

A systematic review and meta-analysis of the effect of art-based psychological distraction on school-aged children's pain and anxiety during painful procedures

Przegląd systematyczny i metaanaliza wpływu psychologicznej dystrakcji opartej na sztuce, na ból i lęk dzieci w wieku szkolnym podczas bolesnych procedur

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STRESZCZENIE

PRZEGLĄD SYSTEMATYCZNY I METAANALIZA WPŁYWU PSYCHOLOGICZNEJ DYSTRAKCJI OPARTEJ NA SZTUCIE, NA BÓL I LĘK DZIECI W WIEKU SZKOLNYM PODCZAS BOLESNYCH PROCEDUR

Wstęp. Celem pracy było zbadanie, czy interwencje oparte na sztuce są skuteczne w zmniejszeniu bólu i lęku u dzieci podczas nakłuwania żyły.

Materiał i metody. Nasze wyszukiwanie obejmowało 9 baz danych, w tym Cumulative Index to Nursing and Allied Health Literature, ScienceDirect, Scopus, MEDLINE, EMBASE przez PsycINFO, LILACS, ERIC, Web of Science, Google Scholar i Dissertation Abstracts International do 31 grudnia 2021 roku. Głównym kryterium kwalifikacji były badania kliniczne u ludzi opublikowane w języku angielskim randomizowane lub nierandomizowane.

Wyniki. W naszym przeglądzie uwzględniliśmy pięć RCT i wszystkie zostały włączone do naszej metaanalizy. Opisano analizę ilościową różnych parametrów klinicznych. W interwencji opartej na sztuce w porównaniu z grupą kontrolną w zakresie redukcji bólu średnie odchylenie wyniosło -0,68; 95% przedział ufności: -1,14, -0,22), natomiast w interwencji opartej na sztuce w porównaniu z grupą kontrolną w zakresie redukcji lęku średnie odchylenie wyniosło -0,78; 95% przedział ufności: -1,47, -0,09) podczas zabiegów wenipunkcji.

Wnioski. W niniejszym badaniu stwierdzono, że interwencje oparte na sztuce są skuteczne w przypadku dzieci poddawanych zabiegom wenipunktury. Jednak większość badań ma wysokie ryzyko błędów systematycznych i jest niskiej jakości, więc wyniki nie mogą być uogólnione.

Słowa kluczowe: ból, niepokój, strach, odwrócenie uwagi, bolesne procedury

ABSTRACT

A SYSTEMATIC REVIEW AND META-ANALYSIS OF THE EFFECT OF ART-BASED PSYCHOLOGICAL DISTRACTION ON SCHOOL-AGED CHILDREN'S PAIN AND ANXIETY DURING PAINFUL PROCEDURES

Aim. This study aimed to investigate whether arts-based interventions are effective in reducing the pain and anxiety of children during venipuncture.

Material and methods. Our search involved 9 databases, including Cumulative Index to Nursing and Allied Health Literature, ScienceDirect, Scopus, MEDLINE, EMBASE via PsycINFO, LILACS, ERIC, Web of Science, Google Scholar, and Dissertation Abstracts International until 31 December 2021. Clinical trials in humans published in English randomized or non-randomized were the main criteria for eligibility.

Results. We included five RCTs in our review and all were included in our meta-analysis. Quantitative analysis of different clinical parameters was described. In the art-based intervention compared with the control group in terms of reduction in pain mean deviation was -0.68 ; 95% confidence interval: $-1.14, -0.22$), whereas the art-based intervention compared with the control group in terms of anxiety reduction mean deviation: -0.78 ; 95% confidence interval: $-1.47, -0.09$) during venipuncture procedures.

Conclusions. In this study, art-based interventions were found to be effective for children undergoing venipuncture. However, most studies have a high risk of bias and are of low quality, so the results cannot be generalized.

Key words: pain, anxiety, fear, distraction, painful procedures

INTRODUCTION

Painful medical procedures, such as venipuncture and cannulation, are a major cause of pain and discomfort in children's hospitals. Children aged from 6 to 12 years often suffer unexpected and severe pain during procedures [1]. Children's pain experiences during unpleasant procedures may provoke emotional and cognitive negative reactions to needle procedures [2]. Children's fear reacts to painful procedures by activating the sympathetic nervous system, which causes vasoconstriction, reducing the rate of success of venipuncture procedures [3].

In addition, fear of needles contributes to medical non-adherence [4]. When parents watch their children in pain as a result of difficult procedures, both parents and children may be afraid to go through similar procedures in the future [5, 6]. Both may also postpone or prevent having medical attention, [4, 7] demonstrate poor compliance [8], or develop needle phobia [4].

Inappropriate pain and anxiety management during painful procedures can result in the development of serious needle phobias, which can begin in childhood and last until adulthood [9]. The aggressive behaviors that occurred during painful procedure crises for children should be treated. The Children's Commissioner [10] suggests that when opportunities for prevention are missed, children can reach the stage of "crisis", where some children self-harm, and become aggressive. As a result, healthcare providers are challenged to minimize children's pain and anxiety during painful procedures in all healthcare settings [8]. Moreover, pain alleviation is linked to patient satisfaction and is seen as a basic human right [11]. Hence, procedural pain must be effectively managed to reduce the pain and anxiety of pediatric patients.

In recent years, there has been a greater understanding of the need to adequately control the pain and discomfort of painful procedures [12]. Evidence-based clinical practices for the control of pain and anxiety during painful procedures have been produced, which include appropriate pharmacological, physical, and psychological approaches [13, 14]. The most commonly used pharmacological strategy for pain relief during medical procedures is the local anesthetic cream [15]. However, local anesthesia creams are not without their drawbacks. For example, children may still experience pain with the use of the local anesthetic cream [16], there is a delay in the onset of action, and there are rare occurrences of adverse effects, such as allergic reactions.

In regards to psychological techniques, the studies found various cognitive and behavioral techniques that are useful during painful procedures (e.g., deep breathing),

as well as some techniques that are unsuccessful for pain during needle procedures (e.g., reassuring comments such as „it won't hurt"). However, these techniques are not appropriate for making children feel fun and enjoying them out of painful situations. Psychological interventions, particularly distraction methods, are recommended for managing procedural pain in children, and these interventions are usually cognitive-behavioral in nature [12]. Cognitive-behavioral approaches to managing procedural pain in children use techniques that distract and relax the children and often include the child's parents and healthcare providers as coaches or facilitators of the activities [17].

Distraction is one of the pain management approaches that use the five senses to redirect the patient's attention to other stimuli and so manage pain more effectively [2, 3]. Most of these distraction techniques require training to implement, are expensive, and need a helper to distract children, such as digital technology distractions (App, video games, robots, and virtual reality computer educational programs [18, 19], and some of them are not effective, such as Mandala creative and puzzle as a distraction [20, 21], additionally, some of them may require training and cost-effect as well as are not attractive or fun as art activities for children [22].

In contrast to other distraction interventions, art-based psychological distraction is more fun and engaging for children [23, 24]. In addition to providing attractive activities for children in medical and non-medical settings, this method requires no training, is inexpensive, and is convenient for nurses and children alike. These factors limit the broad use of distraction strategies in hospitals [23].

In pediatric health care, art intervention strategies can serve a variety of therapeutic purposes, including providing a form of play that not only serves to improve peer relationships, reduce stress, enhance cognitive skills, and improve exploration but also serves as a safe place for the expression of fears and anxieties through prediction and skill in activities [25]. Also, they may result in positive outcomes such as improved coping or lower anxiety levels [26]. Arts-based interventions have been shown to reduce pain and anxiety in children with a variety of conditions and disorders, as well as in a wide range of situations, such as cancer children [27] and hospitalized children [28]. Art therapy is a type of mental health care that involves the creative method of creating art to improve and enhance the physical, mental, and emotional well-being of people of all ages suffering from a variety of disorders, such as chronic diseases, physical impairments, mental illnesses, and cancers [29, 30]. In addition, art intervention promotes learning-by-doing, indirect expression of feelings,

distraction, and relaxation for young people [31]. To our knowledge, no systematic review of the effectiveness of art-based intervention for distraction has been done to date. Therefore, the objective of this study is to summarize the existing studies on the usefulness of art-based distraction measures in painful procedures.

The research question listed will be addressed: What is the effectiveness of art-based approaches on pain and anxiety of school-age children in pediatric acute care settings during painful procedures?

METHODS

The systematic analysis was performed according to the Cochrane Collaboration recommendations for data identification, selection, data extraction, quality assessment, and analysis [32], and was reported following the Preferred Reporting Guideline for Systematic Review and Meta-Analysis (PRISMA) guidelines [33]. The trial was registered in the International prospective register for systematic reviews (PROSPERO) with registration number CRD42021255169.

The eligibility criteria for the studies were defined according to the PICOS guideline and explained in tab. 1. In this review, only venipuncture and peripheral venous cannulation were considered painful procedures because they are the most common and have been little studied [34]. In addition, the occurrence of these procedures during the child's lifetime might be more influenced by a previous negative experience [35].

We conducted a systematic literature search in nine databases (see Fig 1). In order to use literature to reflect on contemporary practice, we searched without restricting the years but restricted the language due to most of the articles being published in English language. Initially, the presence of restricted identifiers (such as MeSH terms, CINAHL headings, PsycINFO thesaurus, and DeCS-Health Science Descriptors) and their counterparts (search terms) in each database were confirmed. Key terms included (Art therapy[Title/Abstract]) OR (art[Title/Abstract]) OR (Painting[Title/Abstract]) OR (Drawing[Title/Abstract])) OR (art work[Title/Abstract]) AND (pain[Title/Abstract]) OR (distress[Title/Abstract]) (anxiety[Title/Abstract]) AND (Children[Title/Abstract]) OR (pediatric[Title/Abstract]) AND (Venipuncture[Title/Abstract]) OR (Cannulation[Title/Abstract]) OR (Painful procedures[Title/Abstract]). The PubMed and subject databases were searched; journals, in which eligible studies were published, were reviewed manually, along with previous systematic reviews focusing on art therapy, to determine their bibliographies. The authors' database search verified the presence of other relevant studies, and the authors were notified by e-mail.

In this study, the data search was conducted separately by two reviewers (SS and AA). To avoid bias, we reviewed the title then the abstract, and the full text of studies on the Rayyan website to include studies. To use a standardized approach, the following data were collected separately from each study: First author and year, research design, nation, setting, method, participants, intervention, control,

result and assessment instrument, post-intervention outcome, and other comments. Then, the spreadsheets were combined into one. In the event that the reviewers disagreed, the article was reevaluated by two more reviewers (SN and KE), who then made the final decision. For each step of the screening, Cohen's Kappa was used to measure inter-coder agreement.

The Cochrane Risk of Bias Tool was used to assess the risk of bias in the included studies. A variety of biases were assessed in each study, including Randomization, concealed allocation, implementation bias, detection bias, incomplete outcome data, the presence of bias in reporting, and others. The authors assessed each criterion as „low risk” or „high risk,” and if data was insufficient, the risk was rated as „unclear”. One point is added to the overall score for a „low-risk” response. The study quality was measured by the summary ratings. The included studies were categorized as „good” (5-6 points), „moderate” (3-4 points), or „poor” (0-2 points). Two authors individually evaluated the listed studies' methodological quality (SS, AA). In case of disagreement, a third researcher was consulted to reach an agreement (SN).

Review Manager Software was used for the statistical analysis (RevMan 5.3.5) [13]. The mean, standard deviation (SD), and the number of participants were used to calculate standardized mean differences (SMDs) and 95% confidence intervals (CIs) between effective interventions and usual care groups. Heterogeneity between studies was tested by evaluating forest plots for overlapping confidence intervals, using the chi-square test with a P value of 0.05 for statistical significance, and using the I² test statistic; 25% was classified as low, 50% as a medium, and 75% as high. Statistical significance was set at p < 0.05. We selected the random-effects model because trials differed in terms of interventions, controls, time points of evaluation, and population. To evaluate the pooled effect, the random-effects model was used because the research design contained a high degree of clinical and methodological heterogeneity, such as different strategies, intervention variables, and outcome measures. Egger's and Begg's tests, as well as funnel plots, were used to examine publication bias.

A meta-analysis was performed when information from many studies was available on the same outcome. In this review, pain and anxiety post-procedure were measured as outcomes. The outcomes are presented by comparing the intervention group with the control group.

■ Tab. 1. Eligibility criteria of the studies included

PICOS strategy	Inclusion criteria
P – Population	Children 6-12 years of age are hospitalized for acute or chronic illness and undergoing peripheral venous cannulation or venipuncture.
I – Intervention	Art-based intervention (drawing, coloring, painting, and other forms of art) during procedures
C – Comparison	Routine care or other arts-based interventions
O – Outcome	Pain and anxiety were measured with standardized scales during or immediately after the painful procedure
S – Study design	Randomized controlled trial (RCT) and quasi-experimental study
Limitation	English Language

RESULTS

The search retrieved 703 unique citations. A total of 690 citations were screened according to the title and abstract, and 10 hits were found for full-text screening resulting in the exclusion of 4 studies. According to the reviewers, we included five studies that met all eligibility criteria and answered the research question (Fig 1).

The characteristics of the included studies are shown in table 2. This review included 5 studies: 4 from Turkey [36-39], and one study from the Netherlands[21]. The authors of these studies were nurses and psychologists. All included studies were designed as RCTs. Among the 5 parallel arm trials, there were two trials with four arms, one trial with three arms, and two trials with two arms, which accounted for the differences in study designs. All studies included in the quantitative analysis have small sample sizes of 10-63 per group. Four studies [36-39] included participants who required venipuncture in the acute care setting; in addition, one study [21] referred 20 outpatient participants to a dedicated pediatric venipuncture unit.

These participants were aged from 6 to 12 years old in all studies. A total number of 389 participants were analyzed for pain intensity and anxiety levels in the acute care setting. All studies reported outcomes in terms of pain intensity and anxiety.

This study used pain intensity and anxiety levels scales, three scales were used to assess children’s pain through self-assessment after completing venipuncture procedures. The Wong-Baker FACES scale, including six faces numbered from 0 to 10, with 0 representing no pain and 10 representing the worst pain, were used in three studies [36, 37, 39]. In one study, the Faces Pain Scale-Revised (FPS-R) was used. This scale ranges from 0 to 10, with six cartoon faces ranging from a slight smile („0 – no pain”) to a screaming face („10 – severe pain”) [38]. A visual analog scale (VAS) that consisted of numbers from 0 to 10 represents the severity of the pain and 0 represents no pain at all [21].

Children’s anxiety was assessed by parents after completion of venipuncture using three different scales. The Child Anxiety Scale, which consists of five faces representing 0 – no anxiety and 4 – severe anxiety and was used in the three studies [36, 37, 39], The visual analog

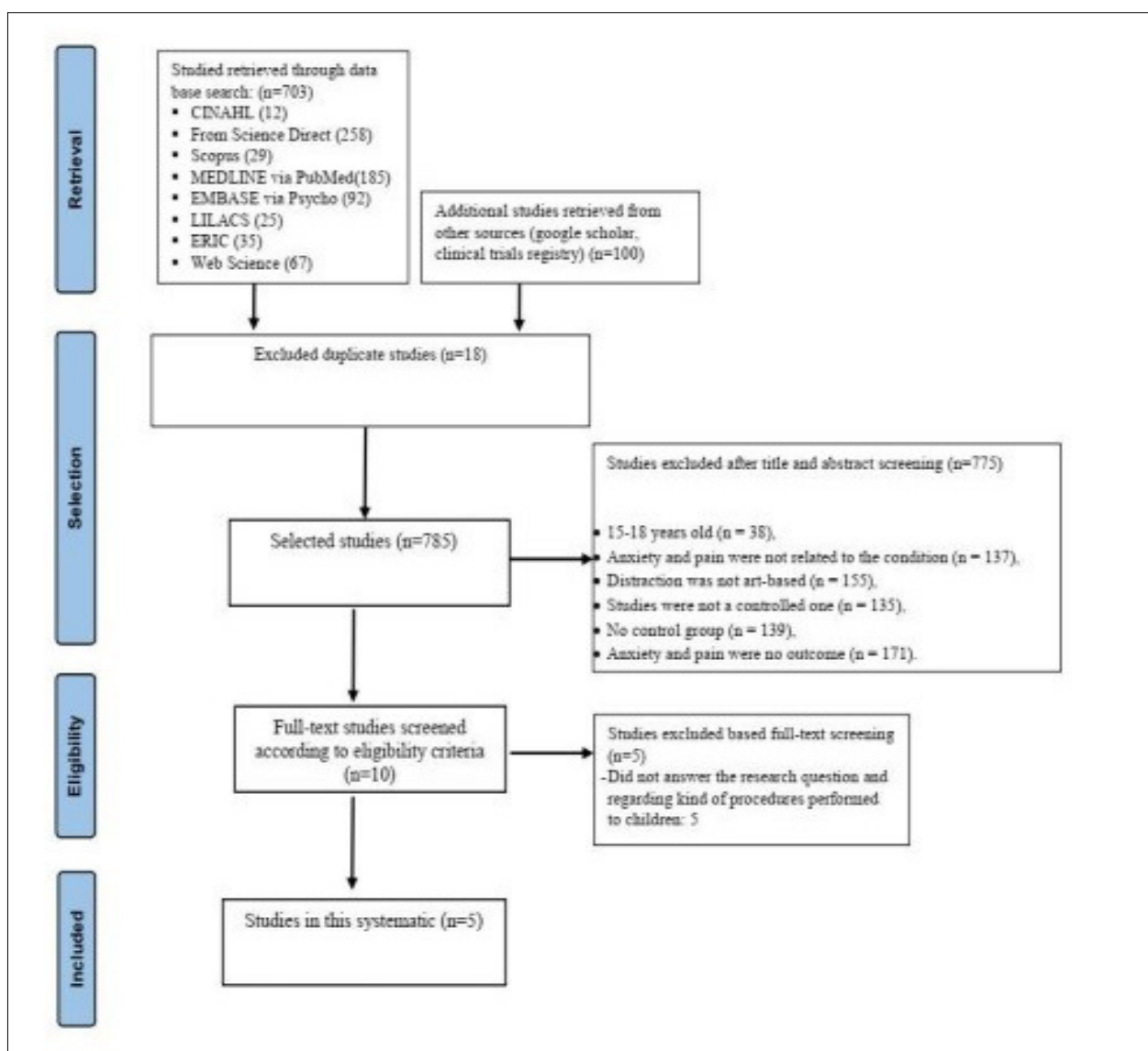


Fig 1. Flow chart of selection studies (PRISMA)

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■ Tab. 2. Characteristics of the included studies and Kappa test

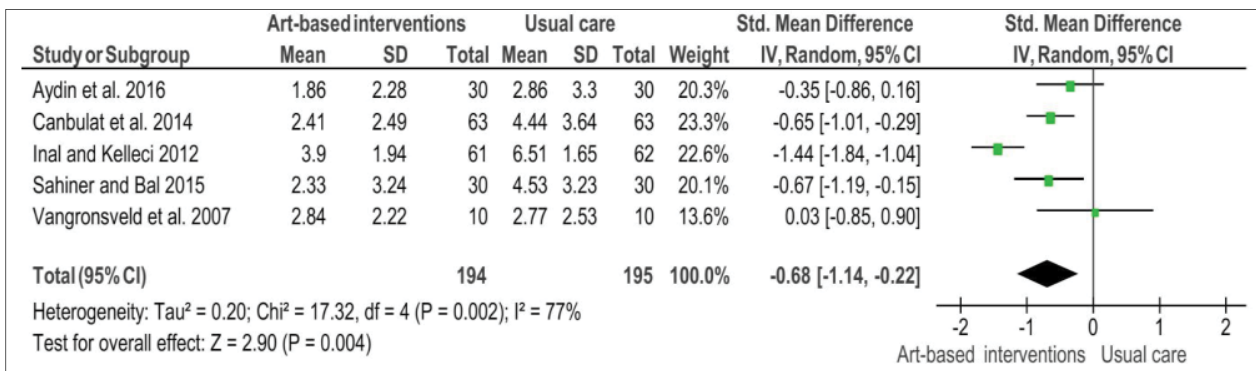
Author (Year)	Specialist	Country	Design	Population	Randomization	Procedures	Groups (Interventions)	Measures Tools	Result	Fund (conflict)
Sahiner and Bal (2015)	Nursing	Turkey	RCT	120 children (6-12 years) Inpatient (IP)	Simple random (random number generator)	Venipuncture	4 groups • distraction cards (n=30) • listening to the music of cartoons (n=30) • balloon inflation(n=30) • Routine care group (n=30)	Pain: The Wong-Baker FACES Scale was used to measure children's pain as a self-report measure. Anxiety: Children Fear Scale (Parents used this scale to measure children's anxiety levels).	Pain was more significantly decreased than other distraction groups by self-report. Anxiety levels were not decreased between groups through parent assessment.	Note: there are no Funds
Aydin et al. (2016)	Nursing	Turkey	RCT	120 children (7-12 Yrs) Inpatient	Simple random (computer list)	Phlebotomy	4 groups • Ball Squeezing (n=30) • Balloon inflation (n=30) • Distraction Cards (n=30) • Routine care (n=30)	Pain: The Wong-Baker FACES Scale was used to measure children's pain as a self-report measure. Anxiety: Children Fear Scale (Parents used this scale to measure children's anxiety levels).	Decreased pain and anxiety	Noted that there are no funding and conflicts of interest
Canbulat et al. (2014)	Nursing	Turkey	RCT	126 children (7-11 Yrs) Inpatient	Simple random (computer list)	Phlebotomy	3 groups • Distraction Cards (n=63) • Kaleidoscope group (n=62) • Routine care (n=63)	Pain: The Wong-Baker FACES Scale was used to measure children's pain as a self-report measure. Anxiety: Children Fear Scale (Parents used this scale to measure children's anxiety levels).	Decreased Pain and anxiety	Noted that there is funding and no conflicts of interest
Inal and Kelleci (2012)	Nursing	Turkey	RCT	123 children (school-aged) Inpatient	Simple random (computer list)	Phlebotomy	2 groups • Distraction Cards group (n=61) • Control group (n=63)	Pain: The Faces Pain Scale-Revised was used to measure children's pain as a self-report. Anxiety: The Children's Anxiety and Pain Scale was used to measure children's anxiety by parents.	Decreased Pain and anxiety	
Vangronsveld et al. (2007)	Psychology	Netherland	RCT	20 children (8 and 11 years) Outpatient	Randomization procedure performed by a person who was not involved in the study	Phlebotomy	2 groups • Distraction (Puzzle) (n=10) • Routine care group (n=10)	Pain and anxiety: The visual analog scale is used by children to self-assess pain, while parents used it to measure their children's anxiety.	Pain and anxiety were not decreased	

Cohen's Kappaa test = 0.64, P= 0.001

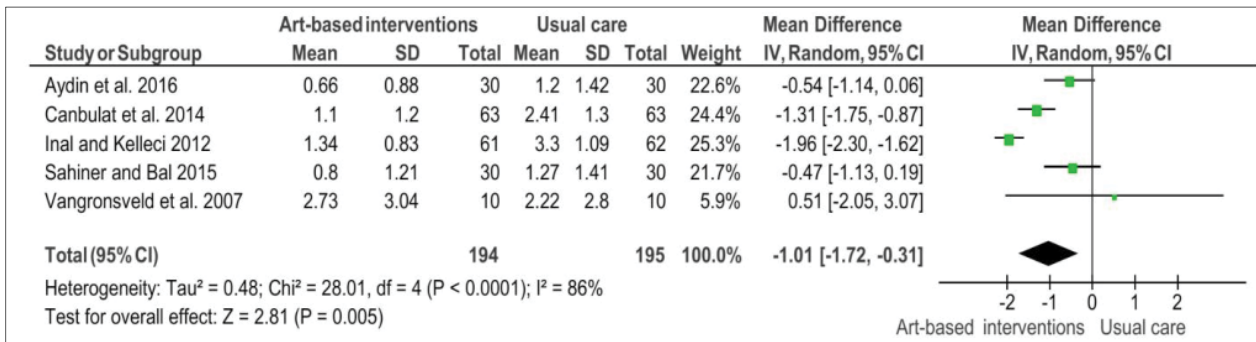
■ Tab. 3. Summary of risk of bias (low, unclear, high)

Studies	Random sequence generation	Allocation concealment	Performance bias	Detection bias	Attrition bias	Reporting bias	Other bias	Overall bias
Aydin et al. (2016)	Low	Low	High	Unclear	Unclear	Low	Low	High risk
Canbulat et al. (2014)	Low	Low	High	High	Low	Low	Low	Low
Inal and Kelleci (2012)	Low	Low	Unclear	Low	Low	Low	Unclear	Low risk
Sahiner and Bal (2015)	Low	Low	Unclear	Unclear	Low	Low	Unclear	Unclear
Vangronsveld et al. (2007)	Low	Unclear	Unclear	High risk	Unclear	Unclear	Unclear	High risk

Risk of bias between raters was measured by Kappa coefficient = Kappa value 0.68, CI 95% (0.43, .93), P=0.000,



■ Fig 2. Children's pain-Art-based intervention vs. usual care



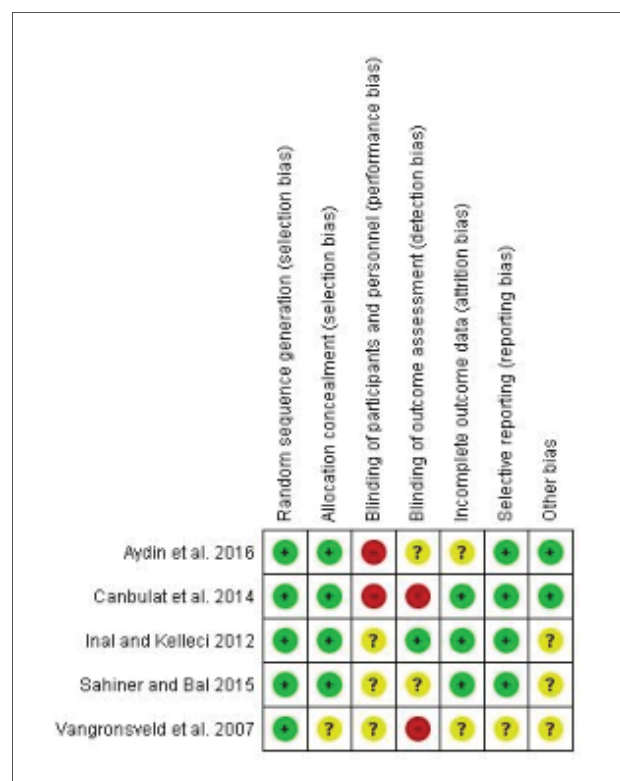
■ Fig 3. Children's anxiety-Art-based intervention vs. usual care

scale is another scale for children's anxiety that was used in two studies ranging from 0 to 10, with 10 representing the worst anxiety and 0 representing no anxiety in the two studies [21, 40]. Children's Anxiety and Pain Scales (CAPS) – this scale consisted of a pair of facial expressions scales, one for anxiety and one for pain, and five faces for each facial expression from no pain or anxiety to worst pain or anxiety [38].

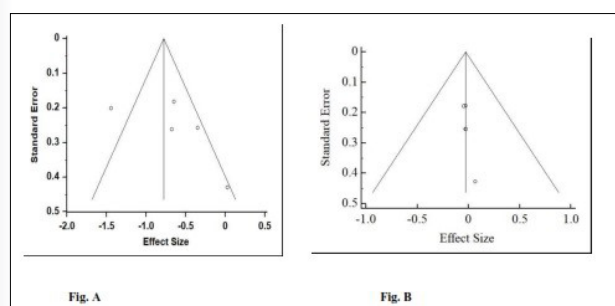
According to the interventions, all populations of studies received a kind of art-based intervention (puzzle and card) as a distraction. The art-based offered interventions varied widely: the puzzles, filling the picture with colored puzzles, and drawing pictures. A study by Vangronsveld et al. [21] evaluated the distraction card versus no distraction in two groups. One group received the puzzle card and the other received the usual care to reduce the pain and anxiety of children during venipuncture.

Card distraction is a colored card used in children with venipuncture procedures [36-39]. Two studies divided study participants into two groups, one receiving art-based activities compared with one receiving routine care [21, 38]. Another two studies divided study participants into four groups, such as the Distraction card, Ball squeezing, Balloon group, and Control group [36, 39]. Only one out of five studies included three study arms (card distraction, Kaleidoscope as distraction, and routine care) [37]. Based on the intervention protocols of the included studies, the art-based interventions ranged from 1 to 4 minutes during venipuncture procedures. In general, the intervention lasted from 1 minute before venipuncture to 3 minutes after the completion of the puncture. While the usual-care group received no distraction tasks or pharmacological interventions in all included studies.

When it comes to 33 of the 35 ratings (6 criteria applied to 5 studies), they were similar. As shown in tab.3, the agreement between the raters is more than 93% and is considered a perfect match according to the kappa coefficient. The discrepancies were discussed and resolved. In tab.3, the column „% of data that are reliable” corresponds to the squared kappa, a directly interpretable equivalent of the squared correlation coefficient.



■ Fig 4. Risk of bias summary



■ Fig 5. Funnel plot and Trim and Fill methods for publication bias (A pain and B anxiety)

The assessment of the risk of bias is shown in tab. 3, the overall domains measured by the risk of bias (RoB2) tool are high in six studies, and only one showed a low risk of bias in five of seven domains. In all studies, participants were randomly assigned; only half of the studies masked participants during distribution. Performance bias; All studies had unclear to high bias risk. Detection bias; only one study showed a minimal probability of outcome bias and provided detailed information on blinded investigators. Attrition bias; only one study had a low risk of missing and managed data and provided detailed information on data missing during follow-up. Reporting bias; all outcomes were reported in most of the included studies. While overall domains; A high risk of bias was indicated for five of the six domains.

Heterogeneity of the included studies of up to 77% as 'high heterogeneity' was found for the assessment of studies on pain and 86% as 'high heterogeneity' for the assessment of studies on anxiety. Despite the relatively large heterogeneity between the included publications, we thought it would be suitable to combine data from all publications on reducing children's pain and anxiety for card distraction as art-based distraction vs. usual care without pharmacologic and non-pharmacologic management in relation to outcomes-response to art-based interventions.

All of the included trials, which comprised 389 individuals, evaluated the efficacy of art-based activities on pain scores during phlebotomy to usual care [21, 36-39]. The art-based intervention showed a statistically significant ($Z = 2.90$ ($P < 0.004$)) improvement in pain scores, with an SMD (95% CI) of -0.68 ($[-1.14, -0.22]$) for the child's pain score (Fig 2). Nevertheless, these results should be interpreted with caution due to the large heterogeneity of the studies ($I^2 = 77\%$, $P < 0.002$). Children's pain was measured using a variety of scales, such as the Wong-Baker FACES in three studies, the VAS in two studies, and the Faces Pain Scale-Revised (FPS-R) in one study. All of these scales were valid and reliable, and the differences in the scales used to measure pain during venipuncture may cause a high degree of heterogeneity.

The meta-analysis included 5 studies, involving 369 participants that compared art-based interventions with usual care during venipuncture procedures [21, 36-39]. An art-based intervention significantly reduced anxiety levels ($Z = 2.81$ ($P = 0.005$), The child's anxiety score had an SMD (95% CI) of -1.01 , CI $[-1.72, -0.31]$) (Fig 3). In the comparison of the studies, considerable heterogeneity

was found ($I^2 = 86\%$). Because of the lack of studies, it was impossible to determine what causes heterogeneity. Children's anxiety was measured with various scales, such as the Child Fear Scale in three studies, the VAS in one study, and the Children's Anxiety and Pain Scale in one study. All of these scales were valid and reliable, and the differences in the scales used to measure anxiety during venipuncture may cause a high degree of heterogeneity.

Publication bias: This meta-analysis found that publication bias was unlikely in five of the included studies, as shown in the funnel plot. Based on the trim-and-fill method, this impression is confirmed: no trial was trimmed, the estimated effect size in black, and the observed effect size in white overlapped (Fig. 5). The following experiments were also conducted to show that publication bias was unlikely:

- Intercept of Egger's linear regression test = 4.15, 95% CI= -7.00 to 15.30 , $P = 0.32$; (Pain scores)
- Egger's linear regression test: Intercept= 0.35 , 95% CI= 0.05 to 0.65 , $P = 0.03$ (Anxiety levels)
- Rank correlation test of Begg and Mazumdar: Kendall's tau= 0.40 , $P = 0.32$ (pain scores).
- Kendall's tau= 0.60 , $P = 0.14$ for Begg and Mazumdar's rank correlation test (anxiety levels).

DISCUSSION

We conducted a systematic review and meta-analyses of the effectiveness of art-based interventions in reducing children's pain and anxiety during venipuncture and cannulation. The results demonstrated that arts-based interventions are more effective than standard care in reducing children's pain and anxiety.

There was a significant and large effect (SMD = -0.68) of the art-based intervention on pain reduction. Furthermore, the art-based intervention had a significant and large effect on reducing children's anxiety during venipuncture (SMD = -1.01) compared to usual care (control group). The results should be interpreted with caution due to the following factors: (1) the small number and low methodological quality of the studied research; (2) the smaller overall participants ($N = 389$), resulting in poor statistical power; and (3) the degree of heterogeneity between research findings, ranging from large to extremely large.

All studies that examined the impact of art-based activities on pain and anxiety in children showed significant heterogeneity. This influence strongly the interpretation of the effects. The sources of heterogeneity may not be equally distributed across countries in the world, as four studies were conducted in Turkey and one in the Netherlands. In addition, most included studies identified a high bias risk, as well as differences between the scales used to measure outcomes in children and the statistical tests used to analyze the effect of arts-based interventions on reducing children's pain and anxiety in the studies. These variables can potentially bias the results and reduce their external validity. All articles included in this study contain small purposive samples, which affects the external validity of the generality.

There is some evidence of effect ascertainment bias, as larger effect sizes were observed in studies with lower precision. In all studies included in this research, post-intervention pain and anxiety were assessed within 2-3 minutes after completion of venipuncture. An important unresolved issue is how long the benefits of art-based interventions (painting or drawing) might last. Evaluating the intervention's effect on some [20] only or particular procedure [20, 21, 36-38, 40], the wide age range of participants (6-12 years), any prior experience with procedural pain, differences in competence and experience with arts-based interventions (not detailed in the trials), as well as the typology of distraction tactics, the intrinsic properties of outcome tools, and self-direction [20, 21, 36-38, 40]. Future research should include larger sample sizes and non-coloring control groups and should pay more attention to the risk of bias, particularly with regard to blinding of those implementing the intervention and information given before or after assignment to intervention groups, because detection bias has greatly affected research findings (Hrobjartsson et al., 2013).

This review has several strengths. Obviously, this was the first systematic review to evaluate the effectiveness of arts-based distraction interventions for pediatric patients. As another strength of this review, the data were analyzed using a meta-analytic approach and a comprehensive search for appropriate studies. However, this review also has its limitations. Firstly, this analysis included only five English-language studies with 419 subjects. Further statistical analyses (such as meta-regression and subgroup analysis) could not be performed because of the small number of studies. Secondly, the involved studies included only four nations with modest sample sizes, ranging from 10 to 65 subjects per group, also our review has low quality, a significant risk of bias, and a significant degree of heterogeneity between studies. Thirdly, in this review, studies were limited to school-age children experiencing pain and anxiety during venipuncture. Therefore, caution should be used when generalizing these results to other populations. Furthermore, there is presently no instruction on how to evaluate the potential of bias in previous studies because no written protocol is available. Moreover, we made a few changes to the Prospero protocol due to the small number of studies included in our systematic review and this change may increase bias in this review. Finally, we searched extensively for studies, however, it is possible we did not find all of the relevant studies, particularly those that had been published in more distant sources or were unpublished, despite our thorough search. It is likely that studies with favorable results favoring treatment will be submitted for publication and ultimately published, therefore resulting in bias.

CONCLUSIONS

In summary, the results of our study suggest that arts-based interventions reduce pain and anxiety significantly more than routine care. However, they should be evaluated with extreme caution because the data come from a small number of low-quality studies that have a substan-

tial risk of bias and a high degree of heterogeneity. In addition, none of the studies reviewed provided information on the adverse effect of the interventions, such as the consequences of materials used on children and the costs of the interventions. Future studies could compare the effect of art-based distraction with other distraction methods (e.g., drawing on an iPad or using virtual reality). We suggest conducting new clinical trials with adequate sample sizes and a low risk of bias.

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