

Procedural Preparation and Support as a Standard of Care in Pediatric Oncology

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Youth with cancer undergo many repeated and invasive medical procedures that are often painful and highly distressing. A systematic review of published research since 1995 identified 65 papers (11 review articles and 54 empirical studies) that investigated preparatory information and psychological interventions for a variety of medical procedures in pediatric cancer. Distraction, combined cognitive-behavioral strategies, and hypnosis were identified as

effective for reducing child pain and increasing child coping. Low- to high-quality evidence informed strong recommendations for all youth with cancer to receive developmentally appropriate preparatory information and psychological intervention for invasive medical procedures. *Pediatr Blood Cancer* 2015;62:S694-S723. © 2015 Wiley Periodicals, Inc.

Key words: anxiety; cognitive-behavioral; distraction; distress; hypnosis; nonpharmacological; pain; pediatric oncology; preparation; procedure; psychosocial; psychological intervention; standards of care; support

INTRODUCTION

Pediatric patients who are diagnosed and treated for cancer undergo many repeated, invasive, and painful medical procedures. Untreated or undertreated procedural-related pain can create significant changes in pain processing, and increased anxiety and distress.[1–3] These sequelae may occur before, during, and even weeks after the procedure [1,4–6] and may contribute to longer lasting psychological symptoms such as post-traumatic stress and anxiety.[7–9] Efforts to reduce these symptoms are critical as unmanaged pain, anxiety, or distress during prior painful procedures has been found to be predictive of difficulty at future procedures [3,10,11] and may result in physiological changes or conditioned responses that impact the way pain is processed.[12–15]

An extensive line of research has been devoted to the provision of information and development of interventions to help youth cope during painful procedures.[see Refs. 16–32] However, over the past few decades, pharmacological interventions, including local and general anesthesia, are being increasingly utilized and creating a paradigm shift in the way youth experience procedures. Therefore, what is stressful to children currently diagnosed and treated for pediatric cancer is different than in previous decades. Despite availability and advances in effective pharmacological approaches, their use remains underutilized and at times ineffective.[33,34] The most effective pain management approaches are multifaceted and combine pharmacological approaches with psychosocial procedural preparation and intervention.[20,35–40]

A review of the literature on procedural preparation has established that special care is required to prepare children to undergo painful medical procedures.[41–44] Preparatory information provides children and adolescents with a sense of predictability and control.[45] Foundational research in pediatric psychology established the importance of providing children with information about procedures through modeling, rehearsal, books, puppets, or medical play.[46–51] focusing on sensory information.[16,52] or combining procedural-sensory information.[17,53–56] It represents the beginning efforts to help children cope with painful and invasive medical procedures. Additional research helped to establish that preparation should be well timed, developmentally appropriate, and include descriptions of the sequence of events that will occur, as well

Psychosocial Standard of Care

All youth with cancer should receive developmentally appropriate preparatory information about invasive medical procedures. All youth should receive psychological intervention for invasive medical procedures.

as accurate and honest information about what pain and sensations to expect.[57–63]

There is a significant body of empirical evidence to suggest that children and adolescents benefit from psychological interventions when undergoing painful medical procedures.[64–67] Psychological interventions allow youth to learn, rehearse, and incorporate coping strategies, which often lead to increased self-efficacy. Overall, psychological interventions have been shown to lower self-, parent-, and observer-reported pain, anxiety, and distress, as well as lower physiological arousal in children and adolescents during medical procedures. Empirical evidence and multiple consensus statements agree that providing children information about procedures and implementing psychological intervention can ameliorate many of the deleterious effects from invasive medical procedures, increase child coping and cooperation, and prevent increased pain and distress with subsequent procedures.[10,11,68–76]

Abbreviations: BMA, bone marrow aspiration; LP, lumbar puncture; PSCPC, Psychosocial Standards of Care Project for Childhood Cancer; RCT, randomized controlled trial

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Assessment is a crucial component of procedural preparation and intervention. Evaluation of a child's developmental and cognitive abilities as well as their preference for provision of information is paramount. Attaining child preferences allows providers to deliver the type and amount of information needed. Some youth prefer detailed information and others prefer more general descriptions as too much information can increase anxiety. Child preferences and abilities may also inform subsequent approach to intervention.[61]

The primary objective of this review was to assess the existing literature on procedural support to inform evidence-based standards for incorporating procedural preparation and support for all youth with cancer.

METHODS

This review was performed as a part of the collaborative *Psychosocial Standards of Care Project for Childhood Cancer* (PSCPCC) effort.[77] Studies were identified by conducting computerized literature searches of Ovid (PubMed, MEDLINE, Cochrane), PsycINFO, and CINAHL. The searches combined "child," "neoplasm," "procedure," and "intervention" terms and follow-up-related terms and MeSH headings (See Supplementary Table I for full list of search terms). Results of the standardized database searches were supplemented with hand searches to ensure that systematic reviews, randomized clinical trials, and other seminal articles were included. Search criteria were standardized across PSCPCC standards in an effort to maintain consistency and provide readers the most useful and updated overview of the current state of the field and its future directions. Inclusion criteria included youth (up to the age of 18 years); English language; all malignancies; dates of publication (March 1, 1995–March 1, 2015); and the following study designs: clinical trial, comparative study, evaluation studies, guideline, meta-analysis, multicenter study, observational study, practice guideline, and systematic review. Exclusion criteria were as follows: patients over the age of 18 years, foreign language only, noncancer diagnoses, case studies, and commentaries. Systematic reviews published after 1995 were excluded if they reviewed individual studies published prior to 1995.

A multidisciplinary group of providers including pediatric oncologists, pediatric psychologists, and a child life specialist reviewed the recommendations to ensure validity and feasibility for practice. Results of their review impacted the inclusion of adult–patient communication and interactions. Grading of Recommendations Assessment, Development and Evaluation methodology was used to appraise the body of evidence. For a full description of the methods used to develop each standard, the reader can refer to Wiener et al. in this special issue.[78]

RESULTS

Database searches identified over 7,000 articles, of which 65 papers (11 review articles and 54 empirical studies) were included. A PRISMA flowchart of study screening, study identification, and reasons for exclusion is provided in Supplementary Figure 1. Of the empirical studies, 28 were randomized controlled trials (RCTs), 25 were quantitative (e.g., longitudinal, cohort, and observational), one was qualitative,[79] and one used mixed methods.[80] Children aged 2–19 years were represented. Psychological interventions were most often compared

to one another or to standard care, and less frequently with pharmacological interventions.[35,36,40,81,82] Medical procedures were most often bone marrow aspirations (BMAs) and lumbar punctures (LPs), as well as venipuncture/venous access, port access, intravenous insertion, radiation therapy, chemotherapy, dressing change, and stem cell bone marrow transplantation. Most studies included children undergoing repeated medical procedures, with few studies focused on a first procedure [80,83] or coping with hospitalization.[84] Child pain, anxiety, fear, and/or distress were primary outcomes as rated by the child, parent, or nurse, or behavioral observation. Less common outcomes were child coping, mood, compliance/cooperativeness, symptom severity, physiological arousal, need for sedation, adult–child communication, and parent anxiety.

Psychological interventions involve cognitive and/or behavioral components that focus on modifying children's thoughts and beliefs or teaching behavioral strategies to enhance coping and reduce pain and distress from medical procedures.[64–67,79,85–92] Strategies can be implemented prior (immediately or days/weeks before), during, and/or following completion of the procedure. Reviewed interventions included distraction (21 studies), combined cognitive–behavioral (11 studies), hypnosis (six studies), memory reframing (two studies), breathing (one study), art therapy (one study), behavioral training (one study), and biofeedback/relaxation (one study). Additional studies explored the impact of adult behaviors and adult–child communication on children's coping (10 studies).[93]

Distraction includes all efforts to draw attention away from the medical procedure to something more interesting and engaging.[94] Reviewed RCTs and quantitative studies described music, books, toys, videogames, virtual reality, pet therapy, blowing bubbles, or conversations with parents as distraction techniques.[40,80–82,84,90,95–111]. Review articles and almost all studies found some benefit of distraction, such as reduced pain and distress (anxiety/fear).[64,65,67,84,86,90,91] Even when distraction was no more effective than standard care, children and parents still reported it to be helpful, enjoyable, and that they would like to use it again.[80,98] Despite this evidence, it remains unclear what make an effective distraction intervention, although considerations of adult involvement, child choice of distracter, requirement to interact with a distracter, and/or use of technology may be helpful.[64] Pediatric oncology nurses identified distraction as less effective for children with extreme anxiety or fear, children who are not receptive to distraction, children who have had previous negative experiences, or where there is insufficient time.[79] Higher parent anxiety is also associated with decreased distraction efficacy.[106]

Combined cognitive–behavioral interventions as described in the reviewed studies involved at least two of the following strategies, including imagery, coping self-statements, reframing, relaxation, breathing exercises, modeling, rehearsal, desensitization, positive reinforcement, cognitive or behavioral distraction, parent training, and/or parent/staff coaching. Many interventions included specific procedural preparation, such as information, medical play, in-person rehearsal, and/or filmed modeling of the procedure. These strategies familiarize children with medical apparatus, supplies, and equipment.[112] Several RCTs, quantitative studies, and review articles showed benefits of combined cognitive–behavioral interventions,

TABLE I. Procedure Preparation Standard Summary of Evidence Table

Standard	Evidence summary	Methodology	Quality of evidence	Strength of recommendation
All youth with cancer should receive developmentally appropriate preparatory information about invasive medical procedures.	<p>Empirical research for children and adolescents with cancer indicates benefit of preparatory information for decreasing children's distress and increasing coping and compliance during a variety of medical procedures.</p> <p>Evidence gaps:</p> <ul style="list-style-type: none"> • Most of the reviewed evidence for preparatory information post-1995 is within the context of broader combined cognitive-behavioral interventions. More research is needed to determine how well children retain and understand the content of preparatory information across the developmental trajectory, as well as ways to make procedure-specific information optimally delivered and understandable for children and their families across procedures that children currently report as the most distressing. 	Systematic review articles; randomized controlled trials; repeated measures/longitudinal studies	Low ¹ quality of evidence given inconsistent findings and some indirectness of evidence from several well-designed studies of broader psychological intervention.	Strong recommendation, given the impact on children's coping and distress, respect for children and parents, and potential harms of not informing, as well as the supporting evidence available pre-1995 and with other pediatric populations.
All youth should receive psychological intervention for invasive medical procedures.	<p>Empirical research for children and adolescents with cancer indicates significant benefit of psychological interventions for reducing child pain and distress, in addition to other outcomes, during a variety of medical procedures.</p> <p>Psychological interventions with the most supportive evidence include distraction, hypnosis, and combined cognitive-behavioral interventions.</p> <p>Evidence gaps:</p> <ul style="list-style-type: none"> • More research is still needed to assess what components of the interventions are the most effective and for whom. • Several interventions have limited, but promising evidence and additional research is needed, including breathing alone, behavioral training alone, and art therapy. 	Systematic review articles; randomized controlled trials (single and multisite); nonrandomized/quasi-experimental group comparisons; repeated measures/longitudinal; observational studies; qualitative studies	High quality of evidence given numerous well-designed studies with predominantly consistent findings	Strong recommendation, given the benefits for pain and distress, as well as other outcomes

¹It is important to note that much of the literature demonstrating the effectiveness of preparatory information fell outside of our targeted literature search criteria (pre-1995) and therefore was not evaluated for this review despite strong evidence to support its effectiveness.

including reduced child pain and/or distress and reduced parental anxiety.[66,83,87,90,91,113–115] Other studies reported no benefits for pain and distress,[116–118] but did find increased coping, lower physiological reactivity, and subjective perceptions of the intervention as helpful.[119–123] Increased practice of intervention strategies at home prior to the procedure appears associated with more benefit.[115]

Individual RCT, quantitative studies, and review articles support hypnosis for reducing child procedural pain and/or distress,[35,64,67,84,86–88,91,124–127] although some inconsistent evidence is also found.[92,104] Hypnosis is a state of heightened awareness and focused attention, often involving relaxation. It can be direct (focused on pain or analgesic suggestion) or indirect (focused on relaxation suggestion), with both showing reduced child pain and distress as compared with standard care.[35,125,127] Hypnosis can be therapist-led or child-led with training, although therapist-led interventions appear more effective.[127] Children with high levels of hypnotizability receive greater treatment benefit.[104]

Reduced pain and/or distress have also been reported for memory reframing,[10,128] supportive touch,[129,130] breathing,[131] behavioral training,[132] and art therapy,[133] but not biofeedback/relaxation alone.[134] Adult (parent, nurse, and physician) communication with children prior to, during, and following medical procedures is also critical.[93,135–141] Criticism, reassurance, empathy, invalidation, or vague commands were typically associated with increased child distress, whereas humor, praise, distraction, specific commands, and talking *with* rather than *at* the child were generally associated with decreased child distress and increased coping.

While the benefits of procedural preparation and support have been clearly demonstrated, limited evidence informs which strategy is best based on situation characteristics (i.e., child age, temperament, coping style, parent anxiety, and type of procedure). Additional challenges are helping healthcare providers, and families, recognize the benefits of preparatory and psychological intervention despite limited time and resources.

An overall summary of the evidence is available in Table I. Details regarding included studies and reviews such as study design, sample, findings, study rigor, and level of evidence are available in Supplementary Table II.

DISCUSSION

This comprehensive literature search found strong empirical support for providing children and adolescents with cancer with preparatory information and psychological intervention when undergoing painful medical procedures. The benefits are well established across the developmental spectrum for a variety of interventions (distraction, combined cognitive–behavioral, hypnosis) and procedures (BMA, LP, needle procedures) with little to no risk.

Further considerations include the importance of child age and developmental level in the appropriateness and implementation of various psychological interventions, as children's coping abilities and preferences develop significantly throughout childhood and adolescence.[142] Not all youth will require ongoing intervention after learning to cope and adapt, although they may continue to benefit from procedure preparation when undergoing any procedure for the first time. Making first procedures as

comfortable as possible may prevent a learned response and the related ongoing distress that can ensue.[143] Appropriate procedure preparation and intervention can be implemented by child life specialists, psychologists, or other appropriate staff (e.g., nurses).[144,145] Child life specialists have been essential as primary providers of procedural preparation using many of the approaches developed and tested by psychologists. Psychologists and psychiatrists may be appropriate referrals for additional assistance when routine preparation and intervention have been ineffective.

Additionally, as medical care and treatment advances, there are changes in the way procedures are completed. Children used to endure procedures without appropriate analgesics. Now, more effective approaches to invasive painful procedures, such as BMAs and LPs, can be completed with integrative psychosocial and pharmacological interventions, including local and even general anesthetics. Procedural preparation by medical and psychosocial staff will need to adapt to the ongoing medical and treatment advances to ensure optimal coping for children, adolescents, and their families. Training in child development, assessment of anxiety, pain, and distress allows psychosocial and/or medical staff to appropriately identify who will need ongoing psychological intervention.[146]

CONCLUSIONS

This review sought to evaluate the evidence for providing preparatory information and psychological intervention to youth with cancer undergoing painful medical procedures. Surprisingly, there was low quality of evidence to support providing youth with preparatory *information* given the lack of studies within the reviewed period that exclusively investigated the provision of preparatory information in the absence of other psychological intervention (e.g., cognitive–behavioral strategies), the inconsistent benefits for reduced pain and distress reported in those studies, as well as study design (study limitations and reporting bias). Despite limited evidence within this review, the benefits are well established across the developmental spectrum for the provision of information, with additional supporting evidence available pre-1995 and with other pediatric populations. The recommendation that all youth should receive psychological *intervention* for invasive medical procedures is supported by high-quality evidence, given the numerous well-designed studies. There are strong recommendations for both of these standards given the risk–benefit ratio, including decreasing children's pain and distress and increasing coping and compliance during medical procedures.

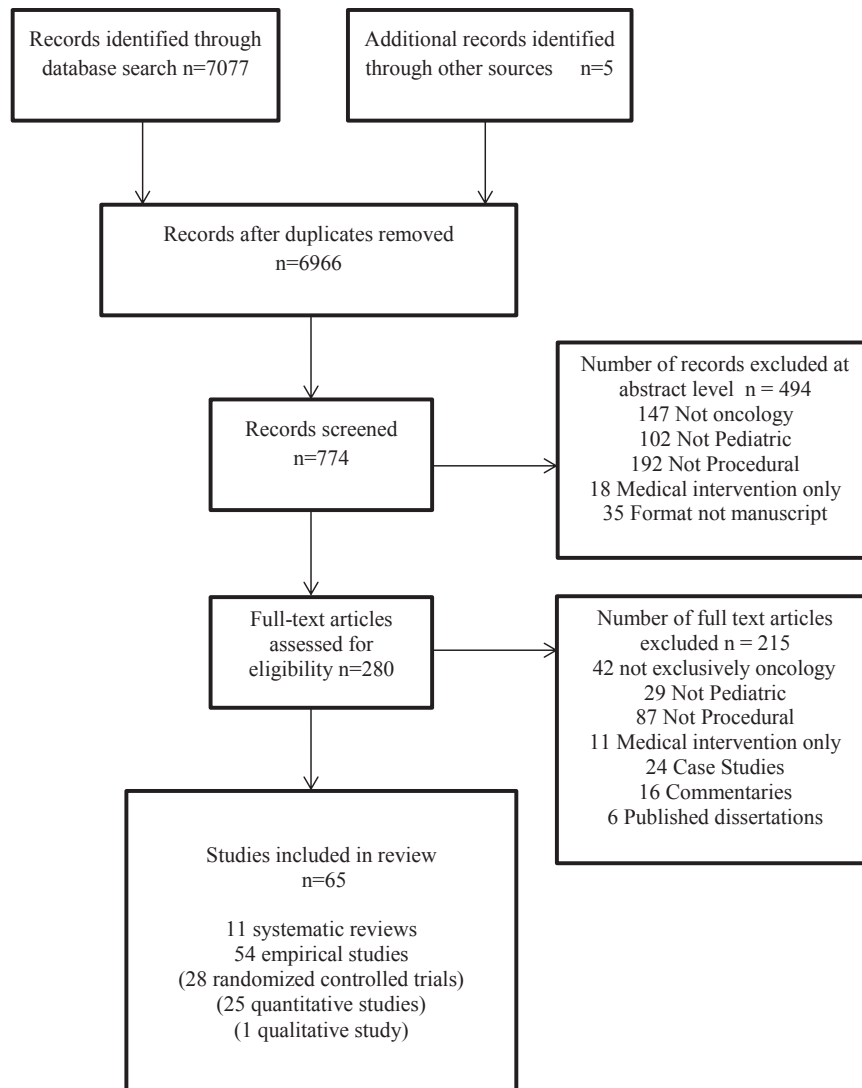
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SUPPLEMENTARY INFORMATION



Supplemental Figure 1. PRISMA Flowchart

SUPPLEMENTAL TABLE I. Search Terms

Search (((((((("childhood cancer") OR child) OR adolescent) OR pediatric) OR paediatric) OR youth) OR children))) AND
 (((((((((((((((((((cancer*) OR maligna*) OR sarcom*) OR tumor*) OR tumour*) OR neoplasm) OR AML) OR B-cell) OR
 carcinom*) OR ewing*) OR gliom*) OR hematolo*) OR hepatoblastom*) OR hepatom*) OR hodgkin*) OR leukaemi*) OR
 leukemi*) OR lymphom*) OR medulloblastom*) OR meningiom*) OR nephroblastom*) OR neuroblastom*) OR non-hodgkin) OR
 oncolog*) OR osteosarcom*) OR PNET*) OR retinoblastom*) OR rhabdomyosarcom*) OR T-cell*) OR teratom*) OR wilms*))
 AND
 (((((((((((((((("procedure preparation") OR "procedure distress") OR "procedural distress") OR "procedure related pain") OR
 "painful procedure") OR "acute pain") OR invasive) OR distress) OR anxiet*) OR fear) OR pain) OR stress) OR discomfort) OR
 venipuncture) OR needle) OR "central line") OR "lumbar puncture") OR "bone marrow") OR intravenous) OR "port access") OR
 portacath) OR injection)) AND (((((((((((((((((psychoed*) OR play) OR "parent training") OR "parent coaching") OR coach*)
 OR modeling) OR desensiti*) OR distract*) OR imagery) OR coping) OR cognitive) OR behavior*) OR behaviour*) OR "cognitive
 behavior*") OR "self talk") OR hypnosis) OR relax*) OR music) OR art) OR "therapeutic touch") OR audiovisual) OR "virtual
 reality") OR preparation) OR mindfulness) OR rehears*) OR reforc*) Filters: Publication date from 1995/03/01 to 2015/03/01;
 Humans; English

SUPPLEMENTAL TABLE II. Literature Review Table

Study	Design	Sample	Psychological intervention(s)	Findings	Study Rigor	Level of evidence
General Systematic Reviews or Studies (i.e., not specific to any procedure)						1
Birnie, Noel, Parker, Chambers, Uman, Kisely, & McGrath (2014) [1]	Systematic review and meta-analysis of controlled clinical trials examining distraction and hypnosis for management of procedural pain and distress ¹	Controlled clinical trials of various needle procedures including BMA, LP, venipuncture, and port access (n = 33 studies)	Distraction – Adult involvement – Use of no/low versus high technology – Active versus passive – Child choice of distractor Hypnosis	<ul style="list-style-type: none"> Distraction had a significant effect on self-reported pain and distress though not on observer-reported pain or distress Behavioral measures of distress but not pain were significantly impacted with distraction Hypnosis significantly reduced self-reported pain but not observer-reported or behavioral measures of pain A significant effect on self-reported and behavioral measures of distress were found with hypnosis No conclusions could be drawn on observer-rated effects of hypnosis There were no statistically significant effects of adult involvement, use of no/low versus high technology, use of active versus passive distractors, or child choice of distractor for pain or distress There were significant effects of distraction for self-reported pain among Middle Childhood aged patients 	Right types of papers included, important, relevant studies included, appropriately assessed for quality of studies, reasonable to combine results in this way, important outcomes considered	
Koller & Goldman (2012) [2]	Systematic review of empirical studies examining active and passive distraction techniques for pain and anxiety ¹	Empirical studies of distraction in pediatric cancer patients receiving LP (n = 2), needle procedures (n = 5), and chemotherapy (n = 1)	Active Distraction – interactive toys – VR – controlled breathing – guided imagery/relaxation Passive Distraction – story – music – watching tv/movies	<ul style="list-style-type: none"> Supports efficacy for use of both active and passive distraction techniques during painful procedures Inconsistent and inconclusive evidence for active over passive distraction techniques Variations in efficacy of interventions likely due to multiple variables: patient age, gender, procedure, parent involvement, Child Life Specialist involvement 	Right types of papers included, important, relevant studies included, appropriately assessed for quality of studies, reasonable to combine results in this way, important outcomes considered	1
Kuppenheimer & Brown (2002) [3]	Systematic review of empirical studies examining cognitive-behavioral or pharmacological interventions for painful medical procedures	Empirical studies of CBT or pharmacological interventions in pediatric cancer patients undergoing painful procedures (n = 27 studies)	CBT Pharmacology	<ul style="list-style-type: none"> Initial findings reported that pharmacological was no more effective than CBT More recent studies with improvements to more effective medications have shown mixed results when compared to CBT indicating that both have distinct benefits and disadvantages Review supports efficacy for use of CBT in managing procedural distress CBT interventions had positive effects on children's self-efficacy Pharmacological interventions have been found to be relatively safe though there is always the possibility an adverse reaction could occur Patients may experience effects up to 24 hours post administration of pharmacological agents Interventions involving pharmacology can reduce patient's movements but increase recovery time 	Right types of papers included, important, relevant studies included, appropriately assessed for quality of studies, reasonable to combine results in this way, important outcomes considered	1

SUPPLEMENTAL TABLE II. (Continued)

Study	Design	Sample	Psychological intervention(s)	Findings	Study Rigor	Level of evidence
Landier & Tse (2010) [4]	Systematic review of complementary and alternative medical (CAM) interventions for procedure pain, anxiety and distress	Case reports, clinical series, or clinical trials that included at least one CAM intervention for children and adolescents (aged 2–18 years old) with cancer undergoing various procedures (n = 32 articles)	Hypnosis Distraction Imagery Relaxation Play	<ul style="list-style-type: none"> • Mind-body therapies were the only CAM interventions studied for procedure management in pediatric oncology. • Distraction was most common intervention (18/32 studies), followed by hypnosis (11/32 studies), imagery (6/32 studies), and other behavioral interventions • Concluded that hypnosis may be more effective than distraction, particularly for highly invasive procedures, and for children with high hypnotizability • 9 studies reported additional use of pharmacological intervention with CAM 	Right types of papers included, important relevant studies, appropriately assessed for study quality, reasonable to combine results in this way, important outcomes considered	1
Olmstead, Scott, Mayan, Koop, & Reed (2014) [5]	Qualitative study of pediatric oncology nurses' use of distraction for procedural pain	Pediatric oncology nurses (n = 7)	Distraction	<ul style="list-style-type: none"> • All nurses indicated benefits of distraction • They identified factors that influence when they find it effective (i.e., child autonomy, nurse experience/knowledge, age appropriate, parental support, window of time) • They also identified circumstances when they find it ineffective (i.e., child with extreme anxiety/fear, child not receptive, negative association, different every time, window of time) 	Research question clearly stated, qualitative approach clearly justified, study context clearly described, role of research not clearly described, sampling strategy appropriate, method of data collection clearly described, method of data analysis appropriate and clearly described	6
Poder & Lemieux (2014) [6]	Systematic review of complementary and alternative medicine during cancer treatment ²	Empirical studies of complementary and alternative therapies in pediatric oncology	Hypnosis Distraction Imagery Art Therapy Music Therapy	<ul style="list-style-type: none"> • Complementary and alternative therapies indicate a positive impact on procedural pain and distress • Study summarized there is a "good to fair" level of evidence for hypnosis and distraction • There is a "fair" level of evidence for imagery, art therapy, and music therapy 	Right types of papers included, important, relevant studies included, reasonable to combine results in this way, important outcomes considered	1

(Continued)

SUPPLEMENTAL TABLE II. (Continued)

Study	Design	Sample	Psychological intervention(s)	Findings	Study Rigor	Level of evidence
Rheingans (2007) [7]	Systematic Review of empirical studies since 1975 examining the use of non-pharmacologic therapies for symptom management ³	Empirical studies of nonpharmacologic therapies in pediatric cancer patients receiving BMA (n = 6), LP (n = 5), BMA and LP (n = 5), needle procedures (n = 5), and radiation therapy (n = 1)	Distraction Hypnosis CBT Breathing Imagery Relaxation and Play Art Therapy Nonessential Touch	<ul style="list-style-type: none"> Studies comparing hypnosis to control groups found hypnosis to reduce pain, anxiety, and/or distress, by self- and/or observer-report in children receiving BMAs, LPs, needle procedures, and/or radiation Some studies did not produce statistically significant results for hypnosis when compared to other interventions (distraction, play) CBT found to have significant reductions in pain, anxiety, distress, and/or pulse by self- and/or other-report in children receiving medical procedures when compared to control groups There were no statistically significant differences between CBT or GA for reduction of pain, fear, or pulse Distraction led to reduction in pain, anxiety, and/or distress when compared to control group Relaxation showed no statistically significant differences when compared to control group Support efficacy of hypnosis for reducing pain and distress as compared to therapist attention or no treatment controls Inconsistent if hypnosis superior to other psychological interventions (i.e., directed play, cognitive distraction, or coping skills). Some variation in intervention efficacy due to child age, hypnotizability, and therapist-directed vs. self-hypnosis The majority of supportive care interventions focused on procedural support (n = 12/22) for radiation therapy, venipunctures or implanted venous access devices, and BMAs or LPs. Interventions included distraction, interactive play, hypnosis, and positioning pillow and were targeted primarily to children with more limited parental involvement. Reviewed studies of distraction and hypnosis showed treatment benefit for procedural support, but were limited by small sample sizes. 	Right types of papers included, important, relevant studies included, appropriately assessed for quality of studies, reasonable to combine results in this way, important outcomes considered	I
Richardson, Smith, McCall, & Pilkington (2006) [8]	Systematic review of controlled clinical trials examining hypnosis for management of procedural pain and distress	Controlled clinical trials in pediatric cancer patients undergoing LP or BMA (n = 8 studies)	Hypnosis	<ul style="list-style-type: none"> Support efficacy of hypnosis for reducing pain and distress as compared to therapist attention or no treatment controls Inconsistent if hypnosis superior to other psychological interventions (i.e., directed play, cognitive distraction, or coping skills). Some variation in intervention efficacy due to child age, hypnotizability, and therapist-directed vs. self-hypnosis 	Right types of papers included, important relevant studies included, appropriately assessed for quality of studies, reasonable to combine results in this way, important outcomes considered	I
Robb, Burns, Stegenga, Haut, Monahan, Meza, Stump, Cherven, Docherty, Hendricks, Ferguson, Kintner, Haight, Wall, & Haase (2014) [9]	Systematic review of supportive care interventions for pediatric cancer published from 1991–2011	Randomized and nonrandomized empirical studies investigating supportive care intervention for children with cancer and their parents for procedural support (n = 12), education/counseling (n = 8) and distress/symptom management (n = 2)	Supportive care interventions (e.g., music therapy, distraction, interactive-educational, cognitive-behavioral, hypnosis)	<ul style="list-style-type: none"> The majority of supportive care interventions focused on procedural support (n = 12/22) for radiation therapy, venipunctures or implanted venous access devices, and BMAs or LPs. Interventions included distraction, interactive play, hypnosis, and positioning pillow and were targeted primarily to children with more limited parental involvement. Reviewed studies of distraction and hypnosis showed treatment benefit for procedural support, but were limited by small sample sizes. 	Right types of papers included, missing relevant papers, not assessed for quality of studies, minimal combination of results, important outcomes considered	I

(Continued)

SUPPLEMENTAL TABLE II. (Continued)

Study	Design	Sample	Psychological intervention(s)	Findings	Study Rigor	Level of evidence
Thrane (2013) [10]	Systematic review of integrative modalities for pain and distress	RCTs of integrative therapies for children and adolescents (aged 1–19 years old) with cancer (n = 13 studies)	Music Art Guided imagery Massage Therapeutic play Breathing Distraction (virtual reality)	<ul style="list-style-type: none"> Reviewed studies revealed variety of integrative therapies to support children, although most rely on some form of distraction Studies revealed medium to very large effect sizes showing benefits of interventions for procedural pain and distress 	Right types of papers included, important relevant studies, informal assessment of study quality, results combined in narrative review, important outcomes considered	1
Uman, Birnie, Noel, Parker, Chambers, McGrath, & Kiseley (2013) [11]	Systematic review and meta-analysis of controlled clinical trials examining psychological interventions for management of procedural pain and distress ¹	Controlled clinical trials of various needle procedures including BMA, LP, venipuncture, and port access (n = 39 studies)	Distraction Hypnosis Cognitive-behavioral Preparation/information Virtual reality Suggestion Blowing out air	<ul style="list-style-type: none"> Strong evidence supporting efficacy of distraction and hypnosis No evidence currently supporting preparation/information, combined cognitive-behavioral interventions, parent coaching plus distraction, suggestion, or virtual reality Additional research needed to examine psychological interventions examined in only single studies, including: memory alteration, parent positioning plus distraction, blowing out air, and distraction plus suggestion 	Right types of papers included, important, relevant studies included for appropriately assessed for quality of studies, reasonable to combine results in this way, important outcomes considered	1
Wild & Espie (2004) [12]	Systematic review of empirical studies since 1982 examining hypnosis for management of procedural pain and distress	Empirical studies in pediatric cancer patients undergoing LP, BMA, venipuncture and/or chemotherapeutic injections (n = 9 studies)	Hypnosis	<ul style="list-style-type: none"> Inconsistent evidence for efficacy of hypnosis for pain management and generally poor methodological quality. Identified only three RCTs with appropriate control groups. Supports justification of large-scale RCTs. 	Right types of papers included, important, relevant studies included for appropriately assessed for quality of studies, reasonable to combine results in this way, important outcomes considered	1

(Continued)

SUPPLEMENTAL TABLE II. (Continued)

Study	Design	Sample	Psychological intervention(s)	Findings	Study Rigor	Level of evidence
Bone Marrow Aspirations Dahlquist, Power, & Carlson (1995) [13]	Observational study of parent-child and physician-child interactions during anticipatory and procedural phases of medical procedure to identify communication patterns and child distress	Children (5–13 years old) with leukemia undergoing BMA or LP (n = 51)	No Intervention	<ul style="list-style-type: none"> Physicians were most likely to engage in non-procedural talk, notice of procedure coming, and verbal reassurance in both the anticipatory and procedure phases Parents were most likely to provide verbal and physical reassurance, behavioral commands, and encouraging coping during anticipatory and procedural phases There was increased use of praise, reassurance, and encouraging coping during procedural period Physician behaviors (humor, talking about general medical status, and overall interaction rate) were negatively correlated with child distress during anticipatory and procedural phases Encouraging coping, behavioral commands, criticism, verbal and physical reassurance and overall interaction rate of parents was positively correlated with child distress 	Sufficient sample size, blinding not applicable, no selective reporting, appropriate analysis, study conducted as planned, no missing data	4
Favara-Scacco, Smirne, Schiliro, & Di Cataldo (2001) [14]	Quasi-experimental design with two groups (Art Therapy and Control) for anxiety and distress	Children (2–14 years old) with leukemia undergoing BMA and/or LP (n = 49)	Art Therapy with components of dialogue, structured drawing, visual imagination, and medical play	<ul style="list-style-type: none"> Children who received individualized art therapy with dialogue and medical play demonstrated more positive and compliant behaviors during invasive procedures than control group 71% of children receiving the intervention were rated as good responders in comparison to only 17% of the control group 	Sufficient sample size, lack of blinding, selective reporting, study completed as planned, no large losses to follow-up or missing data	3
Jay, Elliott, Fitzgibbons, Woody, & Siegel (1995) [15]	RCT including two groups with a repeated-measures counterbalanced design (CBT and GA) for pain and distress	Children (3–12 years old) with leukemia undergoing BMA (n = 18)	CBT – filmed modeling – breathing exercises – imagery/distraction – positive incentive – behavioral rehearsal GA	<ul style="list-style-type: none"> There were no significant differences on self-reported pain, fear, anticipation of next BMA, or pulse between conditions Children did exhibit more behavioral distress in CBT condition for the first minute after lying down parents reported significantly more behavioral adjustment symptoms after GA as compared to CBT condition There were no differences in parental stress and coping between groups 	Insufficient sample size, data collection appropriate to study method, appropriate analysis, study completed as planned, no issues with follow-up or missing data	2

(Continued)

SUPPLEMENTAL TABLE II. (Continued)

Study	Design	Sample	Psychological intervention(s)	Findings	Study Rigor	Level of evidence
Kazak, Penati, Boyer, Himelstein, Brophy, Waibel, Blackall, Daller, & Johnson (1996) [16]	RCT including three groups (pharmacologic only, pharmacologic + individualized psychological intervention, and control) for distress	Children and adolescents newly diagnosed with leukemia undergoing BMA and/or LP (n = 162)	Individualized distraction implemented by parent GA	<ul style="list-style-type: none"> Mothers and nurses of children in the combined intervention group reported significantly lower child distress during the procedure than mothers and nurses in the pharmacological arm or control group Children in the intervention group were observed to have less distress prior to the procedure than children in the control group Mother- father- and nurse-report showed no significant effects of the intervention group over pharmacological support only on either parent or child distress 	Sufficient sample size, lack of blinding, data collection appropriate to study method, selective reporting, appropriate analysis, study completed as planned, issues with follow-up or missing data clearly described	2
Kazak, Penati, Brophy, & Himelstein (1998) [17]	RCT including three groups (pharmacologic only, pharmacologic + parent coaching of distraction, and control) for pain and distress	Children and adolescents with leukemia and/or LP undergoing BMA (n = 162)	Parent coaching distraction	<ul style="list-style-type: none"> Parent coaching in the utilization of distraction during painful medical procedures was an effective distress reduction strategy for children Mothers and nurses (but not fathers or practitioner completing procedure) reported significantly less distress in children in the combined intervention group than children receiving only pharmacological support Distress decreased over time regardless of group as reported by mother and practitioner completing procedure Age and technical difficulty of the procedure are related to child distress 	Sufficient sample size, lack of blinding, data collection appropriate to study method, selective reporting, appropriate analysis, study completed as planned, issues with follow-up or missing data clearly described	2
LaMontagne, Wells, Hepworth, Johnson, & Manes (1999) [18]	Observational study of adult-child interactions before and during procedure for adult and child distress	Children (3–11 years old) with cancer undergoing BMA and/or LP (n = 20)	No intervention	<ul style="list-style-type: none"> Parents identified uncertainty about their role and anticipating the child's distress as the primary stressors Parents who identified being unsure of their role as their primary stressor reported increased stress about when and how much information to provide the child with prior to the procedure Children of parents who felt uncertain of their role exhibited increased behavioral distress 	Small sample size, blinding not applicable, no selective reporting, appropriate analysis, study conducted as planned, no missing data	4
Lioosi & Hatira (1999) [19]	RCT including three groups (hypnosis, cognitive behavioral coping skills training, standard care) for pain and distress	Children and adolescents (5–15 years old) with leukemia undergoing BMAs (n = 30)	Hypnosis; Cognitive behavioral coping skills training	<ul style="list-style-type: none"> Hypnosis and cognitive behavioral coping skills groups more effective for reducing pain and anxiety as compared to standard care. Hypnosis and cognitive behavioral coping skills groups comparable for pain reduction, but less behavioral distress observed in hypnosis group 	Insufficient sample size, lack of blinding, selective reporting, appropriate analysis, study completed as planned, no missing data	2

(Continued)

SUPPLEMENTAL TABLE II. (Continued)

Study	Design	Sample	Psychological intervention(s)	Findings	Study Rigor	Level of evidence
McCarthy, Cool, & Hanrahan (2008) [20]	RCT including two groups (parent coaching or standard care) for pain and distress	Children and adolescents (3–15 years old) with newly diagnosed cancer undergoing BMA, LP, or both (n = 10)	Cognitive behavioral intervention directed at parents and children including filmed modeling, imagery, distraction, controlled breathing, relaxation, medical play, and individual coping plan, with at home practice	<ul style="list-style-type: none"> • Study stopped early due to contamination of control group, so focused report on descriptive and exploratory results, and discussion of practical problems. • Parents, nurses, and doctors very comfortable with parents' use of distraction, reported it as moderately to very effective, and controlled breathing as moderately effective. • Parents successful at implementing distraction and controlled breathing, but spontaneously engage in other unhelpful behaviors (e.g., apology, reassurance, empathy, explanations) • No significant differences in ratings of child pain and distress • Acceptance and interest of parents in the intervention 	Insufficient sample size, lack of blinding, aoms selective reporting, appropriate analysis, study stopped early, some missing data	2
Lumbar Punctures Broome, Rehwaldt, & Fogg (1998) [21]	Repeated measures study with multiple baseline design of CBT for pain and distress	Children and adolescents (4–18 years old) with cancer undergoing repeated LPs (n = 19)	CBT taught to child and parent including relaxation, distraction, and imagery (taught individually and provided with videotape, audiotape, and booklet to practice at home)	<ul style="list-style-type: none"> • As compared to baseline (no treatment), children reported decreased pain, but not observed behavioral distress with the intervention. • Greater at-home practice of skills was associated with greater treatment benefit; higher perceived effectiveness and frequency of practice parents' comfort and perceived effectiveness of the techniques, were associated with decreased procedural pain • Child temperament was related to experienced pain (between positive mood and pain) 	Small sample size, lack of blinding, selective reporting, acceptable analysis, study completed as planned, losses to follow-up with missing data	3
Chen, Zeltzer, Craske, & Katz (1999) [22]	RCT including two groups (memory reframing or attention control) for pain and distress	Children and adolescents (3–18 years old) with leukemia undergoing repeated LPs (n = 50)	Memory reframing immediately following first LP and immediately prior to second LP; involved enhancing children's coping self-efficacy, realistically appraising their responses, and increases subjective memory accuracy	<ul style="list-style-type: none"> • Children who received memory reframing intervention prior to the second LP had reduced anticipatory heart rate and parent-report of anticipated child pain as compared to control group. • At the third LP, children who received intervention had reduced observed behavioral distress, self-reported pain, and greater decreases in pre-LP cortisol 	Sufficient sample, lack of blinding, selective reporting, appropriate analysis, study completed as planned, some missing data	2

(Continued)

SUPPLEMENTAL TABLE II. (Continued)

Study	Design	Sample	Psychological intervention(s)	Findings	Study Rigor	Level of evidence
Chen, Zeltzer, Craske, & Katz (2000) [23]	RCT including two groups (memory reframing or control group) for anxiety, pain, and distress	Children and adolescents (3–18 years old) with leukemia undergoing repeated LPs (n = 55)	Memory reframing immediately following first LP and immediately prior to second LP; involved enhancing children's coping self-efficacy, realistically appraising their responses, and increases subjective memory accuracy	<ul style="list-style-type: none"> Greater parent- and child-reported pain sensitivity was associated with greater anticipatory and procedural anxiety as well as pain ratings by children Pain sensitivity scores were associated with child but not parent or physician ratings of distress Children with higher pain sensitivity who received intervention demonstrated greater decreases in physician reported distress, blood pressure, and parent anxiety when compared to children lower in pain sensitivity Intervention was most efficacious for those who were most pain sensitive Providing pain-sensitive children with intervention decreases parental anxiety 	Sufficient sample, lack of blinding, selective reporting, appropriate analysis, study completed as planned, no missing data	2
Cline, Harper, Penner, Peterson, Taub, & Albrecht (2006) [24]	Observational study to identify prototypical parent-child communication patterns during painful procedures	Children (aged 3–12 years old) with cancer undergoing LP or port access (n = 31)	No intervention	<ul style="list-style-type: none"> Four prototypical parent-child communications were identified: normalizing (reframe medical situation as normal), invalidating (denies, invalidates or challenges), supportive (empathic, supportive, comforting), or distancing (parent disengages) Across all procedure phases, supportive was the most common (41.6%), followed by distancing (24.7%), normalizing (23.4%), and invalidation (10.4%). By phase, normalizing was most common pre-procedure, supportive during procedure, and supportive and distancing post-procedure; some differences were noted based on type of procedure and child sex Invalidated children experienced higher pain and distress 	Sufficient sample size, blinding not applicable, no selective reporting, appropriate analysis, study conducted as planned, no missing data	4
Dahlquist, Pendley, Power, Landthrip, Jones, & Steuber (2001) [25]	Observational study of adult-child interactions during anticipatory phase prior to procedure for adult behaviors and child distress	Children and adolescents (5–15 years old) with cancer undergoing biweekly chemotherapy with LP and IM (n = 45)	No intervention (commands by different adults to child)	<ul style="list-style-type: none"> Younger children displayed more distress prior to procedure Nurses and parents used same types of commands to the child during LPs and IMs; they used more total commands than physicians, particularly for specific direct and vague commands Nurses used more softened commands than parents or physicians Vague commands were associated with increased child distress, as well as specific direct and commands phrased as questions (when given by nurses) Child distress was lower with higher proportion of specific commands from parents 	Sufficient sample size, blinding not applicable to study method, no selective reporting, appropriate analysis, study completed as planned, no missing data	4

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SUPPLEMENTAL TABLE II. (Continued)

Study	Design	Sample	Psychological intervention(s)	Findings	Study Rigor	Level of evidence
Vannorsdall, Dahlquist, Shroff Pendley, & Power (2004) [26]	Observational study of non-essential touch by parent and nurse during anticipatory, procedural, and recovery phases of procedure for distress	Children and adolescents (5–15 years old) with cancer undergoing LP (n = 50)	No intervention	<ul style="list-style-type: none"> Nurses non-essential touch was negatively correlated with anticipatory, procedural, and recovery phases of procedure as well as total distress Parent's non-essential touch was unrelated to child distress in any phase of treatment or total distress Nurses soothing touch during the procedural phase accounted for a significant proportion of variance in recovery Younger children benefitted most from non-essential touch 	Sufficient sample size, blinding not applicable, no selective reporting, appropriate analysis, study conducted as planned, no missing data	4
Hawkins, Liossi, Ewart, Hatira, & Kosmidis (1998) [27]	Randomly assigned within-between-groups comparison of direct and indirect hypnosis for pain and anxiety	Children and adolescents (6–16 years old) with leukemia or non-Hodgkin lymphoma undergoing LPs (n = 30)	Hypnosis (direct and indirect) by a therapist	<ul style="list-style-type: none"> Both groups had significantly reduced self-reported pain and anxiety, and observer-reported distress, during LP with hypnosis as compared to without No significant differences were noted between types of hypnotic intervention (direct vs indirect) Higher level of hypnotizability was associated with increased treatment benefit for self-reported pain, anxiety, and observer-rated distress 	Sufficient sample size, lack of blinding, no selective reporting, correct analysis, study completed as planned, no missing data	2
Liossi & Hatira (2003) [28]	RCT including four groups (direct hypnosis, indirect hypnosis, attention control, standard care) for pain and distress	Children and adolescents (6–16 years old) with leukemia or non-Hodgkin lymphoma undergoing repeated LPs (n = 80)	Hypnosis (direct and indirect) directed by therapist and then self	<ul style="list-style-type: none"> Direct and indirect hypnosis groups were equally effective and reported less pain and anxiety as compared with attention control or standard care groups. Higher levels of child hypnotizability associated with increased treatment benefit. Treatment benefit lessened with self-hypnosis as compared with therapist-directed 	Sufficient sample size, lack of blinding, no selective reporting, appropriate analysis, study completed as planned, no missing data	2
Liossi, White, & Hatira (2006) [29]	RCT including three groups (EMLA, EMLA + hypnosis, EMLA + attention control) for pain and distress	Children and adolescents (6–16 years old) with leukemia or non-Hodgkin lymphoma undergoing repeated LPs (n = 45)	Hypnosis directed by therapist and then by self	<ul style="list-style-type: none"> Group receiving hypnosis, in addition to local anesthetic (EMLA), reported less pain and anxiety, and less observed behavioral distress as compared with other groups. Treatment superiority was maintained when switched to self-hypnosis following therapist-directed hypnosis. Higher levels of child hypnotizability associated with increased treatment benefit 	Sufficient sample size, lack of blinding, no selective reporting, appropriate analysis, study completed as planned, no missing data	2

(Continued)

SUPPLEMENTAL TABLE II. (Continued)

Study	Design	Sample	Psychological intervention(s)	Findings	Study Rigor	Level of evidence
Lioasi, White, Franck, & Hatira (2007) [30]	Prospective longitudinal repeated measures study of CBT for pain and distress	Children and adolescents (7–16 years old) with leukemia or non-Hodgkin lymphoma undergoing repeated LPs (n = 45)	CBT directed by therapist and then by self Directed by therapist: 1 × 40min session prior to procedure teaching relaxation, breathing exercises, and cognitive restructuring Directed by self: 1 × 45min session prior to procedure trained in independent use of previously learned CBT strategies	<ul style="list-style-type: none"> • CBT (both therapist and self-directed) was beneficial for reducing child pain (expected and experienced), distress, and anxiety, and observed behavioral distress. • Although significantly lower than at baseline procedure, child pain and distress was significantly higher during self-directed CBT than when it directed by a therapist during an earlier procedure (i.e., CBT was more effective when delivered by a therapist). • Parent-rated expected pain was only lower than baseline with therapist-directed CBT, and were independent predictors of children's experienced pain with and without any intervention 	Sufficient sample size, lack of blinding, no selective reporting, appropriate analysis, study completed as planned, no missing data	3
Naber, Halstead, Broome, & Rehwaldt (1995) [31]	Qualitative ethnological study examining communication between parents, children, and caregivers during painful procedures	Children and adolescents (4–18 years old) with acute lymphocytic leukemia undergoing LP or BMA (n = 17)	Cognitive behavioral intervention including simple relaxation, distraction, and simple guided imagery	<ul style="list-style-type: none"> • Four distinct phases of procedure identified: phase 1 (drawing blood, starting IV, preparing equipment associated with increased tension), phase 2 (waiting for sedation to take effect and positioning child, associated with decreased tension), phase 3 (placing needle associated with rising tension and procedure-focused talk), and phase 4 (doing treatment associated with decreased tension). • Four themes of adult-child interaction identified: taking WITH, talking TO talking AROUND, and talking AT. The first two seemed associated with less child distress whereas the last seemed to occur with child distress • Focused parental attention during procedure associated with decreased child distress • As compared with the control group, children in the music intervention had significant reduction in self-reported pain (during and after procedure) and anxiety (before and after the procedure) • Significant reductions in heart rate and respiratory (during and after procedure) in music group; blood pressure and oxygen saturation did not differ between groups • Children in music group reported feeling calmer and made the procedure less distressing; they enjoyed the music and felt this procedure had gone better as compared with previous ones 	Research questions clearly stated, qualitative approach not clearly justified, study context clearly described, role of researcher described, sampling strategy appropriate, method of data collection clearly described, method of data analysis described and appropriate	6
Nguyen, Nilsson, Hellstrom, & Bengtson (2010) [32]	RCT including two groups (music or control) for pain and distress	Children (7–12 years old) with leukemia undergoing LPs (n = 40)	Music	<ul style="list-style-type: none"> • Significant reductions in heart rate and respiratory (during and after procedure) in music group; blood pressure and oxygen saturation did not differ between groups • Children in music group reported feeling calmer and made the procedure less distressing; they enjoyed the music and felt this procedure had gone better as compared with previous ones 	Sufficient sample size, lack of blinding, no selective reporting, correct analysis, study completed as planned, no missing data	2

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SUPPLEMENTAL TABLE II. (Continued)

Study	Design	Sample	Psychological intervention(s)	Findings	Study Rigor	Level of evidence
Reeb & Bush (1996) [33]	RCT including two groups (behavioral preparation or control for heart rate, self-and observer-reported distress)	Children and adolescents (4–14 years old) with leukemia undergoing LP (n = 18)	Preparation – filmed modeling – participant modeling – rehearsal – desensitization Deep breathing Imagery	<ul style="list-style-type: none"> Children and adolescents receiving procedural preparation had significantly less observer-rated distress and lower heart rate during LP Self-efficacy was higher among children and adolescents in the treatment group 	Small sample size, observer was blinded, no selective reporting, acceptable analysis, study completed as planned, no missing data	2
Sander Wint, Eshelman, Steele, & Guzzetta (2002) [34]	RCT including two groups (virtual reality video distraction or standard care) for pain	Adolescents (10–19 years old) with cancer undergoing LPs (n = 30)	Virtual reality video distraction	<ul style="list-style-type: none"> No significant difference between groups on self-reported pain. 77% of children who used virtual reality glasses indicated that they helped to distract them 	Sufficient sample size, lack of blinding, selective reporting, acceptable analysis, study completed as planned, no missing data	2
Walco, Conte, Labay, Engel, & Zeltzer (2005) [35]	Observational study of three groups of children (GA, light sedation, CBT) for coping by self-reported anxiety, pain, self-efficacy, behavioral distress, and physiological arousal	Children and adolescents (3–17 years old) with cancer undergoing LPs (n = 48)	No intervention	<ul style="list-style-type: none"> There were no significant differences in behavioral or self-reported measures among groups Physiological changes were apparent for all pain management groups (GA, light sedation, CBT) Just prior to insertion there were changes to physiological response despite no actual painful stimulus for all groups Children using CBT had significantly lower hear rates at the time of needle insertion 	Sufficient sample size, blinding not applicable, selective reporting, acceptable analysis, study completed as planned, some missing data	4
Venipuncture / Venous Access / Port Access Dahlquist & Pendley (2005) [36]	RCT including two groups (distraction or control) for parent anxiety and child distress	Children (2–5 years old) with cancer undergoing portacath or intramuscular injections (n = 29)	Distraction	<ul style="list-style-type: none"> Children with the most anxious parents were less likely to respond favorably to distraction Baseline distress was not higher in the treatment failure group Approximately 90% of treatment failures could be predicted by child age, months since diagnosis, parent anxiety, and child's baseline distress with parent anxiety contributing most significantly 	Sufficient sample size, lack of blinding, selective reporting, acceptable analysis, study completed as planned, no missing data	2

(Continued)

SUPPLEMENTAL TABLE II. (Continued)

Study	Design	Sample	Psychological intervention(s)	Findings	Study Rigor	Level of evidence
Dahlquist, Busby, Slifer, Tucker, Eischen, Hilley, & Sulc (2002) [37]	Quasi-experimental design with three phases (baseline, intervention with parent coaching in how to use distraction, and follow-up) for distress and anxiety	Children (2–8 years old) with hem/onc diagnoses undergoing repeated needle sticks (port access, intramuscular injection, or intravenous access) (n = 6)	Parent coaching distraction	<ul style="list-style-type: none"> Coaching parents in the use of distraction was an effective distress reduction strategy for children undergoing repeated needle sticks Providing distraction prior to needle stick, lowered children's anxiety per parent report Nurses rated children as more cooperative with use of parent coaching and distraction Benefits of parent coaching in distraction was sustained over time 	Insufficient sample size, lack of blinding, appropriate analysis, study completed as planned, no large losses to follow-up or missing data	3
Gelfand & Dahlquist (2003) [38]	Observational study of mother or nurse use of praise and criticism during chemotherapy treatment for child distress	Children and adolescents (2–15 years old) with cancer undergoing LP or IM (n = 141)	No intervention	<ul style="list-style-type: none"> Nurses and mothers used similar rates of criticism (in 5% and 6% of 15-sec intervals, respectively, during procedure), and their use of criticism was correlated Nurses used more praise than mothers (in 11% vs 4% of 15-sec intervals during procedure), and their use of praise was correlated Maternal and nurse criticism were associated with increased child distress before, during, and after procedure, with both contributing uniquely to child distress Relationships between adult criticism and child distress were particularly strong among high socioeconomic status families Maternal praise was associated with decreased child distress before the procedure only; nurse praise was not related to child distress during any phase 	Sufficient sample size, blinding not applicable, some selective reporting, appropriate analysis, study conducted as planned, no missing data	4
Gershon, Zimand, Pickering, Rothbaum, & Hodges (2004) [39]	RCT including three groups (VR distraction, no distraction control, nonVR distraction) for pain and anxiety	Children (7–19 years old) undergoing port access (n = 59)	Virtual reality distraction	<ul style="list-style-type: none"> Children receiving VR distraction had lower physiological arousal (pulse) than children in control condition but not the nonVR distraction group Children in both treatment groups had lower nonverbal indices of distress (muscle tension in torso and legs) Nurses rated children in the VR distraction and nonVR distraction groups as experiencing less pain 	Insufficient sample size, lack of blinding, selective reporting, correct analysis, stopped early	2

(Continued)

SUPPLEMENTAL TABLE II. (Continued)

Study	Design	Sample	Psychological intervention(s)	Findings	Study Rigor	Level of evidence
Heden, von Esson, & Ljungman (2008) [40]	RCT including two groups (all patients subjected to two needle insertions, serving as their own control; standard care then standard care + active distraction or standard care then standard care + passive distraction)	Children (2–7 years old) with leukemia, CNS tumor, or solid tumor undergoing port access (n = 28)	Active distraction (blowing bubbles) Passive distraction (using a heated pillow) Standard Care (EMLA)	<ul style="list-style-type: none"> Parent (but not nurse) reported less fear in both active and passive distraction than during standard care only Active distraction was effective in reducing fear and distress Passive distraction was effective in reducing fear 	Sufficient sample size, lack of blinding, selective reporting, appropriate analysis, study completed as planned, no missing data	2
Lioasi, White, & Hatira (2009) [41]	RCT including three groups (EMLA, EMLA + hypnosis, EMLA + attention control) for pain and distress	Children and adolescents (7–16 years old) with cancer undergoing venipuncture (n = 45)	Hypnosis (self-hypnosis only)	<ul style="list-style-type: none"> Self-hypnosis + local anesthetic (EMLA) reported less anticipatory and experienced anxiety, pain, and observed behavioral distress as compared with other groups. Parents experienced less anxiety in hypnosis group 	Sufficient sample size, lack of blinding, no selective reporting, appropriate analysis, study completed as planned, no missing data	2
Mason, Johnson, & Woolley (1999) [42]	Repeated measures design randomization of group order (control, video, and story) for distress during and after procedure	Children (2–6 years old) undergoing port access or broviac dressing change (n = 8)	Distraction	<ul style="list-style-type: none"> Children were observed to have the least amount of distress in the interactive parent-led distraction task (story) The passive distraction task (viewing video) was less distressing than the control condition as rated by two observers Observers rated significantly less distress after the procedure for children with interactive, parent-led distraction 	Small sample size, lack of blinding, appropriate analysis, study completed as planned, no missing data	3
Nilsson, Finnstrom, Kokinsky, & Enskar (2009) [43]	Non-randomized between groups comparison (virtual reality or control) for pain and distress	Children and adolescents (5–18 years old) with cancer undergoing venous punctures or subcutaneous venous port access (n = 42)	Virtual reality (non-immersive)	<ul style="list-style-type: none"> No significant benefit of treatment for self-reported distress or pain; no significant group differences for heart rate prior to or during the procedure. Treatment group maintained baseline levels of observed behavioral distress during procedure, whereas increased significantly in control group. 15/21 (71%) of children in treatment groups said they would choose VR for future needle procedures; children noted challenges using the equipment, although they reported enjoying it and found it did distract them 	Sufficient sample size, lack of blinding, acceptable analysis, study completed as planned, minor missing data	3

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SUPPLEMENTAL TABLE II. (Continued)

Study	Design	Sample	Psychological intervention(s)	Findings	Study Rigor	Level of evidence
Penner, Cline, Albrecht, Harper, Peterson, Taub, & Ruckdeschel (2008) [44]	Observational study of parent communication prior to, during, and following procedure for pain and distress	Children (3–12 years old) with cancer undergoing port access or LP (n = 41)	No intervention	<ul style="list-style-type: none"> Parent's empathetic responses just prior to procedure were related to increased pain and distress Parents with high empathetic concern for children was negatively associated with subsequent pain/distress Children of parents who were supportive across procedural phases had lower ratings of pain and distress by both child- and nurse-report 	Sufficient sample size, blinding not applicable, no selective reporting, appropriate analysis, study conducted as planned, no missing data	4
Peterson, Cline, Foster, Penner, Parrott, Keller, Naughton, Taub, Ruckdeschel, & Albrecht (2007) [45]	Observational study of parent distance and touch behavior for pain and distress	Children (3–12 years old) with cancer port access or LP (n = 29)	No intervention	<ul style="list-style-type: none"> There was a significant relationship between parent proximity and nurse-reported distress ratings during the procedure Increased supportive touch was significantly related to decreased child pain, observer-rated distress, nurse-reported pain and distress as well as parent-reported distress during the procedure 	Sufficient sample size, blinding not applicable, no selective reporting, appropriate analysis, study conducted as planned, no missing data	4
Pringle, Hilley, Gelfand, Dahlquist, Switkin, Diver, Sulc, & Eskenazi (2001) [46]	Quasi-experimental multi-baseline across subjects design with three phases (baseline, intervention included two components- parent training in coaching and distraction, and follow-up) for distress and anxiety	Children (3–7 years old) with hem/onc diagnoses undergoing needle sticks (n = 8)	Parent training in coaching and distraction	<ul style="list-style-type: none"> Active distraction and parent coaching can effectively reduce child distress during invasive medical procedures Inconsistency in nurse and parent coach report of distress Reductions in distress were maintained over time Variability in the magnitude of distress reduction related to parent investment in coaching 	Small sample size, lack of blinding, data collection appropriate to study method, selective reporting, appropriate analysis, study completed as planned, no issues with follow-up or missing data	3
Smith, Barabasz, & Barabasz (1996) [47]	Repeated measures single group study assessing distraction and hypnosis for pain, anxiety, and distress	Children (3–8 years old) with hem/onc diagnoses undergoing repeated venipuncture or infusaport access (n = 27)	Distraction and hypnosis (balanced treatment sequences)	<ul style="list-style-type: none"> Only children with high hypnotizability had reduced child self-reported pain and anxiety, parent-rated pain, and observer anxiety and distress from hypnosis intervention Children with low hypnotizability in the distraction condition had significantly lower observer-rated anxiety only 	Sufficient sample size, lack of blinding, no selective reporting, adequate analysis, study generally completed as planned, some missing data due to death of participants	4

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SUPPLEMENTAL TABLE II. (Continued)

Study	Design	Sample	Psychological intervention(s)	Findings	Study Rigor	Level of evidence
Spagrud, von Baeyer, Ali, Mpofu, Fennell, Friesen, & Mitchell (2008) [48]	Observational study of parent or nurse communication during venous access for pain and distress	Children (3–18 years old) with cancer undergoing blood work (n = 55)	No Intervention	<ul style="list-style-type: none"> Adult coping-promoting behaviors (i.e., distraction, humor, and nonprocedura-related talk) facilitate child coping Adult distress-promoting behaviors (i.e., reassurance, empathy, criticism, and giving control to the child) increase child distress Child distress is typically an antecedent to adult distress promoting Adult distress-promoting behaviors tend to be a response to child distress rather than initiated by the adult Adult distress-promoting verbalizations were positively correlated with parent and child expected and actual pain as well as nurse observations of pain Child distress was positively correlated with expected and actual pain ratings by child During the live dog condition, children had lower self-reported pain, lower observer-rated pain, and decreased rating of anxiety by parent –report No significant differences were found for physiological variables between conditions 	Sufficient sample size, blinding not applicable, no selective reporting, appropriate analysis, study conducted as planned, no missing data	4
Wells (1998) [49]	Randomly assigned within groups comparison of no dog, stuffed dog, and live dog groups for pain, anxiety, distress, and physiological arousal	Children 4–12 years old) with cancer undergoing port access (n = 8)	Distraction	<ul style="list-style-type: none"> No significant benefit of intervention for children's self-reported pain or fear, or for parent ratings of the child's fear. Children in the intervention group had less fear and distress as rated by a nurse. Significantly more children and parents in the intervention group felt the procedure had gone better than the child's last one. 91% of children (and 100% of parents) in the intervention group felt it had helped and would use it again 	Small sample size, lack of blinding, no selective reporting, study completed as planned, no missing data	2
Windich-Biermeier, Sjoberg, Dale, Eshelman, & Guzzetta (2007) [50]	RCT including two groups (self-selected distraction or standard care) for pain and fear	Children and adolescents (5–18 years old) with cancer undergoing port access or venipuncture (n = 50)	Self-selected distraction (i.e., I-Spy book, music table, virtual reality glasses, or handheld video games)	<ul style="list-style-type: none"> No significant benefit of intervention for children's self-reported pain or fear, or for parent ratings of the child's fear. Children in the intervention group had less fear and distress as rated by a nurse. Significantly more children and parents in the intervention group felt the procedure had gone better than the child's last one. 91% of children (and 100% of parents) in the intervention group felt it had helped and would use it again 	Sufficient sample size, lack of blinding, selective reporting, appropriate analysis, study completed as planned, no missing data	2

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SUPPLEMENTAL TABLE II. (Continued)

Study	Design	Sample	Psychological intervention(s)	Findings	Study Rigor	Level of evidence
Wolitzky, Fivush, Zimand, Hodges, & Rothbaum (2005) [51]	RCT including two groups (immersive VR or control) for pain and distress	Children (7–14 years old) with cancer undergoing port access (n = 20)	Virtual reality distraction (immersive)	<ul style="list-style-type: none"> Children receiving VR distraction had significantly less observed behavioral distress and slower pulse; no significant differences in self-reported pain/distress or pulse after the procedure 	Small sample size, lack of blinding, appropriate analysis, study completed as planned, no missing data	2
IV insertion						
Bisignano & Bush (2006) [52]	RCT including two groups (CD-ROM or standard care) for pain and distress	Children and adolescents (7–18 years old) with cancer undergoing IV insertion (n = 30)	Interactive CBT CD-ROM including education/information, preprocedural preparation (video modeling), breathing exercises, and distracting imagery	<ul style="list-style-type: none"> Although children who received the intervention reported significantly increased coping responses, there was no significant benefit for children's self-reported pain or fear, or for observed behavioral distress Children who received the intervention reported significant lower threat appraisal, although this was not lower than the standard care group 	Sufficient sample size, lack of blinding, appropriate analysis, study completed as planned, missing data	2
Tye, Leigh, Mulhern, Srivastava, & Bruce (1997) [53]	RCT including two groups (cognitive-behavioral therapy (CBT) or standard care) for distress	Children and adolescents (6–18 years old) with central nervous system cancer undergoing IV insertion prior to MRI (n = 55)	CBT including filmed modeling, breathing exercises, emotive imagery, behavioral rehearsal, and positive incentive	<ul style="list-style-type: none"> No significant differences between groups on child distress (self/parent/nurse-report or observed behavioral) post-IV or post-MRI 40% of children in CBT group reported strategies were "a little" to "somewhat" helpful, 60% reported strategies were "pretty much" to "very much" helpful 	Sufficient sample size, lack of blinding, no selective reporting, appropriate analysis, study completed as planned, no missing data	2
Radiation Treatment						
Barry, O'Callaghan, Wheeler, & Grocke (2010) [54]	Mixed methods studies including RCT with two groups (music therapy or standard care) and qualitative feedback for coping and distress	Children and adolescents (aged 6–13 years old) with cancer undergoing initial radiation therapy (n = 11)	Music therapy (child-created CD played during treatment session)	<ul style="list-style-type: none"> No significant differences in child distress between intervention and standard care groups; parents tended to rate child distress as higher than the child's self-report, whereas treatment staff tended to rate child distress as lower than the child Significantly more children in the intervention group used distraction and wishful thinking to cope, and significantly less social withdrawal Children, parents, and treatment staff found intervention provided fun distraction and reduced distress by assisting coping during treatment; it also facilitated psychosocial supports for children and families 	Insufficient sample size, lack of blinding, no selective reporting, appropriate analysis, study completed as planned, some missing data	2

(Continued)

SUPPLEMENTAL TABLE II. (Continued)

Study	Design	Sample	Psychological intervention(s)	Findings	Study Rigor	Level of evidence
Klosky, Tyc, Srivastava, Tong, Kronenberg, Booker, de Armendi, & Merchant (2004) [55]	RCT including two groups (interactive intervention group or modified control group) for distress	Children (aged 2–7 years old) with cancer undergoing radiation therapy (n = 79)	Cognitive-behavioral intervention including interactive animatronic plush Barney character, educational video with filmed modeling, and passive auditory distraction Modified control group received exposure to cartoon video, noninteractive children's control character, and stories	<ul style="list-style-type: none"> No significant differences noted between intervention and control in use of sedation (61% vs. 63%), or level of observed child distress Children in intervention group had lower heart rates at baseline and across the entire treatment 	Sufficient sample size, lack of blinding, no selective reporting, correct analysis, study completed as planned, no missing data	2
Klosky, Garces-Webb, Buscemi, Schum, Tyc, & Merchant (2007) [56]	RCT including two groups (interactive-educational intervention or control) for parental anxiety and distress ⁴	Parents of children (aged 2–7 years old) with cancer undergoing radiation therapy (n = 79)	Cognitive-behavioral intervention including interactive animatronic plush Barney character, educational video with filmed modeling, and passive auditory distraction Modified control group received exposure to cartoon video, noninteractive children's control character, and stories	<ul style="list-style-type: none"> Parents of children in the intervention group experienced significant reductions in trait anxiety from initial simulation to last day of radiation therapy Parents of children in the intervention group rated the Barney character as significantly more effective for reducing child distress, and had more positive overall feelings about the intervention 	Sufficient sample size, lack of blinding, no selective reporting, correct analysis, study completed as planned, no missing data	2
Slifer (1996) [57]	Single group study of intervention for reducing need for sedation during radiation treatment	Children (2.5–7 years old) with cancer undergoing radiation treatment (n = 11)	Behavioral training program prior to procedure, and movie during procedure	<ul style="list-style-type: none"> 9/11 children underwent all radiation planning and treatment sessions successfully without sedation Overall success rate of children showing significant reducing for need of sedation was 90.9%. Mean of 2.3 intervention sessions required; 8/11 children required only one session; psychologist present during average of 3.0 of children's appointments in radiology 	Small sample size, lack of blinding, no selective reporting, adequate analysis, study completed as planned, no missing data	4

(Continued)

SUPPLEMENTAL TABLE II. (Continued)

Study	Design	Sample	Psychological intervention(s)	Findings	Study Rigor	Level of evidence
Willis & Barry (2010) [58]	Case Series including three self-selected groups (closed circuit television, DVD, or microphone) to reduce need for sedation during radiation treatment	Children (2–6 years old) with cancer undergoing radiation treatment (n = 37)	Audiovisual – closed circuit television allowing patient to see and hear caregiver – watch DVD – microphone allowing patient to hear caregiver	<ul style="list-style-type: none"> 92% of patients were able to receive radiation without general anesthesia No clear differences between type of audiovisual intervention selected Parents reported increased confidence and enhanced sense of control in children following audiovisual intervention 	Sufficient sample size, lack of blinding, no selective reporting, lack of analysis, study completed as planned, no missing data	4
Chemotherapy						
Dahlquist, Pendley, Landthrip, Jones, & Steuber (2002) [59]	A repeated measures RCT including two groups (distraction or wait-list control) for distress	Children (2–5 years old) with leukemia or solid tumors undergoing six chemotherapy injections over up to 8 weeks (n = 29) (intramuscular injections or port access)	Distraction (interactive electronic toy)	<ul style="list-style-type: none"> Child distress (behavioral coding and rated by parents/nurses) was significantly lower with distraction This reduced distress during distraction was maintained over several weeks with repeated procedures, with an additional decline in anticipatory distress over time 74% of children saw clinically significant reducing in anticipatory distress, 59% in procedural distress, and 62% in recovery distress (following procedure) 	Sufficient sample size, lack of blinding, no selective reporting, appropriate analysis, study completed as planned, no missing data	2
Pourmovahed, Dehghani, & Sherafat [60]	RCT including two groups (regular breathing group or control) for pain	Children and adolescents (6–15 years old) with leukemia undergoing an intrathecal injection (n = 100)	Hey-Hu breathing technique (the child first takes a deep breath and exhales while whispering 'hey', then inhales deeply again and exhales whispering 'hu')	<ul style="list-style-type: none"> Children in the 'Hey-Hu' breathing group reported significantly less pain than control group, particularly among children > 10 years old 	Sufficient sample size, some blinding, no selective reporting, incorrect analysis, study completed as planned, some missing data	2
Schneider & Workman [61]	Interrupted time series design with removed treatment to assess intervention for symptom distress and anxiety	Children and adolescents (aged 10–17 years old) with cancer undergoing intravenous chemotherapy (n = 11)	Virtual reality	<ul style="list-style-type: none"> There was no difference in children's anxiety for chemotherapy with or without virtual reality intervention Significantly lower symptom distress was reported following chemotherapy with virtual reality intervention, although this was not maintained in the 48 hours post-chemotherapy treatment 	Insufficient sample size, blinding not applicable to study method, no selective reporting, correct analysis, study completed as planned, some missing data	4

(Continued)

SUPPLEMENTAL TABLE II. (Continued)

Study	Design	Sample	Psychological intervention(s)	Findings	Study Rigor	Level of evidence
Schneider & Workman (2000) [62]	Single group study with self-report of feasibility and acceptability of intervention during single chemotherapy treatment	Children and adolescents (10–17 years old) with leukemia or Hodgkin lymphoma receiving outpatient chemotherapy (n = 11)	Virtual reality	<ul style="list-style-type: none"> All participants engaged in the virtual reality for the entire treatment duration All indicated they liked using the VR during treatment and would like to use in the future; 82% said this treatment was better than previous treatments Most participants (82%) had no trouble using the VR headset; 45% indicated the VR headset was comfortable, while 55% disagreed with 27% indicating it gave them a headache 	Insufficient sample size, blinding not applicable to study method, selective reporting, appropriate analysis, study completed as planned, some missing data	4
Shockey, Menzies, Glick, Taylor, Botinott, & Rovnyak (2013) [63]	Single group study using nonrandomized repeated measures design to assess feasibility of intervention for fear and anxiety	Children and adolescents (8–14 years old) with cancer undergoing active chemotherapy treatment (i.e., venous access, LP, or BMA) (n = 12)	Biofeedback and relaxation (4-session weekly intervention)	<ul style="list-style-type: none"> No significant changes in anticipatory fear, but unvalidated modification of measurement tool and low levels of fear reported overall No significant changes in state anxiety or heart rate, but downward trends reported Some evidence of benefit for biofeedback based on heart rate variability 	Insufficient sample size, lack of blinding, selective reporting, unclear and incorrect analysis, study completed as planned, some loss to follow-up	3
Stem Cell Transplantation						
Phipps, Barrera, Vannatta, Xiong, Doyle, & Alderfer (2010) [64]	Multi-site longitudinal RCT including three groups (child-targeted intervention or combined with parent-targeted intervention or standard care) for somatic distress and mood disturbance	Children and adolescents (aged 6–18 years old) with cancer undergoing stem cell bone marrow transplantation (n = 178)	Child-targeted intervention (psychoeducation, massage, and humor) Child-targeted intervention combined with parent-targeted intervention (psychoeducation, massage/relaxation, guided imagery) Standard care	<ul style="list-style-type: none"> Similar trajectories in child and parent distress and positive affect over time with no significant differences between intervention groups No significant group differences for days in hospital, time to engraftment, or use of pharmacological interventions 	Sufficient sample size, lack of blinding, no selective reporting, correct analysis, study mostly completed as planned (some missed intervention sessions), no missing data	2

(Continued)

SUPPLEMENTAL TABLE II. (Continued)

Study	Design	Sample	Psychological intervention(s)	Findings	Study Rigor	Level of evidence
Hospitalization Robb, Clair, Watanabe, Monahan, Azzouz, Stouffer, Ebberts, Darsie, Whitmer, Walker, Nelson, Hanson-Abromet, Lane, & Hannan (2008) [65]	Multi-site RCT including three groups (active music engagement, music listening, or audio storybooks) for three coping-related behaviours (facial affect, active engagement, and initiation) during hospitalization	Children (4–7 years old) with cancer during inpatient hospitalization (n = 83)	Single 30 minute session of Music listening OR Active music engagement (AME); includes (1) age-appropriate music-based activities to create structure; (2) opportunities to choose materials and flexibility of live music for autonomy-support; and (3) music therapist guide for relatedness	<ul style="list-style-type: none"> • In general, significantly greater coping behaviors in the active music engagement group. • More specifically, significantly more positive facial affect was observed in active music engagement, as compared with the other groups, with music listening having significantly more positive affect than the audio storybook group. • Significantly more active engagement in the active music engagement group, as compared with the other groups, which were not different from one another. • Significantly more initiation with another person observed in the active music engagement and music listening groups as compared with the audio storybook group 	Sufficient sample size, lack of blinding, no selective reporting, correct analysis, study completed as planned, no missing data	2

Abbreviations: RCT = randomized controlled trial; LP = lumbar puncture; BMA = bone marrow aspiration; IV = intravenous; CBT = cognitive-behavior therapy; GA = general anesthesia; IM = intramuscular injection

¹Study included needle procedures in multiple patient populations, not exclusive to oncology.

²Study included complementary and alternative therapies for procedural pain, quality of life, health, and well-being. For the purposes of this paper, only procedure-related outcomes were included.

³Study included nonpharmacologic adjunctive therapies for procedural pain, procedural distress, procedural anxiety, nausea/vomiting, procedural fear, anxiety and distress, and depression. For the purposes of this paper, only procedure-related outcomes were included.

⁴Study included the same sample of children as Klosky, 2004, but reports on different outcomes.

Topic Category: Used to sort type of medical procedure or treatment including: General Systematic Reviews, BMA, LP, Venipuncture/Venous Access/Port Access, IV Insertion, Radiation, Chemotherapy, Stem Cell Transplantation, and Hospitalization.

Study Rigor – Studies were evaluated based upon the type of study (i.e., qualitative, quantitative, and review).

Qualitative (select all that apply)

- research question clearly stated;
- qualitative approach clearly justified;
- study context clearly described;
- role of the researcher clearly described;
- sampling strategy appropriate for research question;
- method of data collection clearly described;
- method of data analysis clearly described; analysis appropriate for research question

Quantitative (select all that apply)

- sufficient sample size;
- blinding or data collection appropriate to study method
- appropriate analysis;
- evidence derived from high quality case control or cohort studies;
- reporting comprehensive, clearly described;
- issues with follow-up or missing data clearly described

Review (select all that apply)

- Right types of papers included;
- Important, relevant studies included;
- Appropriately assessed for quality of studies;
- Reasonable to combine results in this way;
- Important outcomes considered

Levels of evidence – Evaluated for the type of study (e.g., RCT, Qualitative, etc.) being reviewing and the level of evidence that the study produces. In the last column, level of evidence was evaluated on a scale of 1–7. See descriptions below.

- 1** = Systematic review or meta-analysis of controlled studies, or evidence-based clinical practice guidelines;
- 2** = Individual experimental studies (RCT);
- 3** = Quasi-experimental studies (no randomized);
- 4** = Non-experimental studies (Case-control, cohort);
- 5** = Systematic reviews of descriptive or qualitative study;
- 6** = Individual descriptive or qualitative study;
- 7** = Opinions of respected authorities and expert committees.

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