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Acoustic stimulation for relieving pain during venipuncture: a systematic review and network meta-analysis

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ABSTRACT

Objectives To assess whether acoustic stimulations relieve venipuncture pain and determine which stimulation is the most effective type.

Design Systematic review and network meta-analysis.

Data sources PubMed, Cochrane Central Register of Controlled Trials, Excerpta Medica dataBASE, Cumulative Index to Nursing and Allied Health Literature, ClinicalTrials.gov and the International Clinical Trials Registry Platform databases were systematically searched in September 2023.

Study selection Randomised controlled trials evaluating the efficacy of acoustic stimulations on patients undergoing venipuncture were eligible. Acoustic stimulations were classified into seven categories: five types of acoustic stimulations (music medicine (researcher selected), music medicine (patient selected), music therapy, sounds with linguistic meaning and sounds without linguistic meaning) and two controls (only wearing headphones and no treatment).

Primary and secondary outcome measures Primary outcomes included self-reported pain intensity assessed during venipuncture and treatment cost, and secondary outcomes were self-reported mental distress and adverse events.

Results Of 6406 citations, this network meta-analysis included 27 studies including 3416 participants; the mean age was 31.5 years, and 57% were men. Among the five types of acoustic stimulations, only musical interventions, such as music medicine (patient selected) (standardised mean difference (SMD) −0.44 (95% CI: −0.84 to −0.03); low confidence), music medicine (researcher selected) (SMD −0.76 (95% CI: −1.10 to −0.42); low confidence) and music therapy (SMD −0.79 (95% CI: −1.44 to −0.14); low confidence), were associated with improved pain relief during venipuncture compared with no treatment. No significant differences existed between the types of acoustic stimulations. Free-of-charge acoustic stimulations were provided to patients, and no specific adverse events were reported. In many studies, the risk of bias was rated high because of the difficulty of blinding the intervention to the participants and the self-reported pain outcome.

Conclusions Music interventions were associated with reduced venipuncture pain. Comparisons between types of acoustic stimulations revealed no significant differences. Therefore, music intervention could be a safe and inexpensive pain relief method for venipuncture.

PROSPERO registration number CRD42022303852.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Acoustic stimulations were classified into seven categories: five types of acoustic stimulations (music medicine (researcher selected), music medicine (patient selected), music therapy, sounds with linguistic meaning and sounds without linguistic meaning) and two controls (only wearing headphones and no treatment).
⇒ This study employs a network meta-analysis that allows comparisons not only between acoustic stimulation and control but also between types of acoustic stimulation.
⇒ We targeted venipuncture pain, which occurs frequently in clinical practice.
⇒ A limitation of the study is that the risk of bias ratings in most studies was high because the intervention was an acoustic stimulation, which makes it difficult to blind participants, and because pain is usually a self-reported outcome.

INTRODUCTION

Venipuncture is a common medical procedure in hospitals, clinics and during home care. Venipuncture is an essential procedure in modern medicine for testing blood and treatments, such as complete blood count, biochemistry tests, donations, intravenous fluids, drugs, and blood products.[1] A needle is used to penetrate the skin and blood vessels.

Almost all patients experience some pain when the needle penetrates the skin.[2] Some patients perceive more pain and may experience a vagal reflex during the procedure, resulting in hypotension and fainting.[3] Needle phobia or extreme fear of needles is a neurological disorder, with an estimated incidence of 3.5%–10%.[4] Avoiding hospital visits because of needle phobia can hinder early disease diagnosis, interfere with the initiation and continuation of treatment and increase the severity of illnesses. For example, pregnant women with severe needle phobia were 61% less likely to undergo prenatal testing than those with mild needle phobia.[5]

Although several pain relief methods have been tested to reduce venipuncture pain, a reliably effective method is yet to be established. Topical or oral analgesics have been used to reduce venipuncture pain. However, topical analgesics need to be prepared approximately 1–2 hours before the procedure[6]; thus, they can only be used for scheduled venipunctures. Moreover, topical analgesics may cause dermatitis.[7] Additionally, oral analgesics such as non-steroidal anti-inflammatory drugs and opioids could cause asthma, kidney damage and dependence as adverse effects[8 9]; as venipuncture is a frequently performed procedure, the use of drugs for each event becomes costly. Hence, it is usually performed without analgesics.

Besides being safe and inexpensive, several randomised controlled trials (RCTs) have reported that acoustic stimulation with music or other sounds is effective in relieving venipuncture pain.[10–13] However, a systematic review and meta-analysis of these studies have not yet been performed. When conducting a meta-analysis of acoustic stimulation, comparisons between acoustic stimulation and control and between the types of stimulation are important as the efficacy may vary depending on the stimulation's contents.[14–16] Therefore, evaluating the efficacy with a traditional meta-analysis that performs only direct comparisons is inadequate; a network meta-analysis is necessary to classify each acoustic stimulation and compare the effects of each stimulation directly and/or indirectly.[17] Herein, we performed a systematic review and network meta-analysis to assess whether acoustic stimulations relieve venipuncture pain and which type of acoustic stimulation is the most effective (online supplemental figure 1 shows a conceptual diagram of the research questions).

METHODS

This study followed the Preferred Reporting Items for Systematic Review and Meta-Analysis for Network Meta-Analyses (PRISMA-NMA) guidelines (online supplemental information 1).[18] The detailed study protocol was uploaded in Open Science Framework (osf.io/7syw6/) on 15 January 2022. The study was registered with PROSPERO, number CRD42022303852, on 14 February 2022.

Study selection

RCTs that investigated the efficacy of acoustic stimulation were selected; these included patients of any age receiving a venipuncture. Venipuncture refers to any procedure wherein the vein was punctured and/or a catheter was placed inside, for example, peripheral vascular puncture, central venous (CV) catheterisation or indwelling CV ports. The included RCTs addressed at least two of the following seven categories (five acoustic stimulations and two controls): (1) music therapy; (2) music medicine (patient selected); (3) music medicine (researcher selected); (4) sounds with linguistic meaning; (5) sounds without linguistic meaning; (6) 'only wearing headphones' (or earphones); and (7) no treatment. These seven categories were determined based on several previous reports.[14–16 19] Music was defined as an orderly arrangement of sounds consisting of melody, harmony, rhythm, tone and pitch.[20] Music therapy was defined as therapy implemented by trained music therapists, whereas music medicine was defined as music interventions administered by medical or healthcare professionals.[14] The flowchart illustrated in online supplemental figure 2 was used to classify the acoustic stimulations into five types (aforementioned categories 1–5).

We assessed the following four outcomes. Primary outcomes included self-reported pain intensity assessed during venipuncture and treatment cost. Secondary outcomes were self-reported mental distress and adverse events. Mental distress was broadly defined as any type of venipuncture-associated negative effect on mental status, such as anxiety, fear and stress. This study applied no restrictions on language, publication status or date of publication. We translated papers that were neither English nor Japanese using the translation software Google Translate.[21]

During study selection, an RCT conducted by Aghbolagh *et al*[22] reporting the Numerical Rating Scale score of pain as an outcome was found; however, the SD was uncharacteristically small. An SE may have been mistakenly reported as SD. Clarifications sought from the corresponding author regarding the possibility of this error did not receive any response. Moreover, although Arts *et al*[23] evaluated a pain scale as an outcome, its SD was not reported. We included these two studies in the meta-analysis by imputing their SDs with the pooled SDs of the other studies.[24] We also performed a sensitivity analysis excluding these studies.

Search strategy and information sources

The PubMed, Cochrane Central Register of Controlled Trials, Excerpta Medica dataBASE, Cumulative Index to Nursing and Allied Health Literature, ClinicalTrials.gov and International Clinical Trials Registry Platform databases were searched on 15 and 16 January 2022 and re-searched on 10 September 2023. Key search terms included intravenous injections, intravenous infusion, catheterisation, phlebotomy, acoustic stimulation, music, sound, noise and audiometry. The full search strategies are listed in online supplemental tables 1–4.

Data extraction and risk of bias assessment

The titles and abstracts of the selected studies were independently screened by two of the four authors (YY, EI, MKitamura and TI), and potentially relevant studies were selected for full-text screening. Disagreements were resolved through discussion with a third reviewer. Data were extracted from the included studies by independent reviewers using a prepared data extraction form. Two reviewers assessed the risk of bias independently using the Cochrane Risk of Bias Tool 2.[25] Each study was classified as having 'low', 'some concerns' or 'high risk of bias'.

Data analysis

The network geometry has been presented graphically, and the size of the nodes and thickness of the edges depend on the number of randomised participants and RCTs conducted, respectively. Frequentist network meta-analysis was performed with a version of the R package netmeta, implemented in MetaInsight.[26] For performing network meta-analysis, we assumed homogeneity within treatment arms, transitivity between treatment arms and consistency between direct and indirect evidence; in fact, the results of the current study did not suggest a violation of that assumption. Intertrial heterogeneity was anticipated; therefore, random effects models were used. For continuous outcomes, the effects were summarised using standardised mean difference (SMD) and CI, as the evaluation methods for the outcome differed in each study. We classified magnitudes of effect according to the following criteria: small or slight (SMD≥0.20 to <0.50), moderate (SMD≥0.50 to <0.80) or large (SMD≥0.80).[27]

We conducted two subgroup analyses: adults or children and the venipuncture technique. However, as for the venipuncture technique, network meta-analysis could not be performed for subgroups other than those who underwent peripheral vascular puncture owing to the small number of studies. Furthermore, sensitivity analyses were conducted excluding RCTs with a 'high risk of bias' and those RCTs whose SDs were imputed. Because of the large differences in the number of participants between studies, a post hoc sensitivity analysis was also performed, excluding patients with a small number of participants.

Confidence in evidence

The confidence in the evidence across trials was assessed using the Confidence in Network Meta-Analysis (CINeMA) approach,[28] which considers the following six domains: within-study bias, reporting bias, indirectness, imprecision, heterogeneity and incoherence. These domains are rated as 'no concerns', 'some concerns' or 'major concerns', except reporting bias, which was rated as 'low risk', 'some concerns' or 'high risk'. In the evaluation of incoherence, a global test for inconsistency was conducted using random effects design-by-treatment interaction model. Appraisals were then summarised across these six domains as 'very low', 'low', 'moderate' or 'high' confidence for comparing each treatment with no treatment (online supplemental information 2). The number of included studies was exceedingly limited for evaluating confidence with regard to the outcomes of treatment cost and adverse events.

Patient and public involvement

No patient or public involvement in the current study.

RESULTS

Study selection and trial population

The PRISMA flowchart for our study selection is illustrated in figure 1. We identified 8446 references, and after the duplicates were removed, 6406 were screened for eligibility by two reviewers. We attempted to collect 102 reports; however, 1 report was unavailable.[29] Thus, we obtained 101 full texts and identified 38 eligible full texts reporting on 27 RCTs.[22 23 30–63] We denote each study by the author's name and year of publication: Aydin 2017,[30] Tapar 2017,[31] Aghbolagh 2020,[22] Arts 1994,[23] Balan 2009,[32] Çelikol 2019,[33] Schaal 2021,[34 35] Jacobson 1999,[36 37] Hsieh 2017,[38] Karaca 2022,[39] Ikenoue 2020,[40–42] Shabandokht-Zarmi 2017,[43 44] Hoseini 2019,[45 46] Momenabadi 2021,[47] Raghibi 2018,[48] Mou 2020,[49] Hartling 2013,[50 51] Jacquier 2022 (52-54) (44, 50, 59), Gerçeker 2019,[55] Nouira 2020,[56] Sahiner 2016,[57] Shahabi 2007,[58] Press 2013,[59] Zengin 2013,[60] Kishida 2019,[61] Fleckenstein 2022[62] and Alemdar 2023.[63]

The detailed characteristics of the studies included in this review are presented in online supplemental tables 5 and 6. The 27 RCTs included 3416 participants. The mean age was 31.5 years and 57% were men. In total, 17 studies were on peripheral vessel puncture, 5 on haemodialysis vascular access cannulation, 1 on CV catheter insertion, 2 on CV port implantation and 1 on peripherally inserted CV catheter. The participants in one study were a mixture of those who underwent CV insertion, peripherally inserted CV catheter insertion and CV port insertion.

Classification of each intervention and network structure

Online supplemental table 7 presents the summary of each category of acoustic stimulations divided using the algorithm illustrated in online supplemental figure 2. The details of intervention were not available in most studies that employed music medicine (patient selected), music medicine (researcher selected) or music therapy, that is, 'music' or 'song' were the only descriptive words. Sounds with linguistic meaning included only radio news. Sounds without linguistic meaning included white noise, nature sounds and roller-coaster sounds. Regarding audio equipment, 60% (18/30) of acoustic stimulations used headphones or earphones, 20% (6/30) used a speaker and 17% did not report details. A total of 20% (6/30) of acoustic stimulations were accompanied by visual stimulation and were considered during the assessment of the indirectness domain of confidence. A detailed description of each intervention is listed in online supplemental table 8.

Figure 2 illustrates network plots for direct evidence between treatments. For the primary outcome of self-reported pain, the most common comparison was music medicine (researcher selected) versus no treatment, followed by music medicine (patient selected) versus no treatment. It was not possible to render a network plot on treatment cost. For self-reported mental distress, the most common comparison was music medicine (patient selected) versus no treatment. No loops were made for adverse events owing to the small number of available studies.

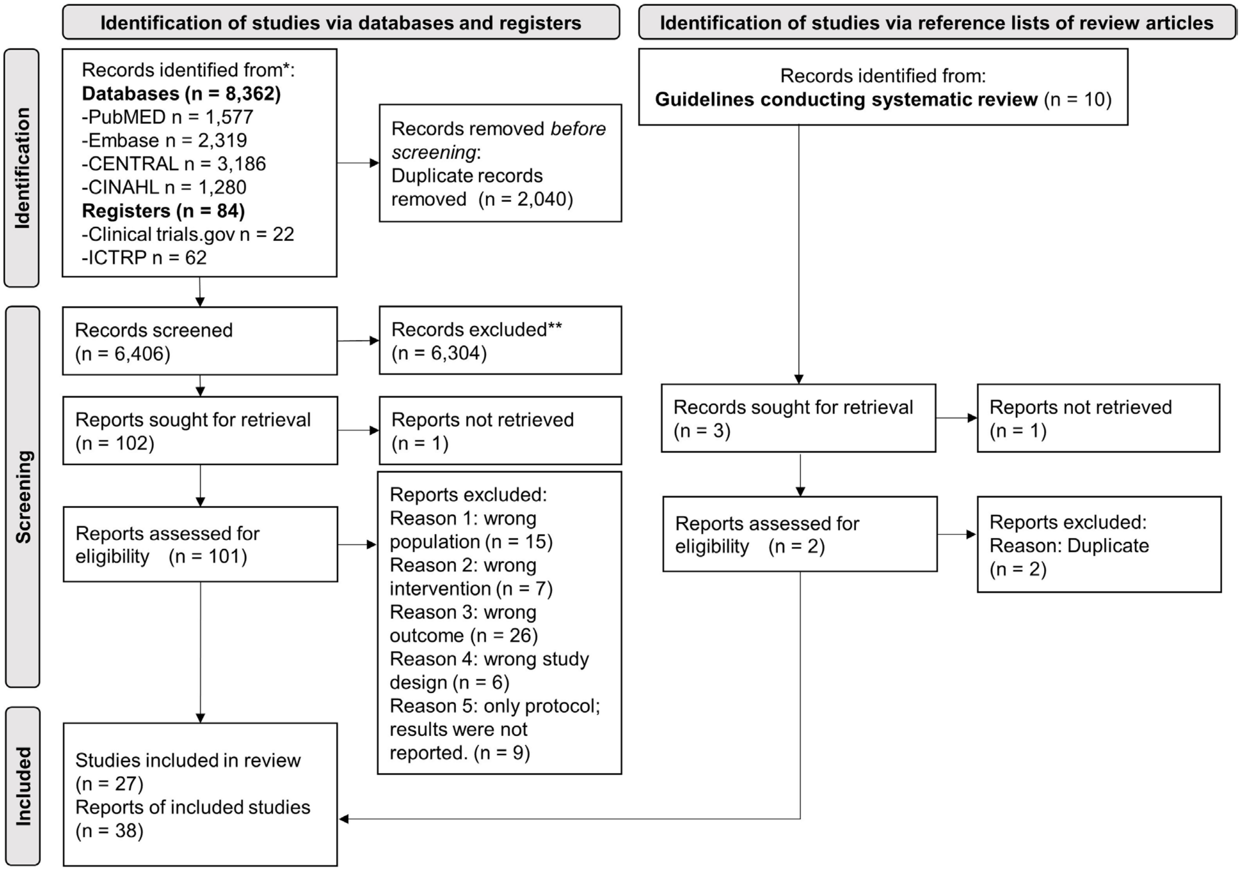

Figure 1 Preferred Reporting Items for Systematic Review and Meta-Analysis flowchart.

Risk of bias

The results of the risk of bias are presented in online supplemental figures 3–5. Regarding self-reported pain and mental distress, most studies were evaluated as having a 'high risk of bias'. This was because Domain 4, 'Measurement of the outcome', was rated 'high' in most studies since the intervention was an acoustic stimulation, which makes it difficult to blind participants, and since pain and mental distress are self-reported outcomes. Domain 5, 'Selection of the reported results', was rated 'some concerns' in almost all studies because they did not disclose the statistical analysis plan. Regarding adverse events, almost all studies were evaluated as 'some concerns'. Treatment cost was unsuitable for the risk of bias evaluation because of the lack of suitable studies.

Trial results

Self-reported pain intensity

Among the included studies, 22 RCTs with 2276 participants reported self-reported pain as an outcome (online supplemental table 5). The study conducted by Aydin and Sahiner was a four-arm comparison study that includes

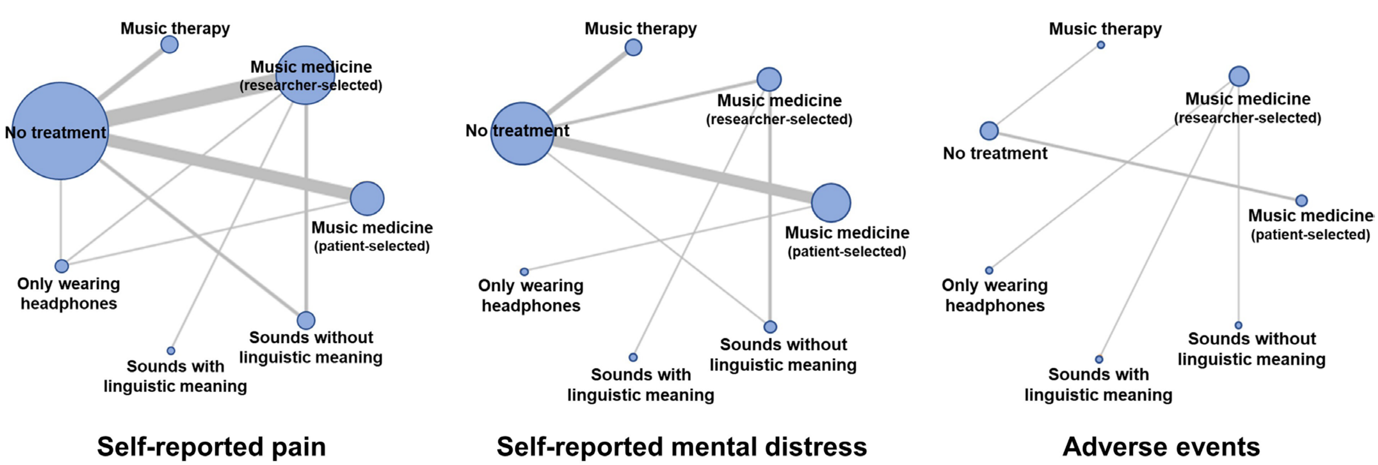

Figure 2 Network plot for each outcome. The size of the nodes and thickness of edges depends on the number of people randomised and trials conducted, respectively.

several targeted interventions, and the analytical treatment is shown in online supplemental information 2.[30] The results of the individual studies are presented in figure 3. In most studies, music-based interventions (music medicine (researcher selected), music medicine (patient selected) and music therapy) reduced pain compared with controls.

Figure 4 depicts the forest plot for all pooled network comparisons compared with no treatment. Compared with no treatment, music medicine (researcher selected) (SMD −0.76 (95% CI: −1.10 to −0.42); low confidence) and music therapy (SMD −0.79 (95% CI: −1.44 to −0.14); low confidence) may reduce self-reported pain. Music medicine (patient selected) possibly reduced pain slightly (SMD −0.44 (95% CI: −0.84 to −0.03); low confidence). Sounds with (SMD −0.67 (95% CI: −2.41 to 1.06); low confidence) and without (SMD −0.56 (95% CI: −1.17 to 0.05); low confidence) linguistic meaning tended to reduce pain; however, there was no significant difference. Conversely, wearing headphones may have increased pain (SMD 1.04 (95% CI: 0.27 to 1.81); very low confidence); however, the evidence is particularly uncertain.

Online supplemental table 9 exhibits the direct (in white) and pooled (in blue) SMD and 95% CIs for comparisons. Most of the five acoustic stimulations were associated with pain relief compared with no treatment and 'only wearing headphones'. The areas bordered by red lines in online supplemental table 9 show comparisons between the different acoustic stimulations and no significant differences were found between them for venipuncture pain relief. Treatments are ranked from best to worst along the leading diagonal; music medicine (researcher selected) was relatively more effective, followed by music therapy (marginal difference).

Treatment cost

Only three studies, Ikenoue *et al*,[40] Momenabadi *et al*[47] and Kishida *et al*[61] reported treatment costs (online supplemental table 5). Ikenoue *et al*[40] compared music medicine (researcher selected) versus sounds without linguistic meaning, whereas Kishida *et al*[61] compared music medicine (researcher selected) versus sounds with linguistic meaning. Both studies used free online music; only tablet computers and headphones/earphones purchased for research purposes were used for sound reproduction. No special labour costs were involved. Momenabadi *et al*[47] compared music medicine (patient selected) versus no treatment and reported that these interventions involved no patient expenses.

Self-reported mental distress

Self-reported mental distress was reported as an outcome in 15 studies that included 1516 patients (online supplemental table 5). The outcome results of the individual studies are exhibited in online supplemental figure 6. As illustrated in figure 4, music medicine (researcher selected) resulted in a reduction in mental distress when compared with no treatment (SMD −1.24 (95% CI: −2.34 to −0.15); low confidence). There were no significant differences between the five types of acoustic stimulations; however, music medicine (researcher selected) was relatively more effective in decreasing mental distress (online supplemental table 10).

Adverse events

Only six studies with 601 patients evaluated adverse events as an outcome (online supplemental table 5). The number of studies was limited; hence, we could not conduct a network meta-analysis. Hence, the results of each study are presented in online supplemental table 11. No adverse events were reported in four of the six studies (0/458 participants). Jacobson[37] reported canulation failure (20/72 participants), and Jacquire *et al*[52] (the study was performed in an intensive care unit setting) reported death (4/71 participants) as an adverse event. However, there were no significant differences between the groups in either study.

Subgroup and sensitivity analyses

We conducted subgroup analyses on the primary outcome of self-reported pain. The results of analyses that divided patients into adults or children (<18 years old) are illustrated in online supplemental figure 7. There were 10 studies for 896 adults and 10 studies for 1140 children. There were no significant differences between the subgroups in the efficacy of the five types of acoustic stimulations when compared with no treatment, although the effect of music medicine (patient selected) tended to be relatively stronger in adults, and the effect of sounds without linguistic meaning tended to be stronger in children. The efficacy of 'only wearing headphones' was different between the subgroups as follows: SMD −0.06 (95% CI: −0.82 to 0.71) for adults and SMD 2.47 (95% CI: 1.34 to 3.60) for children. The results of the subgroup of peripheral cannulation did not differ from those of the overall patient groups (online supplemental figure 8).

Results of sensitivity analysis excluding studies with 'high risk of bias' are exhibited in online supplemental figure 9. When evaluating the risk of bias, Domain 4 was rated as 'high' across most studies (online supplemental figure 3), and sensitivity analysis could not be performed in this case. Therefore, we defined Domain 4 as 'high' only for the study in which the SMD exceeded 2.00, and bias was highly suspected in the outcome measures for this analysis. We excluded six studies with 'high risk of bias'. In this analysis, the effect sizes for most interventions became smaller; regarding 'only wearing headphones', the difference was insignificant when compared with no treatment (SMD 0.12 (95% CI: −0.56 to 0.81)). The results of the two sensitivity analyses, excluding two studies that did not report SD and excluding five studies with a small number of participants, were similar to the overall results (online supplemental figures 10 and 11).

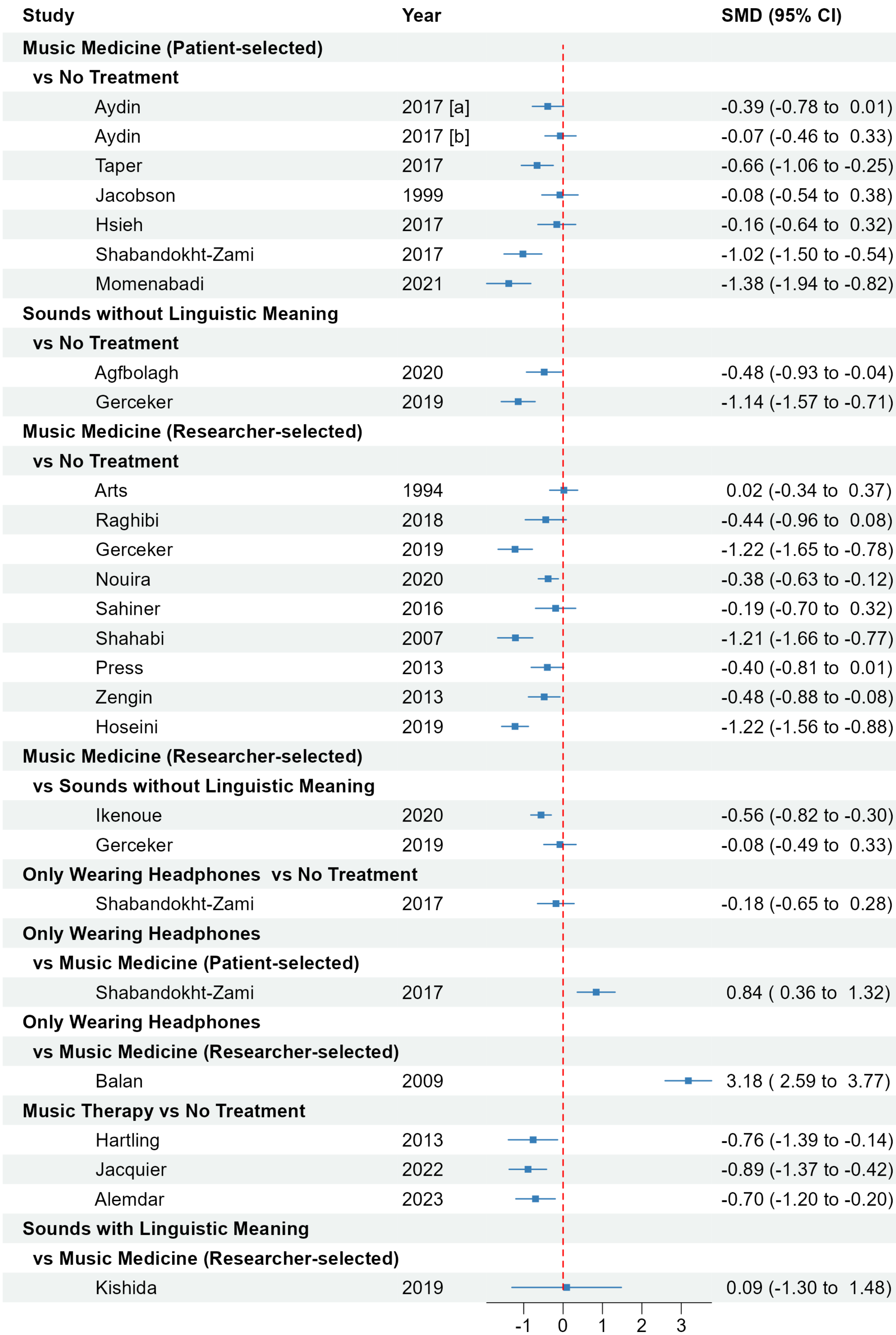

Figure 3 Individual study results in outcome of self-reported pain (for all studies) grouped by treatment comparison. SMD, standardised mean difference.

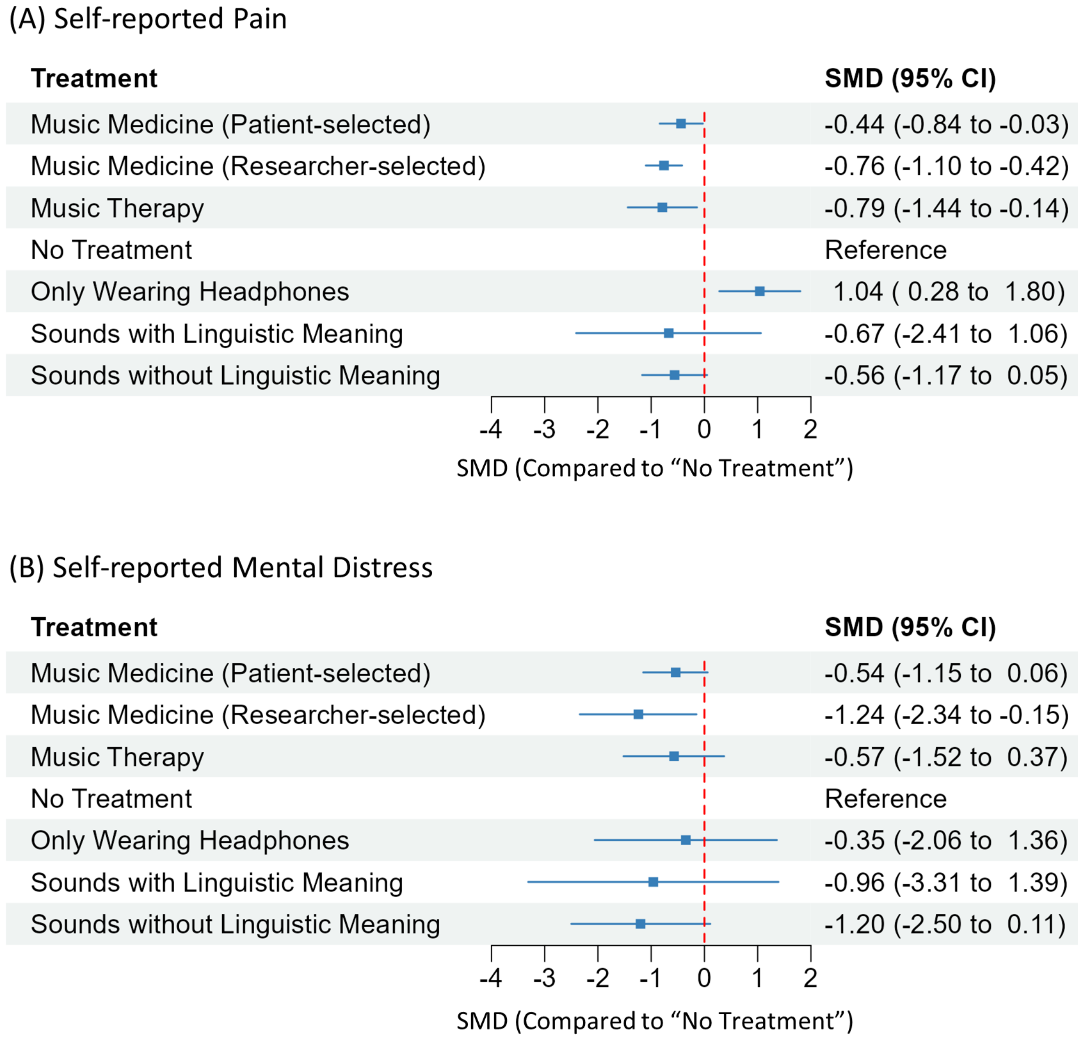

Figure 4 Forest plot for the outcomes of (A) self-reported pain and (B) self-reported mental distress. SMD, standardised mean difference.

Confidence in evidence

The confidence of the comparisons with CINeMA mainly demonstrated low ratings because most studies were rated as having a high risk of bias (online supplemental tables 12 and 13). We rated the confidence of no treatment versus ‘only wearing headphones’ for self-reported pain as ‘very low’ (online supplemental table 12). Incoherence occurred because the result of the direct comparison (SMD 0.18 (95% CI: −0.91 to 1.28)) differed from that of the pooled comparison (SMD −1.04 (95% CI: −1.80 to −0.28)). Therefore, global inconsistency was statistically significant for self-reported pain (online supplemental table 13). As the results obtained by Balan 2009,[32] which directly compared no treatment to ‘only wearing headphones’, exhibited potential heterogeneity, we excluded this study, resulting in a reduction of inconsistency to insignificance. A forest plot excluding Balan 2009 is depicted in online supplemental figure 12. The effect size of ‘only wearing headphones’ diminished (SMD for overall, 1.04 (95% CI 0.28 to 1.80); SMD after excluding Balan 2009, 0.06 (−0.74 to 0.87)), though there was not a substantial change for the other comparisons.

For mental distress, the confidence of no treatment versus ‘only wearing headphones’ was rated ‘very low’ confidence, whereas the others were rated ‘low’ (online supplemental table 14).

DISCUSSION

We conducted the first network meta-analysis on the efficacy and safety of acoustic stimulation for relieving venipuncture pain. Among the five types of acoustic stimulations, only musical interventions, such as music medicine (patient selected), music medicine (researcher selected) and music therapy, were associated with improved pain relief during venipuncture compared with no treatment, although there were no significant differences between the types of acoustic stimulations.

Musical interventions could be useful in the reduction of venipuncture pain. From a psychological perspective, music reportedly alleviates pain by reducing anxiety through distraction.[64] Additionally, music elicits feelings of pleasure and activates the pain-inhibiting fibres in the central nervous system, thereby reducing pain.[65 66]

Moreover, the current meta-analysis revealed that music medicine (researcher selected) also reduced mental distress during venipuncture compared with no treatment. Conversely, animal experiments have shown that sound, even if not music, induces analgesia through corticothalamic circuits.[67] Herein, we could not detect any difference between the types of acoustic stimulations, although music medicine (researcher selected) and music therapy tended to have a larger effect size among the five types.

'Only wearing headphones' could amplify pain when compared with no treatment. The unusual condition of 'only wearing headphones' for research purposes may have caused a nocebo effect.[68] This enhancement effect was more pronounced in the subgroup of children (who are considered more prone to placebo and nocebo effects[69 70]) and smaller in sensitivity analysis, excluding the 'high risk of bias' studies, thereby supporting the aforementioned hypothesis. The direct comparison reported by Balan *et al*[32] of no treatment versus 'only wearing headphones' in children demonstrated a stronger nocebo effect. Hence, excluding Balan 2009 in the analysis resulted in an improvement in global consistency. Furthermore, the headphones could have deprived auditory sense and blocked stimulation by environmental sounds, thereby amplifying the pain.[71] These findings should be considered when designing future investigative studies on the efficacy of acoustic stimulation on pain reduction.

In addition, results of other outcomes revealed several notable findings. Regarding treatment cost, although under-reported, acoustic stimulation was revealed to be an inexpensive treatment. Moreover, most studies found no specific adverse events with acoustic stimulation, indicating that this is a safe pain relief method.

This review has several limitations. First, the current study found that the risk of bias ratings in most studies was high because the intervention was an acoustic stimulation, which makes it difficult to blind participants, and because pain and mental distress are usually self-reported outcomes. Therefore, there were some comparisons wherein the confidence was rated 'very low'. More high-quality results on this research question are expected in the future. Second, there was no significant pain reduction effect for sounds with and without linguistic meaning when compared with no treatment; this could be due to insufficient power owing to the limited number of studies. Third, although the acoustic stimulations were algorithmically classified into five categories, other classification methods may yield different results.

In conclusion, our study revealed that three types of music interventions were associated with reduced venipuncture pain. Comparisons between types of stimulations demonstrated no significant differences. Music medicine (researcher selected) could reduce self-reported procedure-related mental distress. Thus, music intervention may be a safe and inexpensive pain relief method for venipuncture. To further elucidate this research question, studies addressing the risk of bias introduced by the difficulty of blinding and usage of self-reported outcomes are required in the future.

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