

Effectiveness and safety of ear acupuncture for trauma-related mental disorders after large-scale disasters

A PRISMA-compliant systematic review

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Abstract

Background: Large-scale disasters such as earthquakes cause mental health problems in individuals and lead to serious economic burdens on their communities and societies. Effective, simple, and safe intervention is needed to manage survivors of large-scale disasters. The purpose of this systematic review was to summarize and evaluate clinical studies using ear acupuncture for psychological trauma-related disorders after large-scale disasters, to determine its effectiveness, safety, and feasibility.

Methods: A comprehensive search of 15 electronic databases was conducted to collect relevant clinical studies up to November 2019. The methodological quality of the included studies was assessed using appropriate tools according to their study design.

Results: In total, 10 studies including 3 randomized controlled trials (RCTs), 3 before-after studies, 1 case report, 1 qualitative research, and 2 reports of public mental health services were analyzed. Ear acupuncture improved overall post-traumatic stress disorder (PTSD) related symptoms in patients with PTSD after disasters. For insomnia in patients with PTSD, although ear acupuncture improved a few subscales of the Pittsburgh sleep quality index in an RCT, other outcomes including sleep diary, actigraph, and the insomnia severity index were not improved. The methodological quality of RCTs was generally low. Serious adverse events related to ear acupuncture were not reported.

Conclusion: In conclusion, we found limited evidence suggesting the benefits of ear acupuncture in trauma-related mental disorders after large-scale disasters. Because of the small number of studies included and their heterogeneity, we could not draw conclusions about its effectiveness and safety. As 1 of the medical resources available after large-scale disasters, ear acupuncture still needs to be studied further. Registry studies aimed at investigating the results of ear acupuncture at disaster sites may be considered.

PROSPERO registration number: CRD42019134658.

Abbreviations: AMED = allied and complementary medicine database, CAPS = clinician-administered PTSD scale, CBT = cognitive behavioral therapy, CENTRAL = Cochrane central register of controlled trials, CINAHL = cumulative index to nursing and allied health literature, CNKI = China national knowledge infrastructure, DSM = diagnostic and statistical manual of mental disorders, EATMs = East Asian traditional medicines, HAMA = Hamilton anxiety rating scale, HAMD = Hamilton rating scale for depression, IES-R = impact of event scale-revised, ISI = insomnia severity index, KCI = Korea citation index, KISS = Korean studies information service system, KMbase = Korean medical database, NADA = national acupuncture detoxification association, OASIS = Oriental medicine advanced searching integrated system, PCL-M = PTSD checklist-military version, PRISMA = preferred reporting items for systematic reviews and meta-analyses, PSQI = Pittsburgh sleep quality index, PTSD = post-traumatic stress disorder, RCTs = randomized controlled trials, RISS = research information service system, RoB = risk of bias, SAS = Zung self-rating anxiety scale, SDS = Zung self-rating depression scale, SI-PTSD = structured interview for PTSD, STRICTA = standards for reporting interventions

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in clinical trials of acupuncture, TCM = traditional Chinese medicine, TER = total effective rate, TESS = treatment emergent symptom scale, TKM = traditional Korean medicine.

Keywords: ear acupuncture, large-scale disaster, systematic review, trauma-related disorder

1. Introduction

Globally, man-made disasters such as industrial disasters and warfare as well as large-scale natural disasters such as earthquakes, tsunamis, floods, and typhoons pose an unimaginable risk to public physical and mental health. In particular, global climate changes such as global warming have caused catastrophic events, which have a profound impact on the human community.^[1] By 2014, the number of disasters caused by natural events such as climatological, hydrological, meteorological, and geophysical events is estimated to be about 1000.^[2]

Of the psychological problems that arise after such disasters, post-traumatic stress disorder (PTSD) is the most representative. According to World Mental Health Surveys, the prevalence of disaster-related PTSD, particularly among high-income countries, is reported to be up to 3.8% in adults,^[3] and the incidence of PTSD after exposure to the trauma of natural disasters ranged from 3.7% to 60% depending on the study.^[4] It is reported that the probability of experiencing PTSD symptoms after natural disasters is 2.11 times that of young adults in the elderly.^[5] In addition to the diagnosed PTSD, subsyndromal or partial PTSD is an important clinical issue after disaster. According to an epidemiological study after the September 11, 2001 terrorist attack on the World Trade Center, the prevalence of diagnosed PTSD patients was 5.4% in the survivors after an average duration of 3.9 years, while the prevalence of subsyndromal PTSD was 15.4%.^[6] According to a study on United States military veterans and service members, the prevalence of subthreshold PTSD was similar to that of PTSD and the former was related to significant and clinically relevant functional impairment.^[7] Similarly, in the chronic course after a disaster, many patients may experience subsyndromal PTSD, especially women and the elderly.^[8,9] These survivors with subsyndromal PTSD were observed to have a significantly higher risk of probable depression, panic disorders, alcohol use problems, and suicidal ideation, and a higher somatic symptom burden, though it did not exceed the diagnostic threshold.^[6,10]

In the treatment of PTSD, psychotherapy plays an important role, mainly due to the limited effectiveness of pharmacotherapy.^[11,12] However, the labor-intensive nature of this approach makes it difficult to use in managing the mental health of many victims after large-scale disasters.^[13] In addition, disasters often destroy medical facilities, infrastructure, and human resources in the region, so effective disaster response systems and international cooperation are needed.^[14] East Asian traditional medicines (EATMs) have been widely used for physical and mental health care in many Asian countries. Especially, traditional Korean medicine (TKM), traditional Chinese medicine (TCM), and Kampo medicine have been used to manage health-related problems caused by large-scale disasters in Korea, China, and Japan, respectively.^[15–22] Among the modalities of EATMs such as herbal medicine, acupuncture, electro-acupuncture, and acupressure, ear acupuncture and/or ear acupressure, which may play an important role in psychiatric care as well as

treating physical conditions,^[23,24] has the advantage of high availability because of its ease of use, convenience and safety. There is also some clinical evidence of the effectiveness of ear acupuncture in psychiatric conditions such as substance abuse, insomnia, depression, and anxiety as well as immediate pain relief.^[25–28]

Thus, ear acupuncture may be considered an effective physical and mental health modality in solving trauma-related problems due to large-scale disasters. However, relevant clinical studies have not been comprehensively summarized yet. The purpose of this systematic review was to summarize clinical studies using ear acupuncture for psychological trauma-related disorders after large-scale disasters involving man-made disasters and natural disasters, to determine its effectiveness, safety, and feasibility.

2. Methods

This review was reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.^[29] The protocol was published^[30] and registered in PROSPERO (registration number, CRD42019134658). Ethical approval was not required because this was not a clinical study and individual patient data were not included.

2.1. Data sources and search strategy

As described previously, we comprehensively searched the following 15 electronic databases from their inception dates to November 16, 2019 (initial search date: May 31, 2019, update search date: November 16, 2019): 6 English-language databases (Medline (via PubMed), EMBASE (via Elsevier), the Cochrane Central Register of Controlled Trials [CENTRAL], the Allied and Complementary Medicine Database [AMED] (via EBSCO), the Cumulative Index to Nursing and Allied Health Literature [CINAHL] (via EBSCO), and PsycARTICLES (via ProQuest)), 5 Korean-language databases (Oriental Medicine Advanced Searching Integrated System [OASIS], Korean studies Information Service System [KISS], Research Information Service System [RISS], Korean Medical Database [KMedbase], and Korea Citation Index [KCI]), 3 Chinese-language databases (China National Knowledge Infrastructure [CNKI], Wanfang Data, and VIP), and 1 Japanese database (CiNii). Moreover, the reference lists of the included studies were searched and manual search on Google Scholar was performed to identify additional eligible studies and grey literature. The search strategies for each database and the search results are presented in Supplemental Digital Content 1, <http://links.lww.com/MD/D861>.

2.2. Inclusion criteria

2.2.1. Types of studies. All clinical studies with original data such as case reports, before-after studies and nonrandomized controlled trials as well as randomized controlled trials (RCTs) were included, given the difficulty and ethical issue of RCTs in the

setting of psychological trauma-related disorders caused by large-scale disasters.

2.2.2. Types of participants. Participants with any psychological trauma-related disorders after a large-scale disaster were included. “Psychological trauma-related disorders” included diagnosed and subsyndromal PTSD and known PTSD-related symptoms including depression, anxiety, substance use, suicidal ideation, and somatic symptoms like pain and sleep impairment,^[6,10,31] using standardized criteria such as the diagnostic and statistical manual of mental disorders (DSM), the international classification of diseases or the Chinese classification of mental disorders criteria, or using clinician-administered or self-report measures. Moreover, “large-scale disaster” includes natural disasters such as earthquakes, tsunamis, and floods, as well as man-made disasters such as industrial disasters and warfare. There was no restriction on the severity of disorder, sex, age, or race of the participants.

2.2.3. Types of interventions. In the review, ear acupuncture included ear acupressure pressing acupuncture points in the ear non-invasively as well as the application of a needle penetrating into acupuncture points in the ear. For controlled studies, studies which used ear acupuncture as their treatment intervention and used placebo, no treatment, or conventional medical treatments as their control intervention were included. We also included studies comparing ear acupuncture combined with other therapies to other therapies alone. However, studies comparing different methods of ear acupuncture were excluded.

2.2.4. Types of outcome measures. The primary outcome measures were as follows.

1. Traumatic stress-related symptoms measured by validated assessment tools, such as Clinician-Administered PTSD scale (CAPS),^[32] Structured Interview for PTSD (SI-PTSD),^[33] or Impact of Event Scale-Revised (IES-R).^[34]

The secondary outcome measures were as follows.

1. Depression measured by validated assessment tools such as the Hamilton Rating Scale for Depression (HAM-D)^[35] or the Zung Self-Rating Depression Scale (SDS)^[36]
2. Anxiety measured by validated assessment tools such as the Hamilton Anxiety Rating Scale (HAM-A)^[37] or the Zung Self-Rating Anxiety Scale (SAS)^[38]
3. Sleep disturbance measured by validated assessment tools such as the Pittsburgh Sleep Quality Index (PSQI)^[39] or the Insomnia Severity Index (ISI)^[40]
4. Adverse events measured by the Treatment Emergent Symptom Scale (TESS)^[41] or the incidence
5. Total effective rate (TER)

2.3. Study selection

According to the pre-defined criteria, 2 authors (C-Y Kwon and B. Lee) independently conducted the study selection process. For the first inclusion, the titles and abstracts of the searched studies were screened. After the first inclusion, the full texts of potentially relevant articles were evaluated for final inclusion. Any disagreement between the 2 authors was resolved through discussion with other researchers (S-H Kim). To manage quotations from included articles, EndNote X8 (Clarivate Analytics, Philadelphia, USA) was used.

2.4. Data extraction

By using a pre-defined standardized form in Excel 2016 (Microsoft, Redmond, WA, USA), 2 authors (C-Y Kwon and B. Lee) independently performed the data extraction process and double-checked the data extracted. Any disagreement between the 2 authors was resolved through discussion with other researchers (S-H Kim).

The following items were extracted: study characteristics (author, publication year, country, and study design); approval of institutional review board; informed consent; sample size and number of dropouts; diagnostic criteria; details about the participants, intervention, and comparisons (for controlled studies); duration of the intervention and follow-up; outcome measures; outcomes; and adverse events. Moreover, the data on ear acupuncture was extracted with reference to the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) recommendations.^[42] To share the extracted data, Dropbox (Dropbox, Inc., California, USA) folders was used. When the data was insufficient or ambiguous, to request further information, we contacted the corresponding authors of the included studies via e-mail.

2.5. Quality assessment

According to the types of included studies, 2 authors (C-Y Kwon and B. Lee) independently evaluated the methodological quality by using each relevant tool, as follows. Each evaluation was recorded in an Excel 2016 (Microsoft, Redmond, WA, USA) file and was shared among the authors by using Dropbox (Dropbox, Inc., California, USA) folders.

2.5.1. For RCTs. To evaluate the methodological quality of the included RCTs, the Cochrane Collaborations risk of bias (RoB) tool was used, which assesses random sequence generation, allocation concealment, blinding of participants, personnel, and outcome assessors, completeness of outcome data, selective reporting, and other biases as “low risk,” “unclear risk,” or “high risk.”^[23] Regarding the other bias categories, the statistical baseline imbalance including the participants mean age, sex, or disease severity between treatment and control groups were evaluated.

2.5.2. For nonrandomized clinical trials. To evaluate the methodological quality of the included nonrandomized clinical trials, the risk of bias in nonrandomized studies of intervention tool to assess the methodological quality was used.^[43]

2.5.3. For before-after studies. To evaluate the methodological quality of the included before-after studies, a quality assessment tool for before-after (prepost) studies with no control group, which was proposed by the National Heart, Lung, and Blood Institute, was used.^[44]

2.5.4. For case reports/case series. To evaluate the methodological quality of the included case reports/case series, a quality assessment tool for case series studies, which was also proposed by the National Heart, Lung, and Blood Institute, was used.^[44]

2.6. Data analysis

The details of participants, interventions, and outcomes for all included studies were descriptively analyzed. According to our protocol,^[30] meta-analysis was planned to be performed if there

were studies using the same types of intervention, comparison, and outcome measures in included RCTs. However, meta-analysis could not be conducted in this review due to the heterogeneity among the RCTs included. Therefore, we analyzed the included studies only qualitatively.

3. Results

3.1. Study description

Through the comprehensive search, 1585 documents were identified after removing duplications. Among them, the full texts of 22 articles were reviewed for final inclusion. Hence, a total of 10 studies^[45–54] including 3 RCTs,^[48,50,53] 3 before-after studies,^[46,51,52] 1 case report,^[47] 1 qualitative research,^[54] and 2 reports^[45,49] of public mental health service, involving total 292 participants were finally analyzed in this review. All of these studies dealt with trauma-related mental disorders after large-scale disasters, and none of them dealt with somatic symptoms such as chronic pain (Fig. 1).

3.2. Study characteristics

All included studies were published between 2009 and 2016. When classifying by country, America^[46–48,53,54] was the most common (n=5), followed by China^[50–52] (n=3), and Kenya^[49] and Haiti^[45] (n=1, respectively). Two^[50,51] of the studies conducted in China were on PTSD patients after the Sichuan earthquake in 2008 and the other one^[52] was on insomnia patients after the Lusan earthquake in 2013. All the studies conducted in America were on combat stress-related problems: PTSD (n=1),^[47] insomnia (n=1),^[46] and both PTSD and insomnia (n=3).^[48,53,54] The study conducted in Kenya was on civil war-related problems in Uganda,^[49] and the study conducted in Haiti was on earthquake-related problems in 2010.^[45] The studies conducted in Kenya and Uganda are reports by the same team that describe the successful introduction of the National Acupuncture Detoxification Association (NADA) protocol as part of public mental health services, but did not perform pre- and post-intervention assessment.^[45,49] One^[50] of the 3 RCTs included compared scalp electro-acupuncture plus

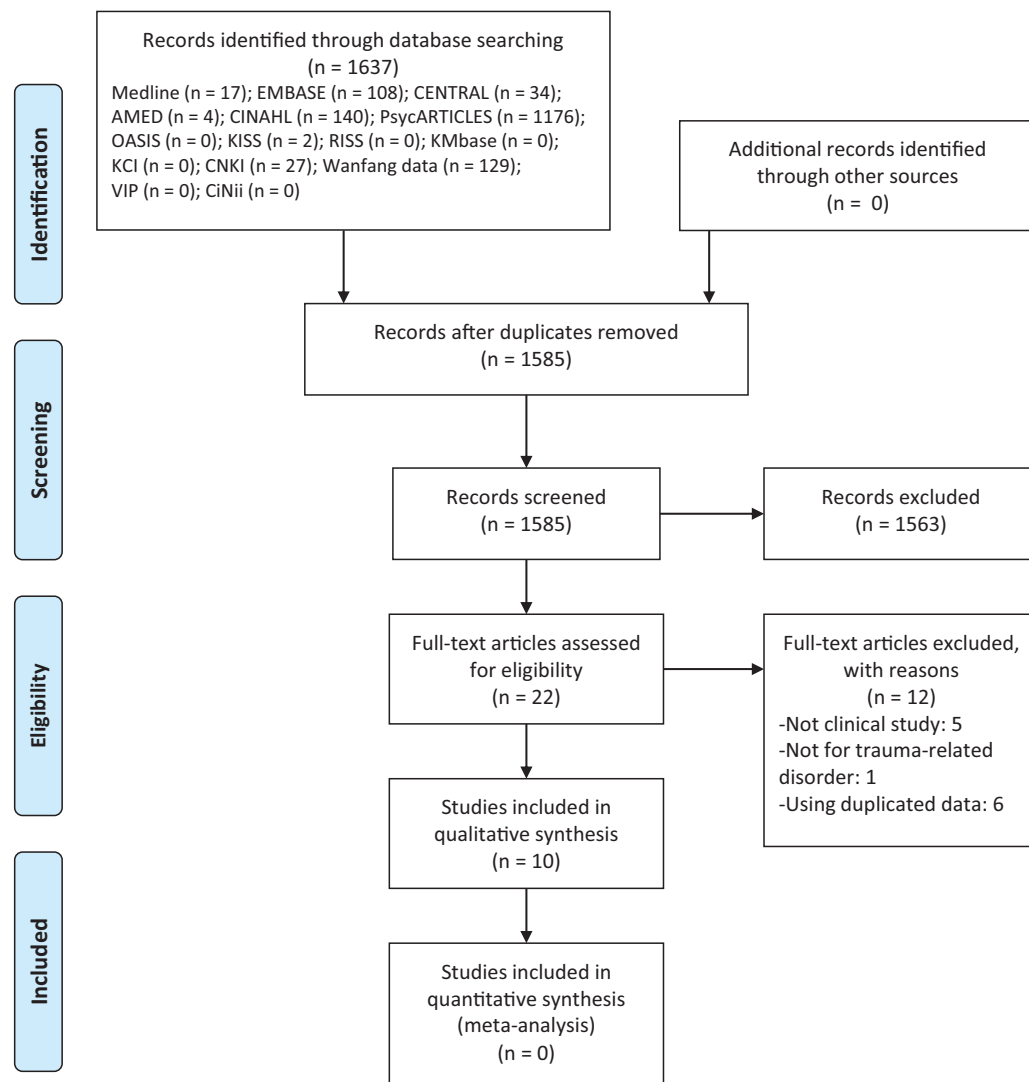


Figure 1. PRISMA flow chart of the study selection process.

ear acupressure to paroxetine, the other^[48] compared conventional care plus ear acupuncture to conventional care plus sham ear acupuncture or conventional care alone, and another^[53] compared conventional care plus ear acupuncture to conventional care alone. Three before-after studies used scalp electroacupuncture plus ear acupressure plus moxibustion,^[51] ear acupuncture,^[46] and ear acupressure^[52] as interventions, respectively. One case report used ear acupuncture as intervention.^[47] One qualitative research^[54] explored self-reported benefits of ear acupuncture among participants in an RCT.^[53] The treatment period varied from 5 days to 6 months (median 8 weeks), and the number of treatment sessions varied from 4 to 36 (median 16 sessions) (Tables 1–3).

3.3. Quality assessment

Of the 3 RCTs evaluated using the RoB tool, Wang^[50] did not describe the method of random sequence generation, and we considered that double-blinding was not performed; therefore, this study was evaluated as unclear risk and high risk in each item. All of the other items were evaluated as low risk. In the case of the other 2 RCTs,^[48,53] the appropriate random sequence generation method was described and evaluated as low risk. However, there was no description of allocation concealment; therefore, it was evaluated as having unclear risk. The blinding of participants, personnel, and outcome assessors was not performed and per protocol, analysis results were applied to the missing data; therefore, the RoB was evaluated as high risk in each item (Supplemental Digital Content 2, <http://links.lww.com/MD/D862>).

All 3 before-after studies clearly described the purpose of the study.^[46,51,52] However, the information about the recruitment period of the subjects, the description of the pre-specified eligibility criteria, and the estimation of the sample size were missing. In these studies, the representativeness of the subjects were acknowledged and the intervention was consistently applied to all subjects. In the case of Wang,^[51] only TER was reported as an outcome and the study was considered as not using a clearly validated outcome measure. There were no descriptions of assessment-blinding in all studies. Follow-up assessments were performed in only the study by Cronin,^[46] and the follow-up rate was evaluated as appropriate. Except for Wang,^[51] who reported only TER that did not require statistical analysis, all the remaining studies used appropriate statistical analyses. In addition, except for Wang,^[51] who reported only TER that do not require multiple evaluations, all of the remaining studies performed proper multiple evaluations. No group-level intervention was performed in all studies (Supplemental Digital Content 2, <http://links.lww.com/MD/D862>).

In 1 case report,^[47] the purpose of the study, the characteristics of the participants and the intervention, and the results of the study were well documented. A clearly defined outcome measure was used and the duration of follow-up was also adequate (Supplemental Digital Content 2, <http://links.lww.com/MD/D862>, <http://links.lww.com/MD/D863>).

3.4. Effectiveness and safety of ear acupuncture

Although all 3 RCTs were performed on PTSD patients,^[48,50,53] no meta-analysis was performed due to the heterogeneity of the intervention and outcome measure. There were 5 studies^[47,48,50,51,53] involving patients with diagnosed PTSD. Two

studies^[45,49] did not evaluate the effectiveness or safety of ear acupuncture, and rather described its utility at the disaster site.

3.4.1. Effectiveness for diagnosed PTSD patients. In Prisco,^[48] an RCT, 35 PTSD veterans with insomnia related to combat stress received conventional care plus ear acupuncture, conventional care plus sham ear acupuncture, or conventional care alone for 8 weeks. The conventional care included referral to a trauma services department, cognitive behavioral therapy (CBT), evaluation and follow-up with psychiatry, and psychopharmacology if needed. Insomnia symptoms were assessed using ISI, sleep diary, and actigraph, and the changes to hypnotic medications were also assessed. Although the severity of insomnia measured by ISI after 1 month significantly improved in the true ear acupuncture group ($P=.0165$), no significant difference was found after 2 months. There was no statistically significant difference between the groups at any time in the other outcomes ($P > .05$, all).

In Wang,^[50] an RCT, 138 PTSD participants after the Sichuan earthquake received scalp electroacupuncture plus ear acupressure or paroxetine 20mg 1T qd for 12 weeks. Trauma-related symptoms, depression, and anxiety were assessed by using CAPS, HAMD, and HAMA, respectively. After 12 weeks, the CAPS, HAMD, and HAMA scores of the treatment group decreased significantly from 67.40 ± 24.90 , 13.83 ± 6.96 , and 10.75 ± 5.53 to 29.43 ± 17.15 , 6.06 ± 4.59 , and 5.23 ± 3.07 , respectively ($P=.000$, all). On the other hand, in the control group, there was also significant reduction from 66.77 ± 21.26 , 12.66 ± 5.20 , and 11.67 ± 5.85 before treatment to 31.19 ± 18.97 , 6.11 ± 3.89 , and 5.59 ± 3.18 after 12 weeks, respectively ($P=.000$, all). However, no significant difference was found between the 2 groups ($P > .05$, all).

In King,^[53] an RCT, 20 PTSD veterans with insomnia related to combat stress received conventional care plus ear acupuncture or conventional care alone for 3 weeks. The conventional care included cognitive processing therapy, educational classes, exercise programs, community involvement, and psychoeducational sleep didactic. Insomnia symptoms were assessed using the sleep diary, actigraph, and PSQI. At the 5th week, there were no significant differences between the groups in sleep diary or actigraph data, while in some PSQI subscales including sleep quality ($P=.003$) and daytime dysfunction ($P=.004$), ear acupuncture group showed significantly better results. Moreover, the 5-point Likert scale results for assessing acceptability were significantly more favorable for the acupuncture group ($P=.004$). The participants of the RCT^[53] were further investigated in a qualitative research,^[54] to explore self-reported benefits of ear acupuncture. As results, 4 themes were found to be associated with the treatment among the participants as follows: Ear acupuncture ‘

1. improved sleep quality;
2. increased relaxation;
3. decreased pain; and
4. veterans liked/loved the treatments.

In Wang,^[51] a before-after study, 69 PTSD participants after the Sichuan earthquake received scalp electroacupuncture plus ear acupressure plus moxibustion for 12 weeks. The TER evaluated by improvement of psychological symptoms was used as the outcome. After 12 weeks, the rates of cured, improved, and invalid participants were 55.1% ($n=38$), 39.1% ($n=27$), and 5.8% ($n=4$), respectively.

Table 1
Characteristics of included randomized controlled trials.

Study (country)	Sample size (included → analyzed)	Mean age (range) (years)	Sex (M:F)	Population (diagnostic tool)	Related disaster	Treatment intervention	Control intervention	Duration of treatment / f/u	Outcome	Results reported
Wang 2010 (China)	138(69:69) → 129(65:64)	TG: 48.26 ± 13.32 (NR) CG: 50.30 ± 12.29 (NR)	TG(26:39) CG(28:36)	PTSD (DSM-IV)	Sichuan earthquake (May, 2008)	(1) scalp electro-acupuncture (2) ear acupressure	Paroxetine 20 mg 1T qd	12 wks (36 sessions) / 3 mo, 6 mo f/u	(1) CAPS (2) HAMD (3) HAMA	(1) post-treatment: N.S (P= .381) f/u 6 mo: N.S (2) post-treatment: N.S (P= .878) f/u 6 mo: N.S (3) post-treatment: N.S (P= .273) f/u 6 mo: N.S
Prisco 2013 (America)	35(12:12:11) → 25(8:8:9)	TG: 37.8 ± 11.4 (NR) CG1: 37.9 ± 10.3 (NR) CG2: 37.6 ± 8.0 (NR)	TG(10:2) CG1(8:5) CG2(7:4)	PTSD (DSM-IV-TR) & Insomnia (8 points or more of ISI score)	Combat stress	(1) conventional care (referral to trauma services department, CBT, evaluation and f/u by psychiatry and psychopharmacology) (2) ear acupuncture	CG1 (1) conventional care (2) sham ear acupuncture (non-acupoints) CG2 (1) conventional care	8 wks (16 sessions) / NR	(1) ISI (2) SD refreshment rating (3) SD soundness rating (4) SD TST (5) SD SOL (6) SD SE (7) SD Naps (8) ATG TST (9) ATG SOL (10) ATG SE (11) ATG Naps (12) Hypnotic medications changes	(1) post-treatment: N.S (P= .3705) (2) post-treatment: N.S (P= .5782) (3) post-treatment: N.S (P= .7382) (4) post-treatment: N.S (P= .0783) (5) post-treatment: N.S (P= .8444) (6) post-treatment: N.S (P= .7548) (7) post-treatment: N.S (P= .0666) (8) post-treatment: N.S (P= .2409) (9) post-treatment: N.S (P= .6603) (10) post-treatment: N.S (P= .5633) (11) post-treatment: N.S (P= .1241) (12) post-treatment: N.S (P= .588)
King 2015 (America)	29(15:14) → 20 (12:8)	TG: 33.3 ± 6.1 (NR) CG: 32.8 ± 9.2 (NR)	TG(12:0) CG(8:0)	PTSD (DSM-IV) & Insomnia (self-reported sleep disturbances)	Combat stress	(1) conventional care (cognitive processing therapy, educational classes, exercise programs, community involvement, psychoeducational sleep didactic) (2) ear acupuncture	(1) conventional care	3 wks (9 sessions) / NR	(1) SD SOL (2) SD WASO (3) SD SE (4) SD NOA (5) SD TST (6) ATG SOL (7) ATG WASO (8) ATG SE (9) ATG NOA (10) ATG TST (11) PSQI global score (12) PSQI sleep quality (13) PSQI daytime dysfunction (14) PSQI SL (15) PSQI sleep duration (16) PSQI SE (17) PSQI sleep disturbance (18) PSQI use of sleep medication (19) 5-point Likert scale (acceptability)	(1) post-treatment: N.S (P= .557) (2) post-treatment: N.S (P= .816) (3) post-treatment: N.S (P= 6:49) (4) post-treatment: N.S (P= 6:56) (5) post-treatment: N.S (P= .755) (6) post-treatment: N.S (P= .500) (7) post-treatment: N.S (P= .244) (8) post-treatment: N.S (P= .361) (9) post-treatment: N.S (P= .140) (10) post-treatment: N.S (P= .81) (11) post-treatment: N.S (P= .082) (12) post-treatment: TG < CG (P= .003) (13) post-treatment: TG < CG (P= .004) (14) post-treatment: N.S (P= .288) (15) post-treatment: N.S (P= .23) (16) post-treatment: N.S (P= .759) (17) post-treatment: N.S (P= .307) (18) post-treatment: N.S (P= .517) (19) post-treatment: TG > CG (P= .004)

ATG = acupoint, CAPS = clinician administered PTSD scale, CBT = cognitive behavioral therapy, CG = control group, DSM = the diagnostic and statistical manual of mental disorders, f/u = follow up, HAMA = Hamilton anxiety rating scale, HAMD = Hamilton rating scale for depression, ISI = the insomnia severity index, N.S = not significant, NOA = number of awakenings, NR = not reported, PSQI = Pittsburgh sleep quality index, PTSD = post-traumatic stress disorder, SD = sleep diary, SE = sleep efficiency, SOL = sleep onset latency, TG = treatment group, TST = total sleep time, WASO = wake after sleep onset.

Table 2

Characteristics of included before-after studies.

Study (country)	Sample size	Mean age (range) (years)	Sex (M:F)	Population (diagnostic tool)	Related disaster	Treatment intervention	Duration of treatment / f/u	Outcome	Results reported
Wang 2009 (China)	69	NR (31–69)	26:43	PTSD (NR)	Sichuan Earthquake (May, 2008)	(1) Scalp electro-acupuncture (2) ear acupressure (3) moxibustion	12 wks (36 sessions)	TER (improvement of psychological symptoms)	Cure: 38 cases (55.1%) Improved: 27 cases (39.1%) Invalid: 4 cases (5.8%)
Cronin 2013 (America)	3	NR	NR	Insomnia (Lichstein criteria)	Combat stress	(1) ear acupuncture (NADA protocol)	5 days (5 sessions) / 1 wk f/u	(1) PSQI (2) PCL-M (3) Subcategories of PSQI	(1) post-treatment: improved ($P=0.04$), f/u 1 wk: improved ($P=.04$) (2) post-treatment: improved ($P=.05$), f/u 1 wk: improved ($P=.05$) (3) 3-1. post-treatment: N.S ($P=.35$), f/u 1 wk: N.S ($P=.20$) 3-2. post-treatment: N.S ($P=.19$), f/u 1 wk: N.S ($P=.09$) 3-3. post-treatment: N.S ($P=.09$), f/u 1 wk: N.S ($P=.20$) 3-4. post-treatment: N.S ($P=.50$), f/u 1 wk: N.S ($P=.20$) 3-5. post-treatment: improved ($P=.05$), f/u 1 wk: N.S ($P=.13$) 3-6. post-treatment: N.S ($P=.09$), f/u 1 wk: N.S ($P=.36$)
Chen 2014 (China)	26	42 (14-78)	17:9	Insomnia (8 points or more of PSQI score)	Lusan earthquake (April, 2013)	(1) ear acupressure	2 weeks (4 sessions)	(1) PSQI (2) subcategories of PSQI	(1) post-treatment: improved ($P<.01$) (2) 2-1. post-treatment: improved ($P<.01$) 2-2. post-treatment: N.S 2-3. post-treatment: improved ($P<.01$) 2-4. post-treatment: improved ($P<.01$) 2-5. post-treatment: improved ($P<.01$)
								(1) PSQI (2) subcategories of PSQI	4-1. post-treatment: N.S ($P=.16$), f/u 1 wk: improved ($P=.04$) 4-2. post-treatment: N.S ($P=.09$), f/u 1 wk: N.S ($P=.08$) 4-3. post-treatment: improved ($P=.003$), f/u 1 wk: N.S ($P=.06$) (1) post-treatment: improved ($P<.01$) (2) 2-1. post-treatment: improved ($P<.01$) 2-2. post-treatment: N.S 2-3. post-treatment: improved ($P<.01$) 2-4. post-treatment: improved ($P<.01$) 2-5. post-treatment: improved ($P<.01$)

DSM = the diagnostic and statistical manual of mental disorders; N.S = not significant, NADA = the national acupuncture detoxification association, NR = not reported, PCL-M = the PTSD checklist - military version, PSQI = Pittsburgh sleep quality index, PTSD = post-traumatic stress disorder, TER = total effective rate.

Table 3
Characteristics of included case reports.

Study (country)	Sample size	age	Population (diagnostic tool)	Related disaster	Treatment intervention	Duration of treatment / f/u	Results reported
Golden 2012 (America)	1 (male)	60 years old	PTSD (DSM-IV)	Vietnam War (1955–1975)	(1) ear acupuncture (NADA protocol)	6 months (18 sessions)/ 7 months f/u	Over the course of 18 treatments during 6 months, the patient progressed from reporting symptoms of irritability, anger, panic, physical fatigue, sleeplessness, nightmares, and nameless irrational fears to describing days with increased calm and improved moods, an ability to deal with stress, decreased anger, increased physical energy, nights of up to 6 hours of uninterrupted sleep, an improved relationship with his wife and teenage son, and a loss of irrational fears. At a f/u approximately 7 months after the patient discontinued care, 9 out of 11 symptoms improved or were completely resolved in the PTSD symptoms checklist. (Alcoholism/Substance abuse, Depression/Grief, General anxiety, Headaches, Insomnia, Irritability, quick temper, other anger issues, Nightmares, Panic Attacks, and Skin rashes and other skin problems)

DSM = the diagnostic and statistical manual of mental disorders, NADA = the national acupuncture detoxification association, PTSD = post-traumatic stress disorder.

In Golden,^[47] a case report, 1 PTSD veteran received ear acupuncture for 6 months. They used their own 13-item checklist to assess PTSD symptoms, and asked the patient to answer “yes”, “sometimes”, or “no” to each item. After 6 months, the symptoms of irritability, anger, panic, physical fatigue, sleeplessness, nightmares, and nameless irrational fears were relieved, and his mood, sleep, and relationship with his wife and teenage son improved. Even at 7-months follow-up, 9 out of 11 symptoms improved or were completely resolved in the checklist: alcoholism/substance abuse, depression/grief, general anxiety, headaches, insomnia, irritability, quick temper, other anger issues, nightmares, panic attacks, and skin rashes and other skin problems.

3.4.2. Effectiveness for other clinical populations after disaster. In Cronin,^[46] a before-after study, 3 veterans with insomnia related to combat stress received ear acupuncture for 5 days. Trauma-related symptoms were assessed by using the PTSD checklist - military version (PCL-M) and insomnia symptoms were assessed using PSQI. After 5 days, the total and hypervigilance subcategory scores of PCL-M significantly improved ($P=.04$ and $.003$, respectively). Moreover, the total and sleep efficiency subcategory scores of PSQI significantly improved ($P=.04$ and $.05$, respectively). The total scores of the PCL-M and PSQI were also maintained at 1-week follow-up ($P=.05$ and $P=.04$, respectively), but not for the hypervigilance subcategory ($P=.06$) and sleep efficiency subcategory ($P=.13$). However, at 1-week follow-up, the score of the re-experiencing subcategory showed to be significantly improved ($P=.04$).

In Chen,^[52] a before-after study, 26 insomnia participants after the Lusan earthquake received ear acupressure for 2 weeks. Insomnia symptoms were assessed using the PSQI. After 2 weeks, the total, sleep quality, sleep duration, sleep efficiency, and day disturbance scores of the PSQI significantly improved from 10.27 ± 2.183 , 1.500 ± 0.510 , 2.308 ± 0.736 , 2.615 ± 0.697 , and 0.885 ± 0.653 to 8.000 ± 3.046 , 1.154 ± 0.368 , 1.846 ± 1.008 , 2.154 ± 0.967 , and 0.346 ± 0.562 , respectively ($P < .001$, all). However, there was no significant change in the sleep latency subcategory (from 2.00 ± 0.800 to 1.73 ± 0.827 , $P > .05$).

3.4.3. Utility in large-scale disasters. Yarberr^[49] and Cole^[45] described the use of the NADA protocol in large-scale disasters of the civil war in Uganda and the Haiti earthquake, respectively. Although they did not specifically report data on the subjects, interventions, outcomes, and results, they used the NADA protocol in these large-scale disasters to improve public mental health.

First, in Yarberr,^[49] the author trained the Kenyan refugees after the 2007 postelection violence using the NADA protocol. Interestingly, although the standard NADA protocol uses 5 needles, they were trained in the strategy of using 3 for simplicity. In this case, among the auricular points included in the NADA protocol, the *sympathetic* and *shenmen* points were included, and the *lung* point was mainly selected. They trained 21 trainees through a training course, who provided more than 500 treatments to their fellow refugees. After 6 months of the training, the author visited the community again, and the NADA practitioners said they had provided 18,000 treatments in the meantime. Based on this experience, the author concluded that the NADA protocol can have a significant impact on communities experiencing hardships and transitions, and listed factors that were critical to the success of the training as follows: “. . . including sponsorship by an international agency, contacts among local service-providing organizations, inclusion of community members in decision-making, follow-up communication with all collaborators and participants, and complete flexibility around clearly defined goals.”

Secondly, in Cole,^[45] the authors were the same team that did the project at Yarberr.^[49] This time they trained the Haitian communities affected by PTSD due to earthquakes, in the NADA protocol with an outline similar to that in Uganda. This led to the training of 24 local Haitians. The authors visited Haiti again 2 months later, and 2 NADA practitioners said they provided more than 2000 treatments within 7 weeks after the end of the training, to a population still enduring trauma, upheaval, and illness. The authors described the success factors in their project as follows:

1. Previous experience implementing similar trainings;
2. Clear intentions;
3. Complete flexibility;

Table 4**The methods of ear acupuncture among the included studies.**

Study	Acupoints	Stimulation methods	Treatment side	Treatment cycle	Retention time	Treatment periods
Wang, 2010	<i>Subcortex, Shenmen, Sympathetic, Heart, Liver, Kidney</i>	acupressure using <i>vaccaria seeds</i>	unilateral/alternatively at each session	3 sessions/week	2-3 days	12 weeks
Prisco, 2013	<i>Shenmen, Sympathetic, Liver, Kidney, Hippocampus</i>	acupuncture using needle	unclear	2 sessions/week	45 minutes	8 weeks
King, 2015	<i>Shenmen, Point zero, Brain, Thalamus, Pineal gland, Master cerebral, Insomnia points 1 and 2, Kidney, Heart, Occiput, Forehead</i>	acupuncture using needle	unclear	3 sessions/week	30 minutes	3 weeks
Wang, 2009	<i>Subcortex, Shenmen, Sympathetic, Heart, Liver, Kidney</i>	acupressure using <i>vaccaria seeds</i>	unilateral / alternatively at each session	3 sessions/week	2 days	12 weeks
Cronin, 2013	<i>Shenmen, Sympathetic, Liver, Kidney, Lung</i>	acupuncture using needle	bilateral	daily	45 minutes	5 days
Chen, 2014	<i>Subcortex, Shenmen, Sympathetic, Heart, Endocrine, Kidney</i>	acupressure using seeds (unclear material), self-acupressure 3–5 times/day	unilateral / alternatively at each session	2 sessions/week	3 days	2 weeks
Golden, 2012	<i>Shenmen, Sympathetic, Liver, Kidney, Lung</i>	acupuncture using needle	bilateral	1 session/week (first 7 weeks), 1 session/1–4 weeks	30 minutes	6 months

4. Honoring local customs & protocols;
5. Cohesive team work;
6. Collaboration with NGOs working locally; and
7. Follow up visit to training sites.

3.4.4. Safety. Only 3 RCTs reported adverse events.^[48,50] First, in Wang,^[50] there was no adverse event in the scalp electroacupuncture plus ear acupressure group, while 1 case of leukopenia was reported in the paroxetine group (1/64, 1.56%). Second, in Prisco,^[48] there was no adverse event in the true ear acupuncture group and conventional care group. However, 1 participant in the sham ear acupuncture group requested withdrawal from the study due to the uncomfortable needling sensation (1/8, 12.50%). Last, in King,^[53] though 5 adverse events occurred during the study period, 4 cases occurred before ear acupuncture procedure and 1 case occurred 3 days after ear acupuncture. However, the authors determined that the adverse event was not directly related to ear acupuncture.

3.5. Analysis of ear acupuncture procedure

Except the 2 reports of public mental health service and qualitative research,^[45,49,54] 5 or 6 acupuncture points were used in the most studies. However, King^[53] used 12 acupuncture points. Among them, *Shenmen* and *Kidney* were the most frequently used acupoint in 7 clinical studies,^[46–48,50–53] followed by *Sympathetic* (n=6),^[46–48,50–52] *Liver* (n=5),^[46–48,50,51] *Heart* (n=4),^[50–53] *Subcortex* (n=3),^[50–52] *Lung* (n=2),^[46,47] and *Hippocampus*,^[48] *Endocrine*,^[52] *Point zero*,^[53] *Brain*,^[53] *Thalamus*,^[53] *Pineal gland*,^[53] *Master cerebral*,^[53] *Insomnia points 1 and 2*,^[53] *Occiput*,^[53] and *Forehead*^[53] (n=1, respectively). In 3 studies,^[50–52] ear acupressure by applying seeds, mainly *Vaccaria seeds*, was performed, and in the remaining 4 studies,^[46–48,53] ear acupuncture by inserting needles was performed. Unilateral acupuncture points were used in ear acupressure studies and bilateral acupuncture points in ear acupuncture studies, except for 2 studies^[48,53] that did not specify the treatment side. The treatment frequency varied from once a day to once every 1 to 4 weeks, but in most cases treatment was

performed 2 to 3 times per week.^[48,50–53] For ear acupressure studies,^[50–52] the retention time of the seeds was 2 to 3 days, and for ear acupuncture studies,^[46–48,53] the retention time of the needles was 30 to 45 minutes (Table 4).

3.6. Publication bias

Because the number of studies included was limited and meta-analysis was not performed due to heterogeneity among the studies, publication bias could not be assessed.

4. Discussion

In this systematic literature review, we investigated the effectiveness, safety, and application of using ear acupuncture in psychological trauma-related disorders after large-scale disasters. Through comprehensive searches, a total of 10 studies^[45–54] were included in the analysis.

In this review, the included studies were classified into either studies on patients with diagnosed PTSD or those on patients with other clinical conditions after disaster. Among the diagnosed PTSD patients after disaster, compared to baseline, ear acupuncture improved the overall PTSD symptoms assessed by CAPS or PCL-M, and also improved depression and anxiety as assessed by HAMD and HAMA, respectively. Importantly, in a study done by Wang,^[50] ear acupuncture and scalp electroacupuncture did not show any significant difference from paroxetine on CAPS, HAMD, and HAMA. Since, this study was not a noninferiority trial, it can not be concluded that the former has equivalent effects to the latter. However, these results are indicative of the effective size of ear acupuncture and scalp electroacupuncture. The benefits of the additional use of ear acupuncture for conventional care in veterans with both PTSD and insomnia associated with combat stress were examined in 2 RCTs.^[48,53] In both of these studies, ear acupuncture as adjunctive therapy did not significantly affect sleep-related parameters measured by sleep diary and actigraph, but 1 study^[53] found significant benefits in some subscales of PSQI. However, the other study^[48] did not find any significant effects of

ear acupuncture on the ISI total score among the participants. For insomnia in patients without diagnosed PTSD, ear acupuncture or ear acupressure had the effect of improving sleep quality as measured by PSQI. These effects after combat stress or earthquake were examined in 2 before-after studies.^[46,52] In both of these studies, ear acupuncture or ear acupressure significantly improved global score and some subscales of PSQI. Importantly, in a study done by Cronin,^[46] he performed 5 sessions of ear acupuncture for 5 days and followed up for 1 week after the treatment, and the significant improvements on PSQI was observed. Of the included studies, only 3 RCTs reported adverse events, and there were no side effects associated with ear acupuncture. King^[53] used a 5-point Likert scale to assess the acceptability of ear acupuncture in combat stress-related PTSD veterans, indicating that the acceptability of this treatment was very high in this population. In addition, qualitative research of the participants was performed by King.^[54] As a result, these patients reported that ear acupuncture improved their sleep quality and pain, increased relaxation, and was easy to accept. Yarberr^[49] and Cole^[45] reported the use of the NADA protocol in large-scale disasters of civil war in Uganda and the Haiti earthquake, respectively. Interestingly, they educated the practitioners about ear acupuncture in refugee or earthquake survivors, which was successfully popularized in the community. Based on their valuable experience, they highlighted the success factors of the project and emphasized the need for simple and clear goals, an organized team, and international cooperation.

The qualities of clinical studies included in this review were assessed according to their design. Overall, 3 before-after studies^[46,51,52] and 1 case report^[47] were fairly adequate in quality, but methodological limitations were found in 3 RCTs.^[48,50,53] Although it should be considered that blinding is difficult to perform due to the characteristics of ear acupuncture, the absence of blinding of participants and personnel is likely to show a different effect size from the actual. In addition, because of the small number of included studies, especially RCTs, we cannot draw conclusions about the effectiveness and safety of ear acupuncture for trauma-related mental disorders after large-scale disasters.

Although our review failed to obtain enough clinical evidence for the effectiveness and safety of ear acupuncture, its applicability should still be considered. In general, the efficacy of some antidepressants for PTSD is positive, however the effect size is not sufficient^[12] and the importance of non-pharmacotherapy, including psychotherapy, has been emphasized.^[11] Furthermore, because there is little evidence of pharmacotherapy for children and adolescents, medication for the prevention and treatment of PTSD in this population is not recommended.^[11] One of the advantages of ear acupuncture in trauma management is that the patient does not need to talk in detail about the painful memory, as in the case of psychotherapy. The procedure is performed very quietly, and after 30 to 45 minutes of acupuncture, the patient naturally returns to normal life. Sometimes, patients are recommended to hold the ear acupuncture or ear acupressure applied to the ear for 3 to 4 days. In other words, ear acupuncture is a simple nonpharmacological approach and can be used for mental health management without the components of exposure therapy. This implies that ear acupuncture may be used in people who have difficulty in applying exposure therapy, or ear acupuncture may be used in addition to psychotherapy including exposure therapy. Another advantage of ear acupuncture is that it can help improve

symptoms other than mental health. For example, with regard to pain, a systematic review of 18 clinical studies suggested that the effect of psychological intervention alone is limited in patients with concurrent PTSD and pain.^[55] It is also reported that acupuncture and massage therapies effectively reduced the pain of disaster victims in Japan.^[17] Since immediate pain-relief effect of ear acupuncture has been well established in various pain conditions,^[28] the application of ear acupuncture may be considered in survivors with concurrent trauma-related problems and pain. However, to the best of our knowledge, there was no report on ear acupuncture for postdisaster pain.

This review has the following limitations and suggestions for future research:

1. Because the number of studies included was low, especially rigorous study designs (i.e., RCTs), this review could not draw any conclusions on its effectiveness and safety for psychological trauma-related symptoms after large-scale disasters. However, it should be taken into consideration that conducting RCT research will be challenging due to the nature of this topic. There is already some clinical evidence of the role of ear acupuncture in the improvement of mental health as well as pain,^[23–28] and some international relief organizations such as NADA have already adopted ear acupuncture at the disaster site.^[48,49] Therefore, future research based on real-world situations should be performed. Furthermore, in order to understand the benefits of this simple and inexpensive treatment in a large-scale disaster area, which has a huge economic impact, it is necessary to investigate its cost-effectiveness. Solutions to this problem may include registry research designs that can be used to assess the clinical and cost effectiveness of ear acupuncture.^[56,57] To do this, a registry can be built around international relief organizations, or an existing medical registry can be used.
2. In some included studies, other interventions such as CBT, acupuncture, and moxibustion were used with ear acupuncture. In fact, it is important to identify the optimal therapeutic strategies of available resources at the disaster site, but due to the heterogeneity of the included studies it was not possible. Therefore, future studies should address the relative effectiveness of the combination interventions including ear acupuncture.
3. Among the included studies, studies on pain after trauma were lacking. Pain associated with PTSD is an important clinical problem, and psychotherapy has limitations in such pain management.^[55] Thus, we hypothesized that ear acupuncture would complement these shortcomings, but could not draw conclusions due to the lack of included studies. In future studies, ear acupuncture should be investigated for features that complement existing treatments, particularly those associated with pain conditions after trauma.
4. Interestingly, in the included studies, acupoints used for ear acupuncture were similar, regardless of the country in which they were performed. However, a unified strategy is still required to systematically establish the evidence of ear acupuncture. The authors believe that the NADA protocol, consisting of *Shenmen*, *Sympathetic*, *Kidney*, *Liver*, and *Lung*, points can be promising because of the already established cooperating organizations internationally, such as the Acupuncture Without Borders.
5. Although our pre-defined protocol^[30] initially did not include insomnia-related outcomes, their importance was recognized during the study and the effects of ear acupuncture in insomnia

patients with or without diagnosed PTSD as secondary outcomes was analyzed.

This undoubtedly suggests that the author's attitude may have influenced our findings and it may have caused a reporting bias. Future researchers should design the study of ear acupuncture in disaster, considering that insomnia is an important clinical issue for survivors with or without diagnosed PTSD after a disaster.

In conclusion, this systematic review found limited evidence suggesting the benefits of ear acupuncture for trauma-related mental disorders after large-scale disasters. Since the number of studies involved was small and heterogenous, we could not draw conclusions about its effectiveness and safety. Some studies have described successful cases of ear acupuncture education and practitioner training in disaster-affected communities. As one of the medical resources available after large-scale disasters, ear acupuncture still needs to be studied further. Registry studies aimed at investigating the results of ear acupuncture at disaster sites may be considered.

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