

# Simple Psychological Interventions for Reducing Pain From Common Needle Procedures in Adults

## *Systematic Review of Randomized and Quasi-Randomized Controlled Trials*

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**Background:** This systematic review evaluated the effectiveness of simple psychological interventions for managing pain and fear in adults undergoing vaccination or related common needle procedures (ie, venipuncture/venous cannulation).

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**Design/Methods:** Databases were searched to identify relevant randomized and quasi-randomized controlled trials. Self-reported pain and fear were prioritized as critically important outcomes. Data were combined using standardized mean difference (SMD) or relative risk (RR) with 95% confidence intervals (CI).

**Results:** No studies involving vaccination met inclusion criteria; evidence was drawn from 8 studies of other common needle procedures (eg, venous cannulation, venipuncture) in adults. Two trials evaluating the impact of neutral signaling of the impending procedure (eg, "ready?") as compared with signaling of impending pain (eg, "sharp scratch") demonstrated lower pain when signaled about the procedure (n = 199): SMD = -0.97 (95% CI, -1.26, -0.68), after removal of 1 trial where self-reported pain was significantly lower than the other 2 included trials. Two trials evaluated music distraction (n = 156) and demonstrated no difference in pain: SMD = 0.10 (95% CI, -0.48, 0.27), or fear: SMD = -0.25 (95% CI, -0.61, 0.10). Two trials evaluated visual distraction and demonstrated no difference in pain (n = 177): SMD = -0.57 (95% CI, -1.82, 0.68), or fear (n = 81): SMD = -0.05 (95% CI, -0.50, 0.40). Two trials evaluating breathing interventions found less pain in intervention groups (n = 138): SMD = -0.82 (95% CI, -1.21, -0.43). The quality of evidence across all trials was very low.

**Conclusions:** There are no published studies of simple psychological interventions for vaccination pain in adults. There is some evidence of a benefit from other needle procedures for breathing strategies and neutral signaling of the start of the procedure. There is no evidence for use of music or visual distraction.

**Key Words:** pain management, randomized controlled trial, systematic review, psychological, needle pain

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Vaccine injections are widely used across the lifespan, including in adults of all ages (eg, annual influenza vaccination, immunizations necessary for travel or employment). Multiple forms of interventions are available to manage pain from vaccinations, including pharmacological, psychological, procedural, physical, and process approaches. There are many benefits to simple and feasible psychological approaches, such as music distraction or simple verbal statements from health professionals, as they are time and cost efficient, use widely available resources, and often require little to no training for use; hence, can be easily implemented by health care providers carrying out the procedure. While pain management during vaccine injections has been emphasized in children,<sup>1</sup> it is critical to also examine the efficacy of such strategies in adults, as adults report desiring

treatment for their needle pain<sup>2</sup> and report that decreased immunization pain is related to an increased willingness to be immunized.<sup>3</sup> This highlights the importance of considering how pain can optimally be managed for adults in this context.

In previous reviews, support was found for several psychological interventions for use with children,<sup>4</sup> which were incorporated as recommendations in a clinical practice guideline for vaccination pain management in children.<sup>1</sup> The literature on psychological approaches for managing needle pain in children continues to grow,<sup>5</sup> including attempts to identify specific characteristics of interventions that may contribute to their efficacy.<sup>6</sup> To date, there has been no systematic synthesis of the available literature on psychological interventions for vaccination pain management in adults. Major developmental differences in cognitive domains could contribute to differential efficacy of treatments between children and adults, including differences in preferences, attention, executive and other cognitive functions, coping, and ability to regulate emotions.<sup>7</sup> The objective of the current systematic review was to address this gap to synthesize existing literature to inform development of clinical practice guidelines for psychological approaches to managing vaccination pain in adults.

This review describes the synthesis of results from trials that examined the effect of the following simple psychological interventions on pain: (1) providing a signal about the impending procedure (eg, “ready?,” “beware”) as compared with providing a signal about the impending pain (eg, “sharp scratch,” “sting”); (2) the use of music as distraction during the procedure; (3) the use of visual distraction (looking in a kaleidoscope) during the procedure; and (4) the use of breathing intervention (eg, coughing, breath-holding). Given the lack of direct evidence for the effects of psychological interventions in adults undergoing vaccinations, our synthesis examined indirect evidence (ie, venipuncture and venous cannulation). Separate reviews explore the effectiveness of psychological interventions in young children (0 to 3 y old) and children and adolescents (> 3 to 17 y old), as well as pharmacological, physical, and procedural approaches for infants, children, adolescents, and adults.<sup>8–13</sup>

## METHODS

A consistent approach was used to carry out all systematic reviews examining various pain management intervention types; the methodological details of the approach are described elsewhere.<sup>14</sup> Briefly, both the GRADE (Grading of Recommendations, Assessments, Development and Evaluation)<sup>15</sup> and Cochrane<sup>16</sup> methodologies were used to guide the review. The search strategy was developed with the assistance of an experienced librarian and was conducted in the following databases: EMBASE, Medline, PsycINFO, CINAHL, and ProQuest Dissertations & Theses Global. Relevant citations were screened and included as per the protocol described in a separate manuscript.<sup>14</sup>

Given the purpose of this review was to inform the development of clinical practice guidelines for pain management for vaccine injections across the lifespan, this review prioritized studies including adults undergoing vaccination in any setting, or if not undergoing vaccination, the closest related needle procedure (venipuncture and venous cannulation). Only randomized or quasi-randomized study designs were examined. We included studies published as a full report,

short report, or published academic theses. The included interventions and outcomes included in the review were identified by a national multidisciplinary team, Help ELiminate Pain in Kids and Adults (HELPinKids&Adults), assembled for the specific purpose of undertaking knowledge translation activities in immunization pain management. As described in the accompanying manuscript describing the methodology of this series of reviews,<sup>14</sup> a broad search was used to identify relevant literature for consideration of clinical questions, including previously published clinical practice guidelines, existing research, and clinical experience of the team. The aforementioned team voted on candidate questions, and questions that at least two-thirds of the HELPinKids&Adults team considered to be important were included.<sup>14</sup> For the present review, only simple psychological interventions (ie, interventions that could be implemented with minimal/no training and equipment, and that were time and cost efficient to deliver) were included due to feasibility and ease of implementation within the immunization context. Self-reported pain and fear were prioritized as critically important outcomes, and data from these outcomes were extracted as available. Important outcomes included distress (observer-rated), procedure outcomes, compliance, memory, preference, use of intervention, and satisfaction. A list of included clinical questions and critically important and important outcomes is shown in Table 1.

The Cochrane risk of bias tool (<https://bmg.cochrane.org/assessing-risk-bias-included-studies>) was used to evaluate the methodological quality of the included studies. Data were pooled and analyzed using the RevMan software program (version 5.2; Cochrane Collaboration, Copenhagen, Denmark). The effect of each intervention was expressed as a standardized mean difference (SMD) for continuous variables, or relative risk for dichotomous variables, with accompanying 95% confidence interval (CI). A random-effects model was used for all analyses, with the  $I^2$  and  $\chi^2$  tests used to assess for statistical heterogeneity.<sup>14</sup>

When not reported in the published manuscript text, means and SDs were estimated from medians, ranges, SEs, 95% CI, and graphs provided in published papers. Authors of trials were contacted for further details and provision of original data when not available. As needed, the original data were modified (eg, range conversion to SD) on a very restricted predefined basis, according to established methods.<sup>14</sup> Evidence profiles and summary of findings tables were created using the GRADE profiler software (version 3.6.1).

## RESULTS

A total of 114,251 references were retrieved from the databases, with an additional 138 references identified separately from manual searches. All references were saved in an EndNote library that identified 32,155 duplicates. The remaining 82,234 references were reviewed by 2 of the authors (A.T., V.S.) against the inclusion criteria.<sup>14</sup> No studies directly examining vaccination met inclusion criteria. Eight studies investigating psychological interventions for venipuncture/venous cannulation (ie, indirect evidence) were included in the review.<sup>17–24</sup> The profile summarizing the trial flow is shown in Figure 1.

Characteristics of included trials are reported in Table 2. Excluded studies included: (1) complex psychological interventions (eg, functional relaxation)<sup>25</sup> ( $n = 1$ ); (2) head-to-head comparisons<sup>26,27</sup> ( $n = 2$ ); (3) studies in which participants were sedated with benzodiazepine and unable to give

TABLE 1. Clinical Questions and Outcomes

Clinical Questions	Critical Outcomes*	Important Outcomes
<b>Psychological interventions</b>		
Should a verbal signal of the impending procedure be used (rather than signal of impending pain) by clinicians during vaccine injections in individuals of all ages?	Pain or distress, fear	Distress, procedure outcomes, compliance, memory, preference, satisfaction
Should music distraction be used during vaccine injections in adults?	Pain, fear	Distress, procedure outcomes, use of intervention, compliance, memory, preference, satisfaction
Should visual distraction be used during vaccine injections in adults?	Pain, fear	Distress, procedure outcomes, use of intervention, compliance, memory, preference, satisfaction
Should breathing interventions (cough, breath-hold) be used during vaccine injections in adults?	Pain, fear	Distress, procedure outcomes, use of intervention, compliance, memory, preference, satisfaction

\*Distress is the critical outcome in the absence of data for pain and/or fear in individuals incapable of self-report (eg, infants). As the present sample included only adults who could self-report their pain and fear, this was not considered a critical outcome in the present study.

self-report<sup>28,29</sup> (n = 2); (4) studies where all participants had a choice of which intervention they preferred and were therefore not randomized<sup>30</sup> (n = 1); and (5) systematic reviews<sup>31</sup> (n = 1). In addition, 1 study was excluded as it presented data from the same sample as an included study, but did not examine any critical outcomes.<sup>32</sup> Altogether, 7 studies used a between-groups (parallel) design, and 1 study used a cross-over design. All studies provided data for 2 or more treatment arms. Included studies took place in a variety of clinical settings (ie, tertiary care hospitals, outpatient clinics). Of the 8 included studies, 3 examined venous cannulation, and 5 examined venipuncture. Studies included both healthy participants as well as patients awaiting surgery.

### Quality of Studies and Risk of Bias

Table 3 shows the results for the risk of bias assessment for critically important outcomes. All trials had a high overall risk of bias primarily due to lack of blinding of important personnel, outcome assessors (eg, participants, immunizers), or both, and unclear allocation concealment.

### Overall Quality of Evidence and Treatment Effects

A quantitative summary of the treatment effects for available critically important outcomes is provided below. Table 4 displays a qualitative summary of these results. In addition, GRADE evidence profiles and summary of findings tables (Tables, Supplemental Digital Contents 1 to 4, <http://links.lww.com/CJP/A217>, <http://links.lww.com/CJP/A218>, <http://links.lww.com/CJP/A219>, <http://links.lww.com/CJP/A220>) and accompanying forest plots (Figures, Supplemental Digital Contents 1 to 4, <http://links.lww.com/CJP/A221>, <http://links.lww.com/CJP/A222>, <http://links.lww.com/CJP/A223>, <http://links.lww.com/CJP/A224>) for critically important and important outcomes are included as Supplemental Digital Contents.

#### Should a Verbal Signal of the Impending Procedure be Used (Rather Than Signal of Impending Pain) by Clinicians During Vaccine Injections in Individuals of All Ages?

Three trials including 402 adults investigated the impact of signaling about the start of the procedure as compared with signaling about the impending pain during venous cannulation<sup>19</sup> or venipuncture.<sup>22,24</sup> There was very low quality of evidence because of high risk of bias and

imprecision for all outcomes (Table, Supplemental Digital Content 1, <http://links.lww.com/CJP/A217>). All 3 studies measured self-reported pain intensity (n = 391), and there was no evidence of a benefit for individuals who received a signal about the start of the procedure compared with those who received a signal about the impending pain: SMD = -0.60 (95% CI, -1.37, 0.16) (Figure, Supplemental Digital Content 1, <http://links.lww.com/CJP/A221>). However, participants in 1 study<sup>24</sup> reported significantly lower self-reported pain intensity than in the other 2 included studies. When data from this study was removed, a significant difference was observed in pain, with participants who received the signal about the impending procedure reporting significantly lower pain as compared with those who received the signal about the impending pain (n = 199): SMD = -0.97 (95% CI, -1.26, -0.68). Two studies<sup>22,24</sup> examined whether the patient reported that they experienced pain or no pain during the procedure (ie, a score of  $\geq 1$  on a numerical rating scale<sup>22</sup> or a rating of "no pain" on a verbal response scale<sup>24</sup>). No difference in whether pain was present or absent was observed based on the type of signal provided (n = 290): relative risk = 0.29 (95% CI, 0.01, 5.83).

#### Should Music Distraction be Used During Vaccine Injections in Adults?

Two trials including 156 adults investigated the effect of listening to music as distraction.<sup>20,21</sup> Included studies compared listening to preferred music selected from a variety of musical selections on headphones during venous cannulation compared with a control group (no intervention). Music distraction was not associated with lower pain (n = 156): SMD = -0.10 (95% CI, -0.48, 0.27), or fear (n = 156): SMD = -0.25 (95% CI, -0.61, 0.10), when compared with a control group (Figure, Supplemental Digital Content 2, <http://links.lww.com/CJP/A222>). There was very low-quality evidence for critically important outcomes of pain and fear (Table, Supplemental Digital Content 2, <http://links.lww.com/CJP/A218>).

#### Should Visual Distraction be Used During Vaccine Injections in Adults?

Two trials including 177 adults investigated the effect of using kaleidoscopes as visual forms of distraction.<sup>17,21</sup> Included studies compared looking through the eyepiece of a kaleidoscope during a needle procedure (either venous cannulation<sup>21</sup> or venipuncture<sup>17</sup>) to a control group (no

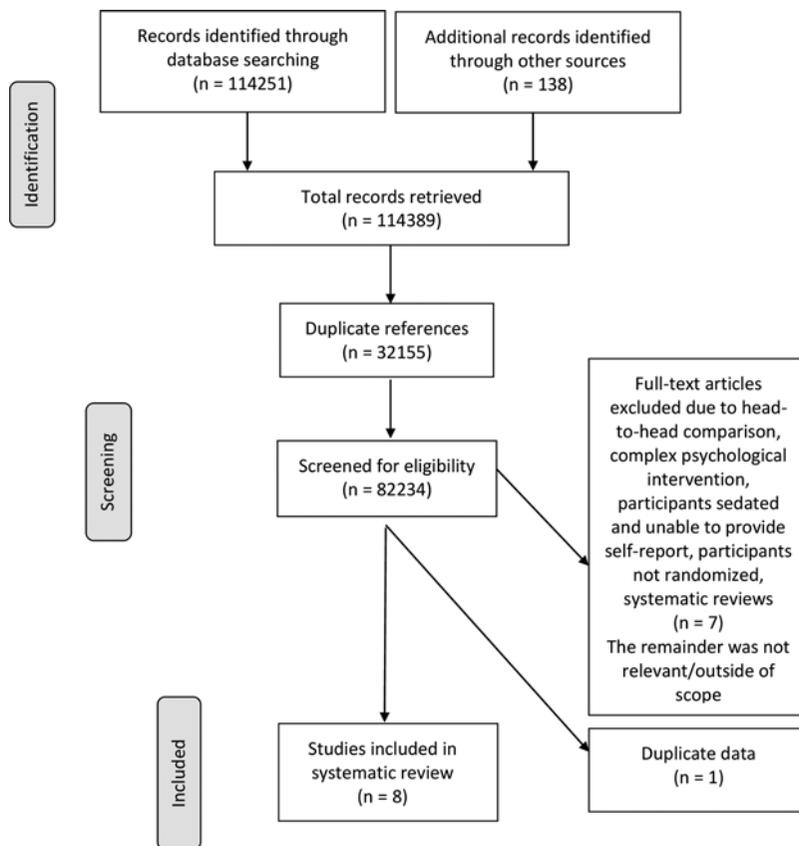


FIGURE 1. Flow of studies.

intervention). Both studies examined the critically important outcome of pain, with no benefit of visual distraction with a kaleidoscope for pain (n = 177): SMD = -0.57 (95% CI, -1.82, 0.68) (Figure, Supplemental Digital Content 3, <http://links.lww.com/CJP/A223>). There was very low-quality evidence for pain, a critical outcome (Table, Supplemental Digital Content 3, <http://links.lww.com/CJP/A219>). One study<sup>21</sup> also examined the critically important outcome of fear, with no benefit of visual distraction with a kaleidoscope (n = 81): SMD = -0.05 (95% CI, -0.50, 0.40), also with very low quality of evidence.

**Should Breathing Interventions (Cough, Breath-Hold) be Used During Vaccine Injections in Adults?**

Two trial including 138 adults compared breathing interventions to a control group (no intervention) during venipuncture. This included the “cough trick” (a modification of acupuncture techniques that involves coughing twice, without moving the arms, with the venous cannulation being performed on the second cough<sup>23</sup>) and the Valsalva maneuver (a deep inhale, followed by a forceful holding of the breath during which the venous cannulation insertion occurs<sup>18</sup>). Less pain was observed for the breathing interventions: SMD = -0.82 (95% CI, -1.21, -0.43) (Figure, Supplemental Digital Content 4, <http://links.lww.com/CJP/A224>). The quality of the evidence was very low (Table, Supplemental Digital Content 4, <http://links.lww.com/CJP/A220>).

**DISCUSSION**

This systematic review was undertaken to determine the effectiveness of simple psychological interventions that can be employed to reduce pain and fear related to vaccine injections in adults. As the literature review did not identify any studies on simple psychological interventions for adults undergoing vaccinations, our synthesis included indirect evidence from other common needle procedures (ie, venipuncture or venous cannulation). There was some evidence for the use of breathing interventions (cough trick, Valsalva maneuver) for reducing pain during venipuncture. There was evidence of an effect of signaling about the procedure (without reference to pain or discomfort) as compared with signaling about the impending pain in studies where participants reported higher levels of pain. There was no evidence for music or visual distraction.

Although the studies examining breathing interventions suggested that the interventions may have provided a distraction to participants while the needle procedure was being completed, physiological mechanisms for treatment benefit are also possible. Usichenko et al<sup>23</sup> suggested that the increased pressure in the subarachnoidal space induced by coughing may activate pain inhibition pathways. Basanranoglu et al<sup>18</sup> provided a similar physiological explanation for the efficacy of the Valsalva maneuver, describing that the action stimulates the vagus nerve, which is involved in the modulation of the pain experience. The impact of breathing interventions on reducing adult procedural pain was observed across both types of breathing interventions, and despite differences in population and methodology in both studies:

**TABLE 2.** Characteristics of Trials Included in the Systematic Review

First Author, Year, Country	Injection Details	Population Enrolled, Design, Setting	Intervention, Sample Size*	Critical Outcomes
Should a verbal signal of the impending procedure be used (rather than signal of impending pain) by clinicians during vaccine injections in individuals of all ages?				
Dutt-Gupta, 2007, <sup>19</sup> Australia	Venous cannulation; 20-gauge needle; dorsum of hand	N = 101; mean age 46-50 y; between-groups design; single-center, hospital	Signal about procedure: Patient told "I am going to apply the tourniquet on the arm. As I do this many people find the arm becomes heavy, numb, and tingly. This allows the drip to be placed more comfortably." (n = 52) or Signal about pain: Patient told "I am going to apply the tourniquet and insert the needle in a few moments. It's a sharp scratch and it may sting a little." (n = 49)	Pain: NRS, Likert scale
Ott, 2012, <sup>22</sup> Austria	Venipuncture; 21-gauge, ¼-inch needle; 15- to 30-degree angle; median cubital vein	N = 98; 19-35 y; between-groups design; single-center, medical university	Participants warned with the word "vorsicht" (German for "beware", considered to be a word not related to pain) directly before insertion of the needle (n = 48) or Participants warned with the word "stich" (German for "sting", considered to be a word related to pain) directly before insertion of the needle (n = 50)	Pain: NRS
Vijayan, 2015, <sup>24</sup> UK	Venipuncture; 22-gauge needle; 30-degree angle; antecubital fossa	N = 192; mean age 51.7 y; between-groups design; single-center; outpatient; clinic	Verbal warning "Ready?" before the procedure (n = 104) or Verbal warning "Sharp scratch" before the procedure (n = 88)	Pain: NRS, Likert scale
Should music distraction be used during vaccine injections in adults?				
Jacobson, 1999, <sup>20</sup> USA	Venous cannulation; no injection details	N = 72; 21-82 y; between-groups design; multicenter, hospital	Participants listened to preferred music (one of 11 CDs with headphones) during entire venous cannulation procedure (n = 36) or Control (no intervention) (n = 36)	Pain: VAS Fear: VAS
Jacobson, 2006 (1,4), <sup>21</sup> USA	Venous cannulation; various IV gauge	N = 324; 18-93 y; between-groups design; multicenter, hospital	Patient self-selected music from a variety of options and received instructions from a research assistant on how to distract themselves with the music. Patient listened to music during the entire venous cannulation procedure (n = 44) or Patient looked into a kaleidoscope to distract themselves during the entire venous cannulation procedure (n = 41)† or Patient listened to a 9-minute guided imagery script with soft music in the background during the entire venous cannulation procedure (n = 41)† or Control (no intervention) (n = 40)	Pain: NRS Fear: NRS
Should visual distraction be used during vaccine injections in adults?				
Cason, 1997, <sup>17</sup> USA	Venipuncture; #21 needle	N = 96; 21-65 y; between-groups design; single-center, family practice clinic	Patients received an illusion kaleidoscope before the application of the tourniquet and looked through the eyepiece until application of the Band-Aid at the end of venipuncture (n = 45) or Control (no intervention) (n = 51)	Pain: FACE-S, VAS, PPI
Jacobson, 2006 (2,5), <sup>21</sup> USA	Venous cannulation; various IV gauge	N = 324; 18-93 y; between-groups design; multicenter, hospital	Patient self-selected music from a variety of options and received instructions from a research assistant on how to distract themselves with the music. Patient listened to music during the entire venous cannulation procedure (n = 44)† or Patient looked into a kaleidoscope to distract themselves during the entire venous cannulation procedure (n = 41)	Pain: NRS Fear: NRS

(Continued)

TABLE 2. (continued)

First Author, Year, Country	Injection Details	Population Enrolled, Design, Setting	Intervention, Sample Size*	Critical Outcomes
			or Patient listened to a 9-min guided imagery script with soft music in the background during the entire venous cannulation procedure (n = 41)†	
			or Control (no intervention) (n = 40)	
Should breathing interventions (cough, breath-hold) be used during vaccine injections in adults?				
Basaranoglu, 2006, <sup>18</sup> Turkey	Venipuncture; 20 gauge needle	N = 98; women mean age, 38-40 y; between-groups design; single-center; hospital	Valsalva maneuver (patient performed a deep inspiration and forcefully held breath) (n = 49)	Pain: NRS
			or Control (n = 49)	
Usichenko, 2004, <sup>23</sup> Germany	Venipuncture; 20-gauge Insyte-W cannula	N = 20; men mean age 20-40 y; cross-over design; single-center, clinic	Cough trick (cough twice turning head away from arm, venipuncture completed during second cough) (n = 20)	Pain: VAS
			or Control (no intervention) (n = 20)	

Studies were identified using the following notation: “First Author” “Year of Publication” [eg, Taddio 2014]. If studies contributed to multiple analyses, then “(#)” was added to enable their discernment [eg, Taddio 2014 (1)]. If the same author published > 1 study in the same year, then a lower case letter was added after the first article in the same year by the same author [eg, Taddio 2014 a (1)].

\*Includes maximum sample size for critically important outcomes.

†Data not included in the analysis.

FACES indicates FACES Pain Scale; NRS, numerical rating scale; PPI, present pain inventory; VAS, visual analog scale.

one study was a cross-over study comprised of only men and using the cough trick,<sup>23</sup> whereas the other study was parallel comprised of only women comparing the Valsalva maneuver to a no-treatment control group.<sup>18</sup> Overall, the mechanisms of treatment benefit from these breathing interventions remain unclear. These results differ to those found in the companion review of psychological interventions for vaccination pain management in children,<sup>10</sup> which found no benefit of coughing for pain. The study of children identified numerous barriers to the implementation of the cough trick in

the clinical setting (eg, children refusing to cough to delay the injection), which may have accounted for some of the differences between the findings for adults and children.<sup>33</sup> As these findings are limited to only 2 trials, and support the efficacy of this intervention, additional trials of these breathing interventions for the adult vaccination setting is warranted.

Given the documented impact of health care provider and caregiver verbalizations on anxiety and pain experienced by adults and children during painful medical procedures,<sup>34,35</sup> examining how health providers interact with

TABLE 3. Assessment of Risk of Bias of Included Trials for Critical Outcomes

First Author, Year	Adequate Sequence Generation	Allocation Concealment	Blinding of Participants and Personnel	Blinding of Outcome Assessment	Incomplete Outcome Data Addressed	Free of Selective Reporting	Free of Other Bias	Overall Risk
Should a verbal signal of the impending procedure be used (rather than signal of impending pain) by clinicians during vaccine injections in individuals of all ages?								
Dutt-Gupta, 2007 <sup>19</sup>	Yes	Yes	No	Yes	Yes	Yes	Unclear	High
Ott, 2012 <sup>22</sup>	Yes	Unclear	No	Yes	Yes	Yes	Yes	High
Vijayan, 2015 <sup>24</sup>	Yes	Unclear	No	No	Yes	Yes	Yes	High
Should music distraction be used during vaccine injections in adults?								
Jacobson, 1999 <sup>20</sup>	Yes	Unclear	No	No	Yes	Yes	Yes	High
Jacobson (1,4), 2006 <sup>21</sup>	Yes	Unclear	No	No	Yes	No	Yes	High
Should visual distraction be used during vaccine injections in adults?								
Cason, 1997 <sup>17</sup>	Unclear	Unclear	No	No	Yes	Yes	Unclear	High
Jacobson (2,5), 2006 <sup>21</sup>	Yes	Unclear	No	No	Yes	No	Yes	High
Should breathing interventions (cough, breath-hold) be used during vaccine injections in adults?								
Basaranoglu, 2006 <sup>18</sup>	Unclear	Unclear	No	No	Yes	Yes	Yes	High
Usichenko, 2004 <sup>23</sup>	Unclear	Unclear	No	Yes	Yes	No	Unclear	High

TABLE 4. Summary of Results for Critically Important Outcomes

Clinical Questions	Critical Outcomes*	Benefit of Intervention†	Quality of Evidence‡
<b>Psychological interventions</b>			
Should a verbal signal of the impending procedure be used (rather than signal of impending pain) by clinicians during vaccine injections in individuals of all ages?	Pain	Mixed§	Very low
Should music distraction be used during vaccine injections in adults?	Pain, fear	No	Very low
Should visual distraction be used during vaccine injections in adults?	Pain, fear	No	Very low
Should breathing interventions (cough, breath-hold) be used during vaccine injections in adults?	Pain	Yes	Very low

\*Includes results for the critical outcomes that were evaluated in included studies only.

†The results for the effect of the intervention have been summarized across all evaluated critical outcomes, and are expressed using the following notation: Yes = benefit was observed across all evaluated critical outcomes; Mixed = benefit was observed for one or more but not all evaluated critical outcomes; No = no evidence of benefit was observed for any of the evaluated critical outcomes.

‡Reflects the lowest quality of evidence rating across all evaluated critical outcomes, whereby rankings range from high to moderate to low to very low.

§On the basis of results after removal of one study with a high risk of bias; see text for details.

patients during painful procedures is of great importance. When all 3 studies were combined in the meta-analysis, no effect of signal type on pain was observed, however, when 1 study which had participants with significantly lower pain scores was removed, signaling about the start of the procedure was associated with significantly lower pain scores than signaling about the impending pain. This suggests that this intervention may be more important for those who report higher levels of pain. Of note, there was wide variability in verbal instructions provided to participants across the 3 included studies. Although each study involved a condition in which participants were signaled about the impending procedure and a condition in which participants were signaled about the impending pain, they differed on a number of potentially important characteristics, including language of delivery (English, German), the extent to which the instructions drew attention to nonpain physical sensations in the arm, and the exact words used to describe the impending pain and procedure (eg, “scratch” and “sting” describe different physical sensations; “beware” may signal threat, while “ready” may convey a sense of control; each of these words perhaps evoking different expectancies which may influence the pain response<sup>36–38</sup>). In addition, previous research in children has suggested that vocal tone may impact the interpretation of statements provided during a painful procedure.<sup>35</sup> Future research may benefit from examining not only the content of the statements provided to adults before needle procedures, but also the tone and quality in which the statements are delivered. Increasing the threat value of pain through the use of pain-related threatening words and descriptions increases catastrophizing and decreases tolerance of pain,<sup>39,40</sup> and may reduce the efficacy of other interventions, such as distraction.<sup>41–44</sup> Overall, given the variability in the included studies, and the experimental evidence that verbal statements can decrease pain, more research into this intervention is clearly needed.

The evidence was insufficient to support the use of music or visual distraction (ie, looking through a kaleidoscope) for the management of procedural pain and fear in adults. Distraction has been hypothesized to relieve procedural pain by actively drawing the patient’s finite attentional resources away from the pain,<sup>45</sup> with music in particular being described as having the added benefit of inducing different emotional states.<sup>46</sup> Although distraction has consistently been shown to reduce pain and distress

during childhood vaccination,<sup>5,10</sup> the use of distraction with adults has been a controversial subject in health psychology.<sup>47</sup> A Cochrane review of the use of music for pain management has described the effects of music as being so small that they should not be a first-line choice of treatment, with music showing no effect on procedural pain.<sup>48</sup> The results of the present review reflect previous findings in adult populations suggesting that distraction is not effective for the relief of procedural pain. In particular, findings of the present study are in line with what was reported in a head-to-head trial by Taddio et al,<sup>27</sup> where it was found that self-directed distraction was less effective than liposomal lidocaine, providing support for the generalizability of the present finding to a vaccination context.

Previous research investigating the use of distraction in adult oncology patients described that some patients reported that they found the distraction interventions bothersome and intrusive in their attempts to attend to the procedure being performed.<sup>49</sup> Individual differences, such as the desire to attend or not attend to a medical procedure, may impact an individual’s ability to engage with a distraction.<sup>50</sup> As the studies involved in the present review did not measure engagement of the individual with the distractor, it is difficult to draw any conclusions regarding how effectively the distractor managed to capture the attention of the participants.<sup>51</sup> This is an important area for future research and may inform treatment-tailoring efforts to maximize benefit to individuals.

A major limitation of the findings from this knowledge synthesis is that none of the included trials specifically examined vaccinations. As no studies involving vaccination were eligible for inclusion, related procedures, contexts (eg, venipuncture), or both were examined instead. There are numerous factors that differentiate the vaccination context from other needle procedures, which should be taken into consideration when extrapolating results to the vaccination setting. The lack of empirical evaluation of psychological interventions for vaccination pain in adults may reflect the belief that adults should be capable of coping with commonly experienced injections without the need for intervention. In addition, the present review only focused on simple psychological interventions, to prioritize interventions that are feasible, as well as time and cost efficient, to implement. However, for adults who require frequent needle procedures or who experience greater needle anxiety, more complex and longer interventions such as functional relaxation,<sup>25</sup>

or exposure-based interventions (also McMurtry CM, Taddio A, Noel M, et al., unpublished data, 2015),<sup>11</sup> may be warranted. No research to date has synthesized the literature on complex psychological interventions for needle pain management.

The risk of bias was high for all included trials; in all cases blinding of participants or personnel was not performed, and blinding of outcome assessment was rarely employed. In addition, there was considerable heterogeneity in the included studies with regards to population and methodology. For example, several studies included successful and unsuccessful procedures,<sup>20,21</sup> whereas others only included successful first attempts.<sup>17,18,23,24</sup> Many studies excluded participants if there were any factors involved that would make the needle procedure more difficult or painful than usual (eg, participants with a history of difficult venous access<sup>19</sup>), which limits the generalizability of the present findings to populations that may be at higher risk of experiencing pain during vaccination. With regards to the clinical relevance of the present research, it is important to also consider the role that fear may have in the efficacy and patient's ability to engage in psychological interventions for needle pain, given the high prevalence of needle fears in the general population (also McMurtry CM, Taddio A, Noel M, et al., unpublished data, 2015).<sup>11,52</sup> It is possible that individuals who agreed to participate in research involving needle procedures, particularly in those studies that involved healthy volunteers, may have a particularly low level of needle-related fear. In addition, some samples excluded individuals who reported fear of pain or blood draws,<sup>22</sup> or participants who were crying or showing other overt signs of distress at the time of the procedure,<sup>17</sup> which reduced the likelihood that individuals with higher needle fears would have been captured in the populations of the present review. This is of particular relevance given that needle fears are common in adults.<sup>3</sup> The level of needle fear should be considered when determining the appropriateness of an intervention, as individuals with higher pain-related fear have demonstrated an attentional bias toward pain-related stimuli and as such may be more attuned to the specific language used by providers before the procedure.<sup>53</sup> In addition, previous research has found that individuals with high pain-related fear benefit less from distraction, and may in fact derive greater benefit from a sensory-focused intervention instead.<sup>42</sup>

The present review only examined simple psychological interventions. This resulted in a synthesis of data that is relevant for health care providers that perform needle procedures (ie, the information is clinically relevant), and describes the efficacy of interventions that are time and cost effective to deliver. A rigorous approach to the analysis was used, guided by both GRADE and Cochrane methodologies. Other aspects of the methodological approach used in this systematic review<sup>14</sup> and other related systematic reviews in this series are reviewed separately, as are limitations and future directions of this larger body of work by the HELPinKids&Adults Team.<sup>54</sup> In light of current concerns about vaccine hesitancy across the lifespan,<sup>55</sup> our review identifies a considerable need for future empirical work in the area of psychological interventions for procedure pain management in adults.

In conclusion, there is support for the use of breathing interventions for reducing pain during adult venipuncture and venous cannulation. There is evidence for providing a signal about the impending procedure for individuals who report experiencing higher levels of pain. There is no evidence of a benefit of music or visual distraction. This paper makes an important contribution as it provides the first synthesis of available evidence on psychological interventions for use with adults undergoing needle procedures. Our review provides

insight into developmental differences in efficacy of these interventions relative to adolescents and children. More research is needed to explore the role of psychological interventions for vaccine pain management in adults.

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