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The efficacy of socially assistive robots in improving children's pain and negative affectivity during needle-based invasive treatment: A systematic review and meta-analysis

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Abstract

Background The ability of socially assistive robots (SARs) to treat dementia and Alzheimer's disease has been verified. Currently, to increase the range of their application, there is an increasing amount of interest in using SARs to relieve pain and negative emotions among children in routine medical settings. However, there is little consensus regarding the use of these robots.

Objective This study aimed to evaluate the effect of SARs on pain and negative affectivity among children undergoing invasive needle-based procedures.

Design This study was a systematic review and meta-analysis of randomized controlled trials that was conducted in accordance with the Cochrane Handbook guidelines.

Methods The PubMed, CINAHL, Web of Science, Cochrane Library, Embase, CNKI, and WanFang databases were searched from inception to January 2024 to identify relevant randomized controlled trials (RCTs). We used the Cochrane Risk of Bias tool 2.0 (RoB2.0) to assess the risk of bias among the included studies, and we used RevMan 5.4 software to conduct the meta-analysis. The Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) framework was used to assess the quality of the evidence.

Results Ten RCTs involving 815 pediatric subjects were selected for this review and reported outcomes related to pain and emotions during IV placement, port needle insertion, flu vaccination, blood sampling, and dental treatment. Children undergoing needle-related procedures with SARs reported less anxiety (SMD= -0.36; 95% CI= -0.64, -0.09) and fewer distressed avoidance behaviors (SMD= -0.67; 95% CI= -1.04, -0.30) than did those receiving typical care. There were nonsignificant differences between these groups in terms of in pain (SMD = -0.02; 95% CI = − 0.81, 0.78) and fear (SMD = 0.38; 95% CI= -0.06, 0.82). The results of exploratory subgroup analyses revealed no statistically significant differences based on the intervention type of robots or anesthetic use.

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Conclusions The use of SARs is a promising intervention method for alleviating anxiety and distress among children undergoing needle-related procedures. However, additional high-quality randomized controlled trials are needed to further validate these conclusions.

Trial registration The protocol of this study has been registered in the database PROSPERO (registration ID: CRD42023413279).

Keywords Pediatrics, Acute pain, Emotions, Meta-analysis, Systematic review, Robotics

What is known

- Safe and efficient pain management is vital for increasing children's compliance with medical procedures and improving the quality of nursing care.
- Although several randomized controlled trials have used socially assistive robots in routine invasive medical procedures, the effects of these robots on pain and negative emotions among children remain unclear.

What is new

- Socially assistive robots can significantly reduce children's acute anxiety and distress, but the efficacy of these robots for alleviating acute pain and fear remains unclear.
- Socially assistive robots can be classified into two categories based on the theories used to develop them: robots that apply aspects of CBT theory and robots that are only used for distraction.
- Detailed suggestions are proposed to enhance the intelligence of future socially assistive robots and to improve the quality of randomized controlled trials.

Background

Most healthy children have to receive needle-based treatment at some point in their lives, such as vaccination, venipuncture, or blood collection. Furthermore, hospitalized children who are unfortunately ill often receive needle-based treatment [1, 2]. Negative experiences with needle-based treatments can result in procedural pain and negative emotions such as anxiety, fear, and depression. Such emotion can in turn lead to the avoidance of subsequent treatment and medical care [3–5]. In some cases, these negative emotions can even have a long-term detrimental impact on a child's psychological health, e.g., needle phobia [6]. In addition, a lack of trust in healthcare practitioners and the avoidance of medical care can lead to various societal and economic side effects [7]. Therefore, managing pain efficiently is highly valuable for maintaining positive attitudes toward medical care among children and for establishing a healthy environment for the community [8].

Both pharmacological and nonpharmacological methods are extensively used in clinical settings. However, the former has weaker effects than expected on pain remission and is associated with more adverse reactions [9–11]. In contrast, nonpharmacological methods seem to be safe and effective for pain-related outcomes [9, 11]. Furthermore, nonpharmacological methods can be quickly and extensively used in urgent settings [12]. In recent years, several studies have introduced an innovative nonpharmacological technique, namely, socially assistive robots, for reducing pain and negative affectivity during needle-based treatment [13, 14]. According to Duffy et al. [15], a socially assistive robot can be defined as "a physical entity embodiment activated in a complex, dynamic, and social environment sufficiently empowered to behave in a manner conducive to its own goals and those of its community". Building upon this definition, socially assistive robots should have three characteristics: (1) a physical body, (2) (semi)autonomous behavior, and (3) competence in engaging with humans through attributes such as appearance, voice, personality or other adaptation skills. Socially assistive robots are designed to engage and communicate with humans through the use of embodiment, personality, and adaptation skills, and they serve as distractions for children in painful and stressful situations [16].

Despite evidence indicating that socially assistive robots can buffer cognitive deficits in individuals with autism spectrum disorders as well as individuals with Alzheimer's disease [17, 18], the efficacy of socially assistive robots in improving children's pain and negative emotions during needle-based treatment remains unclear. Beran et al. [19] were the first researchers to utilize a socially assistive robot for controlling acute pain during a medical procedure, and they reported a noteworthy magnitude of reduction in both pain and distress. However, Lee-Krueger et al. [20] observed no significant differences in pain or fear between the groups during intravenous venipuncture. Ali et al. [21] conducted a randomized clinical trial and found that humanoid robots impact distress but not pain among children. Most previous systematic reviews have reported the

usefulness of new technology distractions, which include a wide range of digital devices for controlling acute pain, such as virtual reality devices, video games, and smartphones [5, 12, 22].

Nevertheless, limited reviews have explicitly illustrated the use of robotic distraction in acute pain management in children. A systematic review in 2019 [23] and a scoping review [24] in 2021 indicated insufficient evidence to support the claim that such strategies can induce a reduction in children's distress. Furthermore, there is no clear evidence for a reduction in pain.

The aims of this systematic review and meta-analysis of RCTs were as follows: (i) to evaluate the efficacy of socially assistive robots for managing pain and emotions in children during invasive needle-based procedures in comparison to standard care or other typical forms of distraction methods; and (ii) to assess the impacts of different types of socially assistive robots or different situations on pain and negative emotions among children receiving needle-based treatment.

Methods

This review was performed in accordance with the Cochrane Handbook for Systematic Reviews of Interventions [25]. The details of the predetermined protocol for this study can be accessed in the International Prospective Register of Systematic Reviews (CRD42023413279).

Literature search

The PubMed, Embase, CINAHL, Cochrane Library, Web of Science, CNKI and Wanfang databases were searched from inception to January 2024 using text words as well as Medical Subject Heading terms. Based on the purpose of the study, team members identified search terms through discussions after consulting librarians and experts in the related health field to develop a detailed search strategy. We searched for gray literature via the Base database and ClinicalTrials.gov, including studies that reported negative outcomes, ongoing studies or newly completed but unpublished data. The reference lists of relevant original studies and reviews were also scanned to identify additional eligible studies. We also contacted the original investigators of the included studies to identify potentially eligible trials. We used EndNote (version 20; Clarivate Analytics, Philadelphia, PA) to manage the references and remove duplicates. Given that the reviewers are fluent only in English and Chinese, only studies published in Chinese or English were included. The detailed search strategies can be found in Additional file 1.

Eligibility criteria

(1) Participants: Children who received needle-related treatment, including but not limited to vaccination, peripheral intravenous (IV) placement, or blood sampling, irrespective of age and disease status. Children diagnosed with autism spectrum disorder (ASD) were excluded because the efficacy of socially assistive robots in children with ASD has been verified.
(2) Intervention: 1) Only with socially assistive robots, and 2) minimal typical techniques (including but not limited to storytelling, child life specialists, local anesthetics, music therapy, and playing games on smartphones) with socially assistive robots. The focus of robotic interventions should be directed toward managing pain and negative emotions related to needle-based treatment rather than pain caused by disease, surgeries, or wound dressing. We excluded studies that involved habitual intervention (i.e., routine socially assistive robot intervention) because we wanted to measure acute pain.
(3) Comparators: (1) No distraction and (2) minimal typical techniques. Studies were eligible if the intervention and control groups receive identical additional treatments. Study were also eligible is they used robots with no social functions in the control group; these robots could be considered typical digital distractions, such as iPads and smartphones.
(4) Outcomes: The main outcome was pain. The secondary outcomes were affective features influenced by pain, including distress, anxiety and fear. Any forms of measurement are acceptable (e.g., self-reports, proxy reports, and behavioral observations).
(5) Study: Only randomized controlled trials were included, irrespective of publication date, status, or funding support.

Unfortunately, for certain studies, despite our efforts to contact the original authors and attempt to transform the data using statistical formulas, we were unable to access the necessary data to include them in our meta-analysis. As a result, what we can do is to describe and analyze characteristics of these studies.

Study selection

After deduplication, two reviewers (Pan and Nong) independently screened the titles and abstracts of all citations returned from the literature research. The full texts of eligible studies were also inspected by Pan and Nong seperately.

Data extraction and synthesis

First, two reviewers (Pan and Nong) independently reviewed and extracted study characteristics using a predetermined form in Microsoft Excel 2016. The following data were extracted: participant characteristics, setting, intervention, comparison outcome instrument and outcome data. Before the third reviewer performed the meta-analyses, some data were missing or uncertain; we contacted the original authors several times to request detailed data via e-mail. If necessary, we extracted data points from graphs using Plot Digitizer software (http://plotdigitizer.sourceforge.net/).

Risk-of-bias appraisal

As described in the "Cochrane risk of bias assessment tool", which is found in Chap. 8 of the Cochrane Handbook for Systematic Reviews of Interventions (version 6.4, 2023), two reviewers(Nong and Yan) independently used the Revised Cochrane risk-of-bias tool for randomized trials (RoB2; version 2019) to evaluate the quality of the included studies [26]. The quality of the studies was evaluated across 5 domains: the randomization process, deviation from intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result.

Certainty of evidence

The certainty of the body of evidence was evaluated using the Grading of Assessment, Development, Recommendations, and Evaluation (GRADE) approach, as outlined by Guyatt et al [27]. Initially, the evidence certainty of the randomized controlled trials (RCTs) was evaluated as high, and subsequently downgraded to moderate, low, or very low based on several domains. These domains encompassed risk of bias, inconsistency, indirectness of evidence, imprecision of effect estimates, and publication bias. The GRADE assessment was performed individually by two researchers(Nong and Yan), and any disagreements were resolved through discussion with a third review author. Any disagreements in the study selection, data extraction and quality assessment processes were resolved through discussion to reach a consensus, and if conflicts persisted, they were arbitrated by a third reviewer (Ye).

Statistical analyses

We used Review Manager V.5.4 (Cochrane Collaboration, Copenhagen, Denmark) to conduct statistical analyses. $P<0.05$ was considered to indicate statistical significance. Given that the related painful and emotional outcomes in this review were usually continuous values that may use different scales for a single outcome, standardized mean differences (SMDs) based on postintervention value scores were calculated using a random effects model. SMDs and effect sizes were calculated in Review Manager V.5.4.1 using Hedges' g method (similar to Cohen's d). A random effects model was used because differences existed in the actual treatment effects. Effect sizes of 0.2, 0.5 and 0.8 were considered small, moderate and large, respectively. Heterogeneity between studies was assessed using the I^2 test. The degree of heterogeneity was classified as not important ($I^2<40\%$), moderate ($I^2=30–60\%$), substantial ($I^2=50–90\%$), or considerable ($I^2=75–100\%$). We conducted subgroup analyses to explain possible sources of heterogeneity among the studies. The subgroup analyses were based on the use of different theories applied by the socially assistive robots and the use of difference anesthetics. Sensitivity analysis was also performed to explore the sources of heterogeneity and their impact on the results. We assessed the potential for publication bias by considering the completeness of the literature search, checking whether all included studies completely presented the data, and plotting contour-enhanced funnel plots for outcomes that were reported by at least 10 studies [28].

Results

Search results

We screened the titles and abstracts of 586 records, and we excluded 549 records. The detailed exclusion reasons of excluded studies (full texts, $n=27$) can be found in Additional file 2. We subsequently assessed the full texts of the remaining 37 RCTs. Ultimately, ten eligible RCTs (Fig. 1). Seven of the RCTs reported pain outcomes, and ten of these reported affective outcomes. All the RCTs were written in English.

Characteristics of the included studies

The detailed characteristics of the included studies are shown in Table 1. All the included studies were published in the past ten years and were conducted across six countries. A total of 815 participants reported pain-related and affective outcomes during IV placement (5 studies [14, 20, 21, 29, 30]), port needle insertion (1 study [31]), flu vaccination (1 study [19]), blood sampling (1 study [32]) and dental treatment (2 studies [33, 34]). Almost all the children had underlying medical conditions with the exception of 34 healthy children in Beran's trial. All of the 10 included studies had children (≤14 years old) as participants.

Among the included RCTs, seven studies used the NAO robot, which is the most widely employed socially assistive robot in human–robot interaction research. This robot was developed by the French company Aldebaran Robotics in 2008, and it is characterized by affordability and broad functional distribution. It has been used

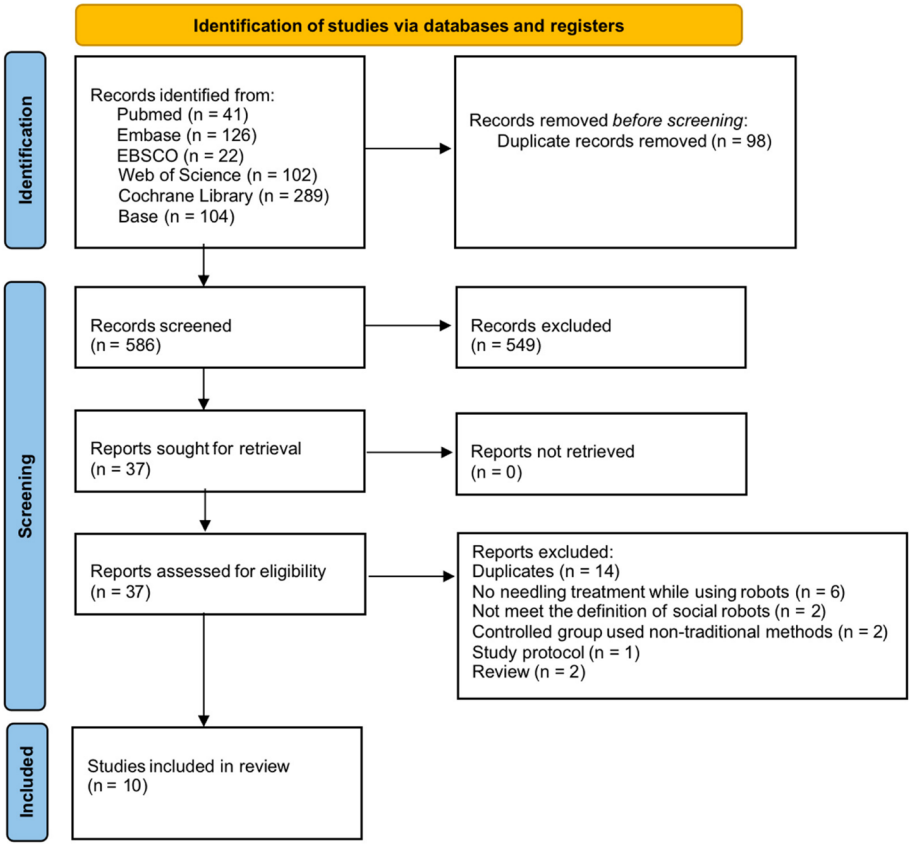

Fig. 1 PRISMA flow chart of study design

in more than 70 countries worldwide [35]. The remaining three studies used socially assistive robots with tablets that could display animations or emotions to interact with children. Despite the different appearances or functions of the robots used in these studies, they were all preprogrammed to execute a series of vocalizations, movements or screenshots to distract children. In addition to the same standard process, socially assistive robots were programmed to greet children first and then encourage children when the treatment was over. The actual intervention methods could be approximately divided into two types depending on whether or not the robots applied cognitive-behavioral theory. Robots that applied cognitive–behavioral therapy (e.g., deep breathing technique, educational storytelling) aimed to change children's negative cognition in addition to distracting them. Other robots only aimed to visually or vocally distract children by playing games, telling them jokes, singing or dancing. Due to ethical considerations, all the studies used other typical minimal forms of distraction (digital or nondigital) as a comparison group, such as emotional support, watching television, counting, or singing.

Methodological quality

Overall, eight of the ten included randomized studies were rated as having some concerns with regard to risk of bias (Fig. 2). All of the studies failed to blind the outcome assessor (domain 4 of RoB2) because almost all the outcomes related to pain intensity were self-reported while participants were aware of the intervention. Considering that measurement bias is avoidable and that children's emotions are usually clear, we judged these studies as having some concerns with regard to risk of bias despite the fact that the risk-of-bias tool deemed these studies to be high-risk. Even if some trials used individuals who were blinded to the research designs to evaluate children's pain-related scores through video data, they may have been able to identify study groups based on audio or repeated behaviors, which could not avoid measurement bias to some extent. Two studies were rated as having a high risk of bias. We could not access patient demographic data after checking the online appendix that Smakman offered [32]. In Kasimoglu's study [34], which was published in 2020, there was no information regarding the randomization method, and there was reason

Table 1 Characteristics of the included studies (n=10)

Study, Year, Country	N (Male Number)	Age Range (mean)	Health States of Participants	Setting	Needling Procedure	Type of Social Robots	Interactive Duration	Whether Combined with CBT	Intervention Group Specific Process	Control Group	Topical Anesthetic /	Pain Outcomes Reported	Measurement Time	Affective Outcomes
Beran et al, 2013, [19] Canada	57 (30)	4-9 (7)	23 children were under medical condition34 children were healthy	Outpatient clinic	Flu vaccination	Humanoid: NAO	During the procedure	Yes	Introduction, chatting, blowing technique, encouragment	Minimal typical distraction	/	Self reported pain, observed pain (FPS-R)	The strongest moment during procedure	Behavioral measure of distress (BAADS)
Jibb et al,2018, [31] Canada	40 (24)	4-9 (6)	Children with cancer	Outpatient clinic	Port needle insertion	Humanoid: NAO (renamed MEDiPORT)	During the procedure	Yes	Introduction, making supportive statements, deep breathing techniques, encouragement	High-tech distraction	Mandatory	Self reported pain (FPS-R)	Post procedure	Behavioral measure of distress (BAADS)
Trost et al,2020, [14] USA	21	4-14 (10)	Children who needed to receive MRI	Radiology suite	IV placement	Humanoid: MAKI (renamed IVEY)	During the procedure	Yes	Robot assisted the child life specialist: provide emotional support based on the child's expressed level, practice deep breathing	The usual distraction provided by child life	/	Self reported pain, Behavioral measure of pain (Wong-Baker FACES scale, FLACC, CHEOPS)	Before interaction, prior to IV placement, post procedure	Self reported fear (CFS)
Kasimoglu et al, 2020, [34] Turkey	200 (98)	4-10 (7)	Children who needed to receive MRI	Dental clinic	Dental treatment	Humanoid: iRobiQ	During the procedure	Only distraction	Singing, displaying animation, performing body movements with facial expressions	Usual distraction	Permitted but not mandatory (100/200)	/	/	Self reported anxiety (FIS)
Kasimoglu et al, 2023, [33] Turkey	102(50)	4-10 (7)	Children who needed pulpotomy	Dental clinic	Dental treatment	Humanoid: NAO	During the procedure	Only distraction	Performing targeted motor tasks to distract	Non-verbal communication, distraction, positive encouragement, voice control, and tell-show-do	Mandatory	/	/	Self reported anxiety (FIS)

Table 1 (continued)

Study, Year, Country	N (Male Number)	Age Range (mean)	Health States of Participants	Setting	Needling Procedure	Type of Social Robots	Interactive Duration	Whether Combined with CBT	Intervention Group Specific Process	Control Group	Topical Anesthetic /	Pain Outcomes Reported	Measurement Time	Affective Outcomes
Ali et al, 2021, [21] Canada	86 (47)	6-11 (9)	Children who had some acute diseases	Emergency department	IV placement	Humanoid: NAO	During the procedure	Yes	Introduction, chatting, deep breathing exercise, encouragement, dancing and Tai Chi	Normal comforting techniques	Permitted but not mandatory (78/86)	Self reported pain (FPS-R)	Before procedure, during procedure	Behavioral measure of distress (OSBD-R)
Smakman et al,2021, [32] Netherlands	137	4-12 (8)	Not mentioned	Blood drawring policlinic	Blood draw	Humanoid: NAO	During the procedure	Only distraction	Robots have three different programs based on ages to distract children1) Lower classes aged 4-6: introduction, singing, dancing and encouragement 2) Middle classes aged 6-9: introduction, Taichi, playing saxophone, telling jokes, dancing and encouraging 3) Higher classes aged 9-12: introduction, telling jokes, playing saxophone, dancing and encouraging	Normal distraction techniques	/	Behavioral measure of pain (FLACC)	Before procedure, during procedure, post procedure	Self reported anxiety (VAS-A)
Lee-Krueger et al, 2021, [20] Canada	103 (57)	4-12 (8)	Children with a systematic disease	Surgery Short Stay Unit	IV placement	Humanoid: NAO (renamed MEDI)	Before the procedure	Yes	Greeting, teaching deep breath, encouraging	Other forms of pain management strategies	Mandatory	Self reported pain, Observed pain (FPS-R)	During procedure	Self reported fear (CFS)

Table 1 (continued)

Study, Year, Country	N (Male Number)	Age Range (mean)	Health States of Participants	Setting	Needling Procedure	Type of Social Robots	Interactive Duration	Whether Combined with CBT	Intervention Group Specific Process	Control Group	Topical Anesthetic /	Pain Outcomes Reported	Measurement Time	Affective Outcomes
Rheel et al, 2022, [29] Belgium	22 (10)	8-12 (9)	Children with chronic disease	Outpatient clinic	IV placement/Port needle insertion	Humanoid: NAO	During the procedure	Only distraction	Playing quiz games, encouraging	Minimal typical distraction	Permitted but not mandatory (13/22)	Self reported pain (FPS-R)	Before procedure, post procedure	Self reported fear (CFS)
Chang Ching-Yi, 2023, [30] Taipei, China	47 (23)	5-12 (7)	Children with mild disease	Inpatient clinic	IV placement	Humanoid (not to mention type)	During the procedure and lasting for 40 minutes	Yes	Social robot using digital storytelling	Video-based storytelling	/	/	/	Behavioral measure of anxiety (mYPAS)

FPS-R Faces Pain Scale-Revised, *FLACC* Face, Legs, Activity, Cry, and Consolability Scale, *CHEOPS* The Children's Hospital of Eastern Ontario Scale, *BAADS* Behavioral Approach-Avoidance Scale, *CFS* Children's Fear Scale, *FIS* Face Image Scale, *OSBDR* Observed Scale of Behavioral Distress-Revised, *VAS-A* Visual Analogue Scale for Anxiety, *mYPAS* modified Yale Preoperative Anxiety Scale

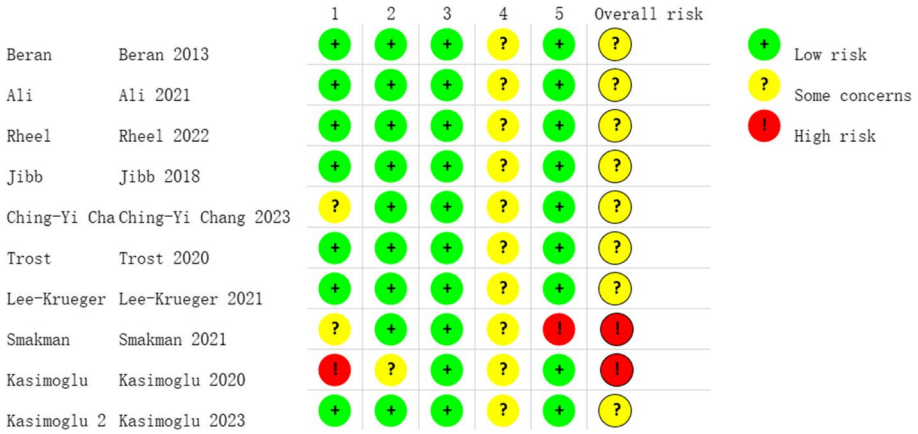

Fig. 2 Summary of risk of bias of each included study. Notes: 1: randomization process 2: deviations from intended interventions 3: missing outcome data 4: measurement of the outcome 5: selection of the reported result

to suspect that either the enrolling investigator or the participant were aware of the intervention they would receive before the participants were assigned.

As shown in Table 2, the certainty of evidence was graded as low for all outcomes. The certainty was downgraded primarily due to the risk of bias of the included studies, small sample sizes and wide confidence intervals.

Meta-analysis

Socially assistive robots and pain management

Two out of seven studies that reported pain-related outcomes were ultimately excluded from this meta-analysis. One of the studies had skewed pain scores that could not be directly transformed to follow a normal distribution [21]. For the other study [14], which only used graphs to characterize their results, we used a program to extract the means but could not extract the standard deviation (SD). The trial authors were contacted to request detailed data but received no further response. Thus, these two studies included qualitative analysis using only published information, but they were excluded from quantitative analysis.

The remaining studies were subjected to meta-analysis to determine whether the use of socially assistive robots alone could produce better results than the use of other nonpharmacological methods. Four studies used the Faces Pain Scale-Revised. Smakman et al. used behavioral data from the Face, Legs, Activity, Cry, and Consolability Scale. As shown in Fig. 3, no significant differences were found between socially assistive robot interventions and other nonpharmacological methods (SMD = -0.02; 95% CI = − 0.81, 0.78; $P = 0.94$). The level of heterogeneity was moderate ($I^2 = 42\%$).

Subgroup analyses was performed based on the use of different theories among the socially assistive robots and the use of different anesthetics. We found that different designs of humanoid robots and anesthetic use were the main sources of heterogeneity because the heterogeneity was significantly decreased after subgroups analysis, as shown in Fig. 4 ($I^2 = 6\%$ for socially assistive robots using CBT theory and $I^2 = 1\%$ for robot-only distraction) and Fig. 5 ($I^2 = 0\%$ for anesthetic and $I^2 = 71\%$ for no anesthetic use). However, the use of CBT theory or the use of different anesthetics did not significantly influence the effects of the socially assistive robots on pain.

Socially assistive robots and the management of negative emotions

For anxiety outcomes, three studies used self-reported scales, including the Face Image Scale and the Visual Analogue Scale for Anxiety. One study used a modified Yale Preoperative Anxiety Scale for behavioral measurements. For the distress outcome, two studies used the Behavioral Approach-Avoidance Scale, and the other used the Observed Scale of Behavioral Distress-Revised. As presented in Figs. 6 and 7, compared with control group, patients in the socially assistive robot group reported significantly lower levels of anxiety (SMD= -0.36; 95% CI= -0.64 to -0.09; $P = 0.01$), and observers reported significantly fewer distressed avoidance behaviors of children during procedural treatment (SMD= -0.67; 95% CI= -1.04 to -0.30; $P = 0.0004$). For fear, two studies used the Children's Fear Scale, which is a widely used self-reported measure. There was no significant difference between the intervention group and the control group in terms of fear (SMD = 0.38; 95% CI= -0.06 to 0.82; $P = 0.09$) (Fig. 8). The level of heterogeneity was acceptable (I^2 ranging from 0–49%).

Table 2 GRADE evidence profile

Patient or population: young children (<18 years old)
Settings: interventions were delivered in the communist health system in Turkey, Canada, Netherlands, Taipei (China) and the USA
Intervention: socially assistive robots
Control: minimal typical distraction including digital and non-digital techniques

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Intervention	Control	Relative(95% CI)	Absolute(95% CI)		
Pain (assessed with: FPS-R, FLACC; Scale from: 0 to 10)												
5	randomised trials	serious[a]	not serious	not serious	serious[b,c]	none	175	172	-	SMD **0.02 SD lower**(0.81 lower to 0.78 higher)	⊕⊕◯◯Low	CRITICAL
Anxiety (assessed with: FIS, VAS-A, mYPAS; Scale from: 0 to 10)												
4	randomised trials	serious[d]	not serious	not serious	serious[b]	none	247	239	-	SMD **0.36 SD lower**(0.64 lower to 0.09 lower)	⊕⊕◯◯Low	IMPORTANT
Distress (assessed with: BAADS, OSBD-R; Scale from: 0 to 10)												
3	randomised trials	serious[e]	not serious	not serious	serious[b,f]	none	89	89	-	SMD **0.67 SD lower**(1.04 lower to 0.3 lower)	⊕⊕◯◯Low	IMPORTANT
Fear (assessed with: CFS; Scale from: 0 to 10)												
2	randomised trials	serious[g]	not serious	not serious	serious[b,h]	none	51	62	-	MD **0.38 higher**(0.06 lower to 0.82 higher)	⊕⊕◯◯Low	IMPORTANT

CI confidence interval, *MD* mean difference, *SMD* standardised mean difference

Explanations

a. Five included studies failed to be blind to the outcome assessors, and one study did not report the patients' demographic data. Thus, most of studies were judged to be at some concerns

b. The forest plot showed a wide confidence interval(CI)

c. Five studies with only 347 participants were included

d. One study did not characterized the randomization method it applied, and the other study did not report the patients' demographic data. Thus, two out of the four were judged to be at high risks of bias

e. Three studies failed to be blind to the outcome assessors, thus being judged as high risks of bias

f. Three studies with only 178 participants were included

g. Tho studies failed to be blind to the outcome assessors, thus being judged as high risks of bias

h. Two studies with only 113 participants were included

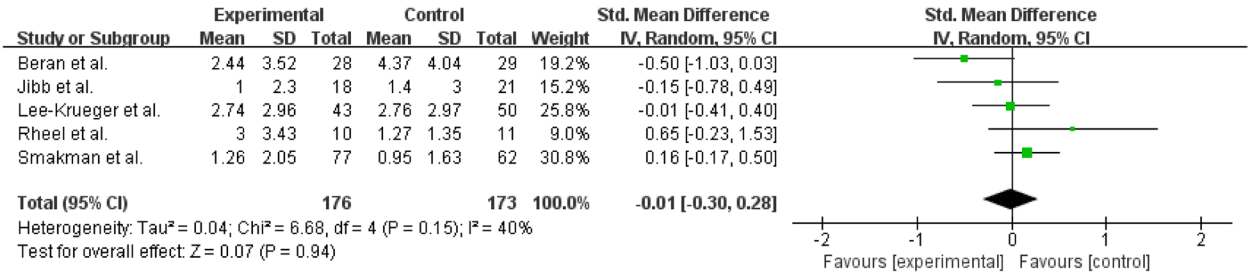

Fig. 3 Forest plot of the total comparison of the socially assistive robot and other forms of distraction on pain-intensity outcome at post/medium treatment

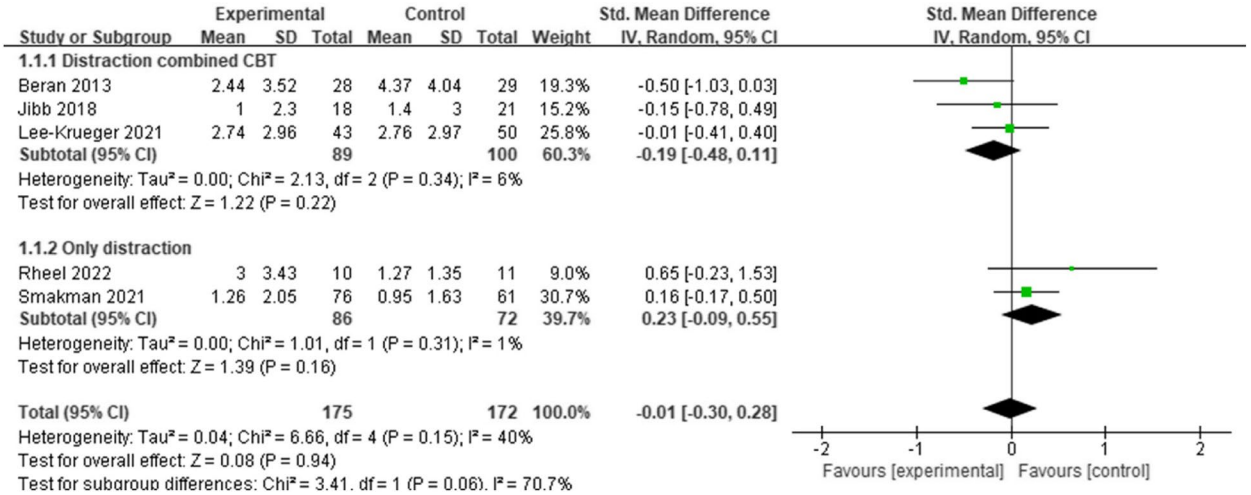

Fig. 4 Forest plot of subgroup-analysis on pain-intensity outcome based on the theory used

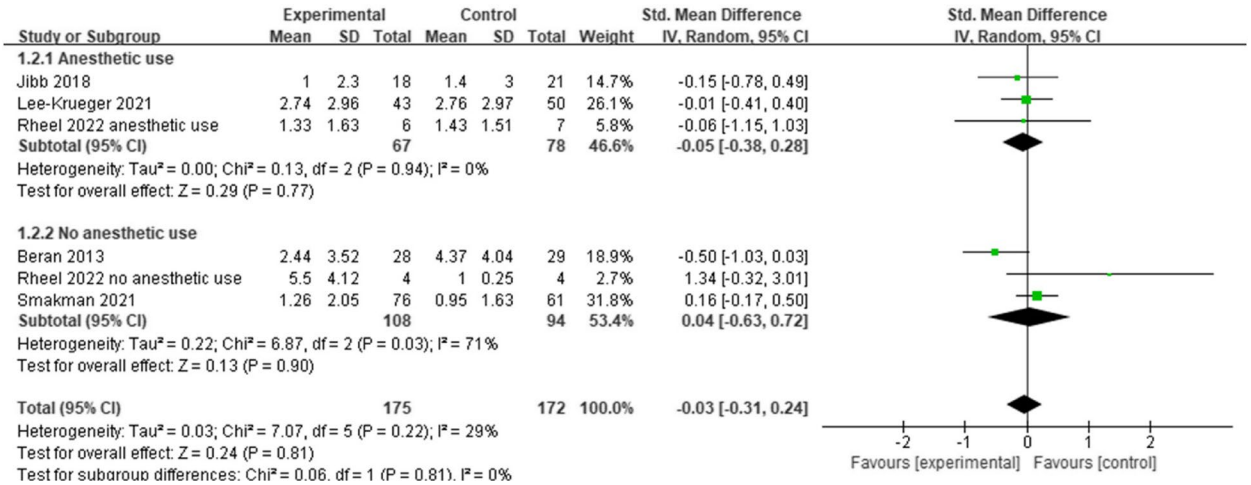

Fig. 5 Forest plot of subgroup-analysis on pain-intensity outcome based on anesthetic use

Sensitivity analysis

Sensitivity analysis was carried out using the leave-one-out method (Additional file 3). The results showed that the combined effect size of the included studies did not change when excluding any individual study, indicating that the meta-analysis results were stable.

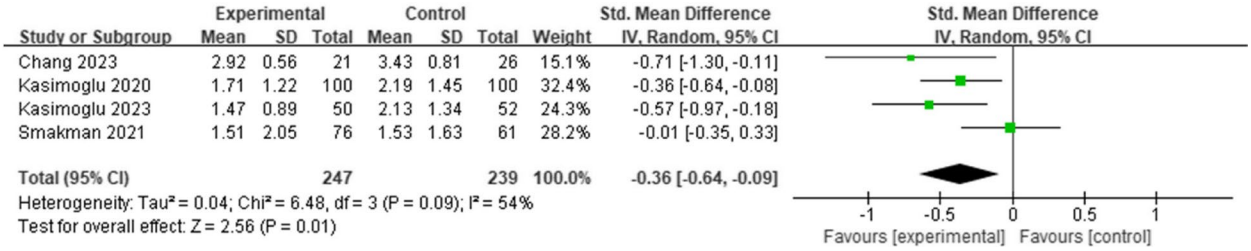

Fig. 6 Forest plot of comparison on anxiety outcome

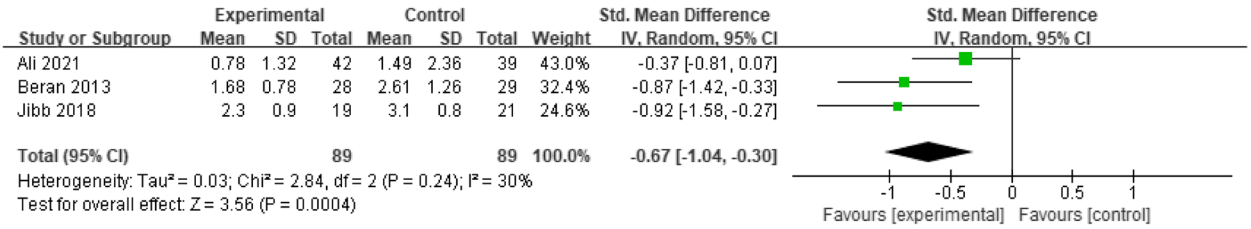

Fig. 7 Forest plot of comparison on distress outcome

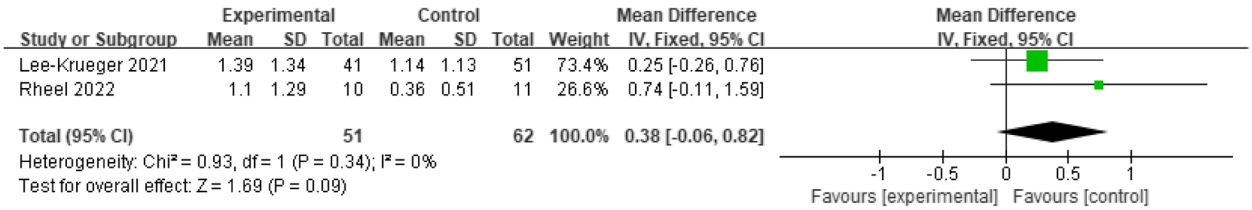

Fig. 8 Forest plot of comparison on fear outcome

Discussion

To our knowledge, this was the first systematic review and meta-analysis of RCTs to examine the effect of socially assistive robots on the management of pain and negative emotions in children receiving needle-related treatment. Several previous reviews found that a limited number of relevant publications could be identified, including explorative and experimental studies [23, 36]. Although some studies have shown that socially assistive robots can distract children from stressful environments to reduce their pain and fear during hospitalization, according to McCaul KD [3], the more intense the painful stressors are perceived to be, the less effective the distraction will be. Therefore, robot-led distraction methods may lead to diverse and unintended outcomes in different situations, especially in some painful treatments. This was one of the reasons we conducted the current review.

A total of 10 studies published from 2013 to 2023 were included in the present review. The effect sizes for pain intensity and negative affective outcomes compared socially assistive robots with other traditional methods were pooled from eight studies. The results can be interpreted as follows.

Overall, the results of the meta-analysis revealed that socially assistive robot intervention can relieve children's distress (SMD= -0.67; 95% CI= -1.04 to -0.30; $P=0.0004$) and anxiety (SMD= -0.36; 95% CI= -0.64 to -0.09; $P=0.01$) during invasive medical treatments compared to other routine distraction methods. No significant differences in pain intensity (SMD = -0.02; 95% CI = −0.81, 0.78; $P=0.94$) or fear (SMD = 0.38; 95% CI= -0.06 to 0.82; $P=0.09$) were found between the two groups. Considering that the overall methodological quality of the included studies was of some concern or represented high risk and that the certainty of evidence for these outcomes was low, additional high-quality randomized controlled trials (RCTs) are needed in the future. Although specific studies were excluded from the meta-analyses due to missing data, they also found partial null effects of robot-led distraction for needle-based procedures among children. Ali et al. [21] reported that humanoid robot-based distraction therapy is associated with a modest positive impact on child distress but not pain in

children after intravenous needle insertion. Trost et al. [23] reported that there were no significant differences between the intervention group and the control group in terms of fear or pain scores.

We identified 2 categories of socially assistive robots based on their adopted theory and assumed that different types of socially assistive robots as well as pharmacological analgesia use would make a difference in the effect. However, after conducting subgroup analyses based on the data we could access, we still did not observe a statistically significant difference between the intervention group and the control group in terms of pain reduction. This conclusion was consistent with those of 2 other studies comparing cognitive-behavioral arms with active distraction arms, which also revealed no significant reduction in pain [14, 31]. Nevertheless, the mean scores on pain scales were lower in the cognitive-behavioral robot group than in the physical distraction group. Researchers in these 2 studies concluded that socially assistive robots based on cognitive-behavioral theory may be more clinically effective than only-distraction robots because cognitive–behavioral therapy is a problem-oriented strategy focused on identifying and changing current distressing thoughts and behavioral patterns. The children in the cognitive-behavioral arm reported that the robots helped them learn more coping skills to overcome distress and feel less pain. Thus, additional high-quality and large-sample RCTs are needed to compare the effects of different intervention regimens for socially assistive robots.

Several potential explanations may account for the nonsignificant effects observed herein. First, from the population perspective, pain intensity is affected by various factors, such as the type of robot and the type of anesthetic used. Smakman et al. [32] and Kasimoglu et al. [34] investigated the influence of children's age on robot intervention and found that children aged approximately 4–9 years old were more sensitive to the robot's ability to mitigate pain or anxiety than younger and older children. The health status of children was also an important factor to consider. Unfortunately, we did not have sufficient data to analyze this factor in the current review. Second, from a statistical perspective, all the included studies reported overall low levels of pain intensity in both the experimental and control groups, possibly inducing a floor effect and restricting the robot's capacity to enhance pain-related outcomes. Next, from the perspective of measurement points, we used the peri-/posttreatment scores to calculate the SMD since these data could be extracted from all the included studies. Nevertheless, this may also explain why some of the studies concluded that the effects of socially assistive robots are not significantly different from those of typical distractions. As Smakman et al. [37] reported, the observer-reported pain scores before surgery were significantly lower in the experimental group ($p < 0.05$), and the scores did not differ significantly during and after surgery. Jibb et al. [31] also found that solely evaluating pain after needle-based treatment may limit the capacity to assess the impact of the robot on pain. Lastly, from the perspective of trial design, the control groups in all the studies received different types of typical pain management, including digital and nondigital methods, which decreased the likelihood of finding significant differences between robot-based distraction and standard care. Several other meta-analyses have also shown little to no difference in the effect of various digital technologies (including socially assistive robots) on pain compared with that of typical distractors [12, 38]. It is necessary to conduct additional head-to-head trials to clarify which type of distraction might work best, in which settings, and for which children.

For other pain-related indicators, a statistically significant but modest effect size was found for decreasing anxiety and decreasing distress. Unlike for alleviating anxiety and distress, there is no exact proof that fear can be diminished by socially assistive robots. Distractions can play a key role in alleviating pain and negative emotions, as they induce an analgesic effect through competition between stimuli [39]. Although the effects of socially assistive robots on relieving negative emotions have not been fully elucidated, it can be said with certainty that distracting children from distressed situations is not the only mechanism underlying the effect. Social presence may be another critical social factor that can explain the efficacy of human–robot interactions. Social presence is defined as the extent to which a robot is considered 'a real person' [40]. Growing evidence shows that more positive moods are achieved when robots are seen as having a stronger social presence [41, 42], and unlike adult users, this effect will not be reduced after children become familiar with robots [43]. Herein, socially assistive robots will be applied broadly and show exceptional promise in healthcare processes when patients can interact with them not only on a haptic level but also on an emotional level, thus enabling socially assistive robots to become their true emotional companions.

In addition, although we did not find a significant difference in reducing experienced fear intensity compared to that associated with typical pain management, recent studies have supported the claim that socially assistive robots may have a long-lasting impact on affective outcomes caused by invasive procedural pain. Rheel et al. [29] observed a moderate effect size for pain intensity memory bias (Hedges' $g = 0.70$) and a very small effect size for pain-related fear memory bias (Hedges' $g = 0.09$)

in favor of the robot-led distraction group. Robot-led distraction interventions could be promising methods for improving pain-related memory bias development but need to be investigated further.

Three of the included studies reported the lack of adverse events, the mean duration and the mean number of insertion attempts between the intervention group and the active control group, which suggests that socially assistive robot intervention is feasible in clinical practice [20, 29, 31]. In addition, individual studies have shown that parents' anxiety decreases and that satisfaction increases more in the socially assistive robot intervention group [14, 21]. Therefore, despite the relatively high cost of socially assistive robots, compared with other conventional distraction methods, they are promising and beneficial intervention methods for children receiving acute needle-related pain management given the overall value of socially assistive robots.

Strengths and limitations

When interpreting the final results of the current review and meta-analyses, the following limitations cannot be overlooked. First, the SMD and CI for negative emotion outcomes were calculated for small sample sizes. Second, the current data could not support us conducting substantial subgroup analyses, such as those on outcomes measuring type, sex, age and type of distraction. Third, due to the imperfection in the designs of some specific randomized controlled trials, we could not estimate whether the effects of the different methods used in the control group confounded the actual effect size of the socially assistive robot intervention.

However, these limitations do not fully negate the findings of this review. The mean pooled effect still provides the most helpful information, especially because no previous meta-analysis has examined the effects of socially assistive robot interventions on pediatric pain management. In addition, although we did not detect statistical significance for pain intensity outcomes, we provided plenty of information and suggestions for future randomized controlled trials concerned with the design of socially assistive robots, outcome measurement points, setting of the control group and so on.

Future research directing

Before implementing a full RCT, it is essential to refine the trial design to avoid compound effects and integrate robot intervention into comprehensive best practice management. Based on our findings and previous randomized controlled trials, several research avenues can be explored as follows: (1) which types of skills led by the robot (e.g., some skills used cognition-behavioral theory or simple audiovisual distraction) are preferred by children?; (2) which type of situation may also be effective, such as pediatric brain surgery, not limited to less stressful routine procedures; and (3) which type of measurement tool and when to measure may show its real valence in reducing children's pain? We recommend taking the Pediatric Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (PedIMMPACT) into consideration, as this approach will assist in the comparison and pooling of data and promote evidence-based treatment, encourage complete reporting of outcomes, simplify the review of proposals and manuscripts, and facilitate clinicians in making informed treatment decisions [44]. (4) Which multifaceted components included in the trial may confuse the intervention results of socially assistive robots? Within-study subgroup analyses (e.g., based on age, sex, type of distractor included in the control group, and disease) can provide valuable information on the applicability of the findings to particular patient groups.

In addition, a qualitative and quantitative methodology that interviews the feasibility of socially assistive robots from various angles (i.e., child, parents, nurses, research team) could be integrated in future research. For example, statistical analyses of procedural duration and insertion attempts showed no differences between the intervention and control groups [20, 29, 31], which means that socially assistive robots could be implemented effectively and had no adverse effects. However, nurses reported challenges and provided suggestions that can be used to guide future work. Some nurses reported that the presence of a socially assistive robot made it take longer to complete the needle-based procedure than usual care and made it more challenging to control the scene since they had to ensure regular operation [29]. Similarly, observers have found that children's attitudes are more positive when their parents are encouraged to engage in their intervention [37]. Therefore, it is crucial to explore ways to optimize robot interventions and establish collaborative efforts among all relevant stakeholders.

Conclusions

There is low certainty evidence supporting the feasibility and efficacy of socially assistive robot intervention for pediatric medical treatment associated with a decreased extent of negative emotions, especially distress. There is currently no evidence for the efficacy of socially assistive robot interventions for pain intensity and fear among children, but future high-quality RCTs could potentially change this..

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12887-024-05116-z.

Additional file 1: PDF Search Strategies

Additional file 2: List of excluded studies (full texts)

Additional file 3: Sensitivity Analysis

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Authors' contributions
Xin-yun Pan: Conceptualization, Data Curation, Writing - Original DraftXuan-yi Bi: Writing - Review & Editing, Formal analysis, ValidationYan-ning Nong: Writing - Review & Editing, Formal analysis, ValidationXu-chun Ye: Supervision, Project administration, Funding acquisitionYan Yan: Writing - Review & EditingJing Shang: Visualization, Writing - Review & EditingYi-min Zhou: Resources, VisualizationYu-zhe Yao: Resources, VisualizationAll authors read and approved the final manuscript.

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Availability of data and materials
All data generated or analysed during this study are included in this published article and its supplementary information files.

Declarations

Ethics approval and consent to participate
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Competing interests
The authors declare no competing interests.

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