.15 mg/kg of oral Valium 30 minutes before the procedure (immediately before the CBT intervention). **Psychologist present in medical treatment room for each of the 2 conditions (coaching in CBT and CBT + Valium). Standardized: yes. Manual: very detailed description, no mention of manual. One 30–45-minute session prior to and same day as procedure.

Outcome. OSBD-rated distress, self-reported pain, and pulse rates lower than baseline for both CBT and CBT + Valium. No differences between the interventions on these measures. Self-reported fear did not change in response to intervention.

Follow-up. No follow-up data reported.


Diagnostic criteria. Leukemia diagnosis, medical protocol included at least 2 BMAs within a 2.5-month period.

Baseline. No baseline.

Experimental design. Repeated-measures counterbalance design contrasting 2 interventions (CBT, General Anesthesia [GA]). Subjects were randomly assigned to 1 of 2 sequences of interventions.

Assessment measures. Observation Scale of Behavioral Distress (OSBD); child self-report of fear (pre and post procedure) and pain (post procedure); pulse rate pre-BMA; anticipatory fear of next BMA; side effect evaluation for GA group (post BMA); Post-Procedure Parent Questionnaire of Behavioral Adjustment (24 hours post BMA for both groups); child and parent preference for CBT or GA.
Treatment protocol. Cognitive-behavioral therapy package = behavioral rehearsal of distraction during the early/anticipatory phase and active coping such as breathing with a party blower or counting during the later/painful phase, child and parent training of skills, reward for participation. **Trainer present for procedure and coached child and parent. Standardized: yes. Manual: very detailed description, no manual. Intervention prior to and same day as procedure.

Outcome. Parent coping promoting behavior: CAMPIS-R rate per minute increased with intervention. Child coping behavior: CAMPIS-R rate per minute increased with intervention for first treatment session for all 3 subjects and persisted for two subjects. Child distress behaviors: OSBD scores and CAMPIS-R rate per minute decreased during the first treatment session for all 3 subjects and persisted for 2 of the 3 subjects.

Follow-up. Maintenance data with no intervention for 2 subjects. One session for 1 subject and 2 sessions for the other subject. Parent coping promoting and child coping remained increased and child distress remained decreased.


Subjects. $N = 92$ in prospective trial (additional 70 in cross-sectional control group). Ages: $M = 5.6$ years (all subjects under age 18). Gender: 49% female; 51% male. Ethnicity: 83% White, 13% African American, 1% Hispanic, 2% Asian, 1% Asian Indian. Representativeness: patients with leukemia undergoing BMAs and/or LPs.

Diagnostic criteria. Leukemia diagnosis.

Baseline. No baseline.

Experimental design. Prospective, randomized (stratified by age) clinical trial contrasting pharmacologic intervention with pharmacologic intervention plus psychological intervention. A cross-sectional control condition (CC) was also incorporated into the design. Subject enrollment over a 36-month period. Prospective trial subjects followed for 1, 2, and 6 months after diagnosis.

Assessment measures. Perception of Procedures Questionnaire; Parent Stress Index (short form); Pediatric Quality of Life Scale; parent ratings of child distress on 7-point Likert scale (post procedure); parent self-rating of distress on 7-point Likert scale (post procedure); staff rating of child distress on 7-point Likert scale (post procedure); staff rating of parent distress on 7-point Likert scale (post procedure).

Treatment protocol. 1. Pharmacologic intervention (PO) = conscious sedation with Midazolam and morphine. 2. Psychological intervention + PO (CI) = distraction (play, imagery, counting, breathing) and conscious sedation. **Parent and interventionist coached child during procedure. Standardized: yes, with individualization a key feature. Manual: no.

Outcome. CI better than PO according to ratings of child distress by mothers and nurses. No other between-group differences found. Parents rated less distress in CI than CC (ratings for before and during the procedure) and PO (before the procedure) at 6 months post diagnosis time point.

Follow-up. No follow-up data reported.


Subjects. $N = 3$. Ages: 11–14 years. Gender: 1 female; 2 males. Ethnicity: unknown. Representativeness: one patient with stage 3 Burkitts lymphoma; two patients with stage 1 osteosarcoma of the femur. Patients had been in treatment for 11, 13, and 3 weeks, respectively. Subjects received intravenous chemotherapy every 1–4 weeks. Eighty-eight percent of venipunctures occurred during a 3–5 day hospitalization; 12% occurred on an outpatient basis.

Diagnostic criteria. Oncology diagnosis undergoing chemotherapy that included repeated venipunctures.

Baseline. Medical procedure sessions (2, 8, and 15, respectively).

Experimental design. Multiple baseline across subjects design.

Assessment measures. Observation Scale of Behavioral Distress (OSBD); parent ratings of child distress on a 7-point Likert scale (at morning of admission,
while driving to hospital, while checking into hospital, during venipunctures, during medication administration, 2–4 hours after medication, and each subsequent day of admission; medical personnel rated child distress on 7-point Likert scale (post procedure); child self-report of distress on a 7-point thermometer scale (same as parent rating time points described above).

Treatment protocol. Cognitive-behavioral therapy package = information about the physiological reactions, specific chemotherapy stimuli, and specific thoughts associated with distress during chemotherapy; progressive muscle relaxation, deep breathing, positive mental imagery, and positive self-talk; earned video game time for use of skills. Standardized: yes. Manual: very detailed description, no mention of a manual.

Outcome. Child distress as measured by OSBD decreased from 46% to 68% from baseline. Child self-report of distress during venipuncture decreased after treatment. Two subjects reported less distress before and after venipuncture. Medical personnel ratings of child distress decreased from 9% to 22%.

Follow-up. Changes were maintained for 2 subjects (1 session for 1 subject and 2 sessions for another subject) without active coaching by a trainer during the venipuncture. No follow-up data available for third subject due to relapse of disease and early termination of CBT package.


Subjects. N = 23. Ages: M = 4.7 years, range: 3–9 years. Gender: 12 female; 11 male. Ethnicity: 65% White, 26% Black, 9% Hispanic. Representativeness: children with an oncology diagnosis who were restrained by their parent or a nurse during a recent venipuncture procedure. Parent regularly accompanied child to outpatient appointment.

Diagnostic criteria. Oncology diagnosis included neuroblastoma, leukemia (n = 13), embryonic rhabdomyosarcoma, Wilm’s tumor, congenital immune disorder, and eosinogranuloma. Subject had to be restrained during a recent venipuncture.

Baseline. None other than an assessment study that showed the child had to be restrained.

Experimental design. Randomized controlled trial contrasting 2 conditions (attentional control [n = 10]) or behavioral intervention [n = 13]). Intervention and assessments during 3 consecutive procedures were 40–60 days apart.

Assessment measures. Procedure Behavior Rating Scale (revised); child self-report of fear and pain (post procedure); parent report of child pain (post procedure); parent self-report of anxiety (post procedure); nurse report on 5-point Likert scale of procedure difficulty, child distress, and their own anxiety.

Treatment protocol. 1. Attentional control = parents instructed to used whatever techniques they had found helpful to control their child’s distress during prior venipunctures. 2. Behavioral intervention = instruction in attentional distraction, paced breathing, and positive reinforcement for cooperation, holding still, and using party blower for distraction and paced breathing. Training took about 10 minutes for session 1 and for brief reviews before sessions 2 and 3.


Follow-up. Maintenance session data indicated that behavioral intervention was better than control for child distress (PBRS and parent report of child pain) and parent self-report of anxiety (this measure was lowest at maintenance session 3). No further follow-up data reported.


Diagnostic criteria. Non-chronically ill children receiving routine immunization.
Baseline. None. Parents rated child on prior distress during injections.

Experimental design. Randomized controlled trial with subjects stratified by parent report of typical distress during injections (high vs. Low); 2 × 2 factorial design with cognitive behavioral therapy compared to no intervention control condition.

Assessment measures. Observation Scale of Behavioral Distress (OSBD); Child-Adult Medical Procedure Interaction Scale-Revised (CAMPIS-R); Behavioral Approach-Avoidance and Distress Scale (BAADS); child self-report of fear (pre procedure) and pain (post procedure); parent ratings of child fear (pre procedure) and pain (post procedure); parent self-ratings of their ability to help child; nurse ratings of child distress and cooperation (post procedure).

Treatment protocol. 1. Cognitive behavioral therapy package = parent taught to distract the child during the early/anticipatory phase and use active coping such as breathing with a party blower during the later/painful phase. Training involved modeling, role-play with behavioral rehearsal, parent training in coaching the child to engage in the coping skills, and desensitization. 2. Control = no intervention. **No trainer was present during the actual procedure. Standardized: yes. Manual: no.


Follow-up. No follow-up data reported.


Subjects. N = 4. Ages: 3–5 years. Gender: 4 females. Ethnicity: White. Representativeness: patients with leukemia who had been in treatment less than 6 months and were on a medical protocol that required IV and/or IM injections every 7–14 days. A parent had to accompany the child on a regular basis to the outpatient clinic. Range of time since diagnosis was 6 days to 5 months, 21 days. Average time between injections sessions ranged from 9.5 to 17.5 days.

Diagnostic criteria. Leukemia diagnosis in subjects between the age of 3 and 5 years.

Baseline. Two to four medical procedure sessions.

Experimental design. Multiple baseline across subjects design.

Assessment measures. Observation Scale of Behavioral Distress (OSBD); Child-Adult Medical Procedure Interaction Scale-Revised (CAMPIS-R); parent ratings of child fear (pre procedure) and pain (post procedure); nurse ratings of child distress and cooperation (post procedure).

Treatment protocol. Cognitive behavioral therapy package = intensive training (IT) including parent and child training components. Specifically, use of distraction during the early/anticipatory phase and active coping (breathing and counting) during the later/painful phase. Maintenance promoting (MP) included short review of skills. IT = 2–4 sessions lasting 45 minutes; MP = 2–4 sessions lasting 15 minutes. Standardized: yes. Manual: very detailed description, no manual.

Outcome. Parent coping promoting behavior: CAMPIS-R rate per minute increased with intervention and maintained during follow-up. Child coping behavior: CAMPIS–R rate per minute increased with intervention and maintained during follow-up. Child distress behaviors: OSBD scores, CAMPIS-R rates per minute, and percentage of 15-second intervals with an OSBD code of restraint decreased with intervention and maintained during follow-up. Nurse ratings of cooperation increased from baseline and maintained at follow-up.

Follow-up. Maintenance data with no intervention collected from 1 month to 6 months after completion of intervention session (IT and MP). All data indicate maintenance of treatment gains with all subjects continued to be improved in comparison to baseline.


Subjects. N = 42. Ages: M = 4.75 years, range: 3–7 years. Gender: 21 females, 21 males. Ethnicity: 21
African Americans, 21 Hispanics. Representativeness: children attending a general pediatric primary care clinic in a large, urban public hospital that serves as a medical school teaching facility. Children were to receive a routine immunization as part of the clinic visit. Lower SES population. Mothers accompanied child to the clinic.

Diagnostic criteria. Non-chronically ill children between age 3 and 7 years who were receiving routine immunizations in a primary care clinic.

Baseline. None.

Experimental design. Randomized controlled trial contrasting 3 conditions (minimal treatment control, maternal reassurance, maternal nonprocedure talk/distraction). Block randomization procedure used to account for age, gender, and ethnicity.

Assessment measures. Adult-Child Medical Procedure Interaction Scale (Codes of Nonprocedural Talk to Child and Reassuring Comments); Modified Frankl Behavior Rating Scale; Observational Scale of Behavioral Distress-Revised (OSBD-R); child self-report of pain (post procedure).

Treatment protocol. 1. Minimal treatment control = attention/time of contact control involving information about transportation to the hospital. 2. Maternal reassurance = mothers learned to use reassuring comments. 3. Maternal nonprocedural talk/distraction = mothers learned to use distracting comments. **For conditions 2 and 3, assistant prompted mother to use the trained skill during procedure. Standardized: yes. Manual: no. Intervention prior to and same day as procedure.

Outcome. Distraction < reassurance and control on measure of child distress (OSBD-R) and on behavior of crying.

Follow-up. None.


Diagnostic criteria. Non-chronically ill children receiving routine immunizations (DPT and MMR). Length of medical procedure was approximately 6 minutes. Study was conducted in August, a peak time for preschool-age children to receive immunizations.

Baseline. None.

Experimental design. Randomized controlled trial contrasting 3 conditions (standard medical care [control], nurse coach [NC], nurse coach plus train parent and child [N + CBT]).

Assessment measures. Child-Adult Medical Procedure Interaction Scale-Revised (CAMPIS-R); child self-report of pain [post procedure]; parent ratings of child distress on 5-point Likert scale (post procedure); parent self-report on their own distress on 5-point Likert scale; nurse ratings of child distress on 5-point Likert scale; nurse self-report of their own distress level on 5-point Likert scale; measure of cost-effectiveness (start up and annual cost per condition).

Treatment protocol. 1. Standard medical care = attention/time of contact control involving information about the hospital. 2. Nurse coach = nurse trained to use questions and comments about a movie to distract the child and use prompts to watch the movie. 3. Nurse coach plus train parent and child = nurse coach as above, plus CBT package as described in Powers et al. (1993) [intensive training (IT) including parent and child training components. Specifically, use of distraction during the early/anticipatory phase and active coping (breathing and counting) during later/painful phase.].

Outcome. Intervention > control on measure of child coping behaviors and parent and nurse coping promoting behaviors. Intervention < control on child report of pain, nurse report of child distress, and parent report of child distress. Cost effectiveness per annum: NC = $454 and no future costs; N + CBT = $1,654 for 600 children and $1,200 annual cost.

Follow-up. No follow-up reported.

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