Pharmacologic and Nonpharmacologic Treatments for Posttraumatic Stress Disorder: 2023 Update of the Evidence Base for the PTSD Trials Standardized Data Repository
Systematic Review

Pharmacologic and Nonpharmacologic Treatments for Posttraumatic Stress Disorder: 2023 Update of the Evidence Base for the PTSD Trials Standardized Data Repository

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None of the investigators have any affiliations or financial involvement that conflicts with the material presented in this report.

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Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of healthcare in the United States. The U.S. Department of Veterans Affairs requested this report from the EPC Program at AHRQ. AHRQ assigned this report to the following EPC: Pacific Northwest Evidence-based Practice Center (Contract Number: 75Q80120D00006).

The reports and assessments provide organizations with comprehensive, evidence-based information on common medical conditions, and new healthcare technologies and strategies. This evidence report provides an overview of key issues related to the interventions included—for example, current indications, relevant patient populations and subgroups of interest, outcomes measured, and contextual factors that may affect decisions regarding the intervention. The report includes data abstracted from published randomized controlled trials on interventions for posttraumatic stress disorder. These data were adapted to support the development of a publicly available repository by the National Center for Posttraumatic Stress Disorder (NCPTSD).

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for healthcare quality improvement projects throughout the Nation. The reports undergo peer review and public comment prior to their release as a final report.

AHRQ expects that the EPC evidence reports and technology assessments, when appropriate, will inform individual health plans, providers, and purchasers as well as the healthcare system as a whole by providing important information to help improve healthcare quality.

If you have comments on this systematic review, they may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857, or by email to epc@ahrq.hhs.gov.

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Technical Expert Panel
In designing the study questions and methodology at the outset of this report, the EPC consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicted opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, methodologic approaches, and/or conclusions do not necessarily represent the views of individual technical and content experts.

Technical Experts must disclose any financial conflicts of interest greater than $5,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

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Pharmacologic and Nonpharmacologic Treatments for Posttraumatic Stress Disorder: 2023 Update of the Evidence Base for the PTSD Trials Standardized Data Repository

Structured Abstract

Objectives. Identify and abstract data from randomized controlled trials (RCTs) examining treatment for posttraumatic stress disorder (PTSD) and comorbid PTSD/substance use disorder to update the previous Agency for Healthcare Research and Quality (AHRQ) report on this topic and the National Center for PTSD (NCPTSD) PTSD Trials Standardized Data Repository (PTSD-Repository) with newly published trials.

Data sources. We searched PTSDpubs, Ovid® MEDLINE®, Cochrane CENTRAL, PsycINFO®, Embase®, CINAHL®, and Scopus® for eligible RCTs published from August 1, 2021, to March 3, 2023.

Review methods. In consultation with AHRQ and NCPTSD, we updated the evidence tables for the PTSD-Repository by including evidence published after publication of the last update and expanding abstraction of results to include calculated standardized effect sizes. The primary publication for each RCT was abstracted; data and citations from secondary publications (i.e., companion papers) appear in the same record. We assessed risk of bias (RoB) for all included studies using the Revised Cochrane Risk of Bias 2 (RoB 2) tool for randomized trials. For studies already in the PTSD-Repository, we will add calculated standardized effect sizes in a future update.

Results. We added 60 new RCTs examining treatments for PTSD, for a total of 496 included studies published from 1988 to March 3, 2023. Among all 496 included RCTs, studies of psychotherapy interventions were the most common (44%), followed by pharmacologic interventions (19%). Most studies were conducted in the United States (59%) and had sample sizes ranging from 25 to 99 participants (58%). Approximately half of the studies enrolled community (i.e., not specifically military) participants (54%), and most were conducted in outpatient settings (78%). Studies typically enrolled participants with a mix of trauma types (51%). Among all 496 included RCTs, RoB was rated as high for 60 percent of studies, 27 percent were rated as having some concerns, and the remaining 14 percent were rated as low RoB.

Among the 60 newly added RCTs, psychotherapy interventions were the most commonly employed (40%), followed by complementary and integrative health (10%). Approximately half of the studies were conducted in the United States (53%), and enrolled community participants (53%) and participants with a mix of trauma types (53%). Studies typically had sample sizes ranging from 25 to 99 participants (53%). Of the newly added RCTs, RoB was rated as high for 67 percent of studies, 17 percent were rated as having some concerns, and the remaining 17 percent were rated as low RoB.
Conclusions. This report updates the previous AHRQ report to include 60 recently published RCTs, for a total of 496 studies. This update adds comprehensive data, standardized effect sizes for PTSD outcomes, and RoB assessment for the newly included RCTs. As with the previous AHRQ update, this report will serve as the updated evidence base for the PTSD-Repository, a comprehensive database of PTSD trials.
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Executive Summary

Main Points

- This update adds 60 newly published randomized controlled trials (RCTs) on posttraumatic stress disorder (PTSD) and comorbid PTSD/substance use disorder (SUD) to the previous Agency for Healthcare Research and Quality (AHRQ) report on this topic and the National Center for PTSD (NCPTSD) PTSD Trials Standardized Data Repository (PTSD-Repository); the new total of included RCTs is 496.
- Across all 496 RCTs:
  - The most commonly studied intervention was psychotherapy (44%), followed by pharmacologic interventions (19%), and complementary and integrative health (6%); 7 percent of studies used both pharmacologic and psychotherapeutic interventions.
  - Overall, most studies were conducted in the United States (59%) and had sample sizes in the range of 25 to 99 participants (58%), with a relatively small number of studies enrolling more than 200 participants (8%).
  - Data on race was reported in 57 percent of studies and ethnicity in 31 percent; 42 percent did not provide information on race or ethnicity.
  - Almost a third of studies (32%) targeted specific types of trauma; combat-related trauma was the most commonly targeted (15% of all studies), followed by terrorism/political violence/forced displacement (5%) and accidents (2%); 51 percent allowed a mix of trauma types, and 17 percent did not provide information on participant trauma types.
- Across the 60 newly added RCTs:
  - The most commonly studied intervention was psychotherapy (40%), followed by complementary and integrative health (10%) and nonpharmacologic biologic interventions (8%); 8 percent of studies used both pharmacologic and psychotherapeutic interventions.
  - Just over half of the newly added RCTs were conducted in the United States (53%), enrolled community (not specifically military) participants, and had sample sizes in the range of 25 to 99 participants (53%); a relatively small number of studies enrolled more than 200 participants (7%).
  - 20 percent of studies targeted a specific trauma type, and about half of studies allowed a mix of trauma types (53%); 27 percent did not provide information on participant trauma types.
- This update also includes risk of bias (RoB) using the updated Cochrane RoB 2 tool for randomized trials for all 496 included RCTs.
  - Across all 496 RCTs, RoB was rated as low RoB for 14 percent, some concerns for 27 percent, and high for the remaining studies (60%).
  - Of the 60 newly added RCTs, RoB was rated as low RoB for 17 percent, some concerns for 17 percent, and high for the remaining studies (67%).

Background and Purpose

PTSD is a disorder that results from being exposed to a traumatic event. People with PTSD have symptoms such as flashbacks, avoidance of trauma-related stimuli, negative beliefs about themselves and/or others, and hypervigilance. These symptoms reduce quality of life and
function. The purpose of this report is to update the previous AHRQ report\(^1\) by identifying and abstracting data from newly published RCTs examining treatment for PTSD and comorbid PTSD/SUD: this project builds upon our previous work.\(^2\,^3\,^4\) These data will inform the subsequent update and expansion of the PTSD-Repository (a publicly accessible clinical trials database maintained by the NCPTSD).\(^5\) A comprehensive data repository allows future systematic reviews to easily identify includable studies and extract data relevant to their review. The PTSD-Repository can also help identify research gaps to determine future research priorities and encourage researchers to adopt standard data elements in research and reporting. In addition, it can serve as a source for patients, clinicians, and policymakers to search for evidence on the effectiveness of specific interventions and augment existing patient education tools.

**Methods**

We followed methods outlined in the AHRQ Evidence-based Practice Center Program Methods Guidance (https://effectivehealthcare.ahrq.gov/topics/cer-methods-guide/overview) where applicable.\(^6\) For this update, we searched PTSDpubs (formerly PILOTS), Ovid\(^\circ\) MEDLINE\(^\circ\), Cochrane CENTRAL, PsycINFO\(^\circ\), Embase\(^\circ\), CINAHL\(^\circ\), and Scopus\(^\circ\) for eligible RCTs published from August 1, 2021, to March 3, 2023. We dually reviewed citations from the literature search and potentially includable full-text articles for eligibility, resolving disagreement by consensus. We developed evidence tables for the prior updates\(^1\,^2\) and for this update; one team member abstracted data from included RCTs into these evidence tables and a second reviewer checked for accuracy and completeness. An investigator assessed RoB for newly added studies using Cochrane’s RoB 2: A Revised Tool for Assessing Risk of Bias in Randomized Trials,\(^7\) and a second reviewer checked for accuracy. For studies included prior to our implementation of RoB 2 (k=388), an investigator reassessed a subset of the 388 studies using RoB 2 and a second reviewer checked for accuracy. We provide summary statistics for RoB 2 assessment of all 496 studies in this update.

**Results**

In this update, we added 60 RCTs examining treatments for PTSD for a total of 496 included RCTs overall. The updated report now includes 136 pharmacologic studies (trials with at least one medication arm) and 360 nonpharmacologic studies (trials with no medication arms). The 496 trials were published from 1988 to 2023. Across all 496 RCTs, the most commonly studied intervention was psychotherapy (44%), followed by pharmacologic interventions (19%), and complementary and integrative health (6%); 7 percent of studies used both pharmacologic and psychotherapeutic interventions. Overall, most studies were conducted in the United States (59%), and enrolled community (i.e., not specifically military) populations (54%). A total of 42,467 participants are represented; sample sizes ranged from 8 to 943 with most studies (58%) enrolling 25 to 99 participants. Across all 496 RCTs, RoB was rated as low RoB for 14 percent, some concerns for 27 percent, and high for the remaining studies (60%).

Among the 60 newly added RCTs, psychotherapy interventions were the most commonly employed (40%), followed by complementary and integrative health (10%). About half of studies were conducted in the United States (53%), enrolled community participants (53%), and enrolled participants with a mix of trauma types (53%). The newly added studies had sample sizes ranging from 20 to 916, with most studies having a sample size between 25 and 99 participants (53%). The Clinician-Administered PTSD Scale (CAPS) and the PTSD CheckList (PCL) were measures most frequently used to assess continuous PTSD outcomes, used in 40
percent and 39 percent of studies, respectively. PTSD diagnostic change or clinically meaningful response were assessed in 50 percent of studies. Among non-PTSD outcomes, depression was the most commonly assessed (60% of the newly added studies). Of the 60 newly added RCTs, 67 percent were rated as high RoB, 17 percent were rated as some concerns, and 17 percent were rated as low RoB.

Limitations

Study inclusion was limited to studies published in English. Many data elements were not reported or were reported in an inconsistent manner across the available body of literature. Data elements that were infrequently reported include the number of participants with a history of traumatic brain injuries, SUD, or suicidal ideation/behavior, and mean number of trauma types per participant.

Implications and Conclusions

This report updates the previous AHRQ report on this topic\(^1\) with comprehensive data, calculated standardized effect sizes for PTSD outcomes, and RoB assessment from 60 recently published trials. This update also includes RoB assessment for all 436 previously included studies. As with the previous AHRQ reports on this topic,\(^1,2,3\) this update will be used by NCPTSD to inform updates to the PTSD-Repository, a publicly available PTSD trials database (accessible at [https://www.ptsd.va.gov/ptsdrepository/index.asp](https://www.ptsd.va.gov/ptsdrepository/index.asp)) that allows clinical, research, education, and policy stakeholders to understand current research on treatment effectiveness and harms, and enables these stakeholders to more quickly and accurately make informed decisions about future research, mental health policy, and clinical care priorities. These updates ensure that all available evidence is included and accessible for a broad range of users. Updating RoB assessment to the same scale for all studies and adding standardized effect sizes will allow for more efficient and accurate comparisons across PTSD trials.

References


1. Introduction

1.1 Background

Posttraumatic stress disorder (PTSD) is a prevalent disorder with significant negative impacts on health, quality of life, and healthcare utilization. Lifetime prevalence of PTSD is estimated to be between 3.4 and 8.0 percent in U.S. civilians and 7.7 to 13.4 percent in U.S. military veterans. Individuals with PTSD are often more likely to experience other mental health comorbidities compared to those without, particularly substance use. For example, studies estimate that around one quarter to one half of individuals who have experienced PTSD in their lifetime also met criteria for a substance use disorder.

Since PTSD was first included by the Diagnostic and Statistical Manual of Mental Disorders, third edition (DSM-III) in 1980, there have been over 400 published randomized controlled trials (RCTs) evaluating a wide range of treatments and treatment modalities (e.g., psychotherapy, psychopharmacotherapy, complementary and integrative approaches, etc.). Many systematic reviews also aim to include nonrandomized comparative studies, which likely number in the thousands. Given the large and varied body of evidence, to make reviews on this topic feasible, even some of the most comprehensive systematic reviews on PTSD have excluded some intervention types (e.g., complementary and integrative approaches) due to the prohibitively large number of studies that would have to be reviewed. Without a comprehensive database containing all published RCTs on PTSD, clinicians and researchers may need to consult multiple reviews in order to synthesize evidence across studies and evaluate the effectiveness and comparative effectiveness of treatments. In addition, heterogeneity of review methods, scope, and data presentation make it difficult to synthesize across reviews and have led to variation in conclusions. Methodological differences, such as data coding approaches and combining treatment categories for analysis, further limit the comparability of findings.

1.2 Purpose and Scope

Answering important clinical questions about PTSD treatments requires the examination of all available data, yet existing systematic reviews do not make this logistically easy, and they may intentionally exclude important treatments due to resource constraints. Furthermore, even when abstracted data are made publicly available, they may be presented in a format that does not readily lend itself to re-analysis without reformatting or re-entry. Hence, there is a need for a single source that provides up-to-date, detailed, comprehensive data on existing PTSD trials to better address current clinical, research, and policy stakeholders’ needs. To address this need, the PTSD Trials Standardized Data Repository or “PTSD-Repository” was created to: (1) serve as a data source for future systematic reviews, meta-analyses, or other cross-study comparisons; (2) help identify research gaps to determine future research priorities; (3) encourage researchers to adopt standard data elements in research and reporting; (4) serve as a source for clinicians seeking information on effectiveness of interventions for patients with particular demographics or exposures; (5) provide the public a source to search for evidence on interventions they or their loved ones are considering; (6) provide policymakers with an up-to-date accounting of evidence to respond to inquiries; and (7) augment and inform the use of existing patient education tools such as PTSD mobile applications or the online PTSD Treatment Decision Aid. The Department of Veterans Affairs’ National Center for PTSD (NCPTSD) partnered with the
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Agency for Healthcare Research and Quality (AHRQ) to develop the evidence tables that form the basis of the PTSD-Repository.

The initial development of the evidence tables and subsequent update have been detailed elsewhere. The purpose of this update review, and the three earlier AHRQ reviews, is to search the literature to identify and abstract data from RCTs examining treatment for PTSD and comorbid PTSD/substance use disorder (SUD) to inform the PTSD-Repository. This publicly accessible clinical trials database is maintained by NCPTSD and available at https://www.ptsd.va.gov/ptsdrepository/index.asp. The initial 2018 report identified 318 studies. The second report was an update to the evidence, published in 2020, with expansion of the inclusion criteria (including adding studies focused on treating comorbid PTSD-SUD on the recommendation of the Technical Expert Panel and NCPTSD) and extension of the search dates to include newly published studies, bringing the total number of included studies to 389. The third report, published in 2022 added 48 studies to the database for a total of 437 included studies. This current update builds on the prior AHRQ reports by adding 60 newly published RCTs, as well as making minor updates to the database for all studies such as adding detailed information on inclusion and exclusion criteria for all included studies. Specifically, this report updates the database to include RCTs of PTSD interventions published from August 1, 2021 through March 3, 2023 (studies published since the completion of the last update). Because one trial previously included was found to be ineligible (due to ineligible study design) and removed, the database now includes a total of 496 RCTs.

As in the previous update, this update used the Cochrane RoB 2 tool to assess RoB (risk of bias) for the newly included studies. In addition, the RoB 2 assessment was completed for all remaining studies in the database, and therefore all 496 included studies have RoB assessed using the same Cochrane RoB 2 assessment.

1.3 Key Question

Key Question 1. What interventions have been studied for the treatment of PTSD alone or with comorbid SUD?

The Key Question is based on updating the same body of literature included in Technical Brief No. 32 and expanded to include interventions targeting comorbid PTSD/SUD, as examined in Comparative Effectiveness Review No. 235. The PICOTS (populations, interventions, comparators, outcomes, timing, settings, study design) criteria are:

- **Population(s):**
  - Adults (≥18 years old) diagnosed with PTSD by a clinician or through a patient-reported assessment tool

- **Interventions:**
  - Pharmacologic and nonpharmacologic interventions, including complementary and integrative approaches, for treatment of PTSD or comorbid PTSD/SUD

- **Comparators:**
  - Any comparator, including another intervention, waitlist/minimal attention, usual care, or placebo

- **Outcomes:**
1. Introduction

- Overall PTSD outcome, PTSD diagnostic change, PTSD clinically meaningful change
- Other outcomes – Anxiety, anger, depression, function, quality of life, sleep, substance use, suicide- and self-directed violence, withdrawal due to adverse events, serious adverse events

- **Timing:**
  - No limitation on study duration or length of followup

- **Settings:**
  - No limitation on study setting

- **Study Design:**
  - RCTs

1.4 Analytic Framework

Figure 1 depicts the Key Question within the context of the PICOTS inclusion and exclusion criteria presented in Table 1 in the Methods chapter. Figure 1 illustrates how PTSD treatments – including pharmacotherapy, psychotherapy, nonpharmacologic biologic treatments (e.g., biofeedback, vagal nerve stimulation), and complementary and integrative approaches – may be associated with health and functional outcomes (such as PTSD symptoms and diagnosis, substance use, anxiety, depression, and quality of life), as well as how these interventions may be associated with harms.

**Figure 1. Analytic framework for treatments of posttraumatic stress disorder**

Abbreviations: KQ = Key Question; PTSD = posttraumatic stress disorder
2. Methods

This report follows the methods suggested in the Agency for Healthcare Research and Quality (AHRQ) Methods Guide for Effectiveness and Comparative Effectiveness Reviews where applicable to creating a systematic data repository. Methods were determined a priori after discussion with AHRQ and the National Center for PTSD (NCPTSD), and are consistent with methods utilized in our first report and the last update. A protocol was published on the AHRQ website (https://effectivehealthcare.ahrq.gov/products/ptsd-pharm-nonpharm-treatment-update/protocol).

2.1 Criteria for Inclusion/Exclusion of Studies in the Review

Detailed inclusion and exclusion criteria for the Key Question are listed in Table 1 following the PICOTS (populations, interventions, comparators, outcomes, timing, settings, study design) criteria identified above (see Key Question). These inclusion and exclusion criteria are the same as those applied in our previous update report. We included treatments for posttraumatic stress disorder (PTSD) and comorbid PTSD/substance use disorder (SUD). Treatments targeting PTSD and a comorbid condition other than SUD were included as long as the treatment could be used for PTSD alone (i.e., without the presence of the comorbid condition). For example, treatments for PTSD and insomnia were included because sleep difficulties are often part of a standalone PTSD diagnosis, and therefore these treatments could be used for PTSD without the presence of another diagnosis. Similarly, treatments for comorbid PTSD and depression were included if they were appropriate for individuals with a standalone PTSD diagnosis because of the frequency of mood-related impacts of PTSD even without a comorbid diagnosis of depression.
## 2. Methods

<table>
<thead>
<tr>
<th>PICOTS</th>
<th>Include</th>
<th>Exclude</th>
</tr>
</thead>
</table>
| **Populations** | • Adults (mean age ≥18 years old) with PTSD diagnosed by a clinician or through the administration of a validated clinician-administered or patient-reported assessment tool | • Children (mean age <18 years old) | **Interventions**

- Pharmacologic and/or nonpharmacologic interventions for PTSD or comorbid PTSD/SUD in adults. Interventions can include any pharmacologic component, whether singly, in combination with other treatment categories, or compared with another intervention category, or complementary and integrative approaches, nonpharmacologic biologic treatments, and psychotherapeutic treatments
- Interventions designed to treat insomnia and nightmares related to PTSD

- Interventions designed to simultaneously target PTSD and comorbid conditions other than SUD if they cannot be standalone PTSD interventions (i.e., interventions targeting PTSD and a comorbidity such as depression are included if the intervention can be a treatment for PTSD alone). Interventions designed to prevent PTSD, treat self-stigma, or facilitate posttraumatic growth are excluded unless they are designed to treat PTSD directly as well.

| Comparators | • No limitations applied. Direct head-to-head comparison of PTSD interventions were included. | None |

- Interventions such as waitlist/minimal attention, usual care, placebo, or other minimally-active treatment (e.g., education or attention control) are categorized as “Controls”

| Outcomes | • Any overall PTSD outcome | • Studies reporting only individual symptoms or symptom clusters without overall PTSD outcome |

| Timing | • Any study duration and length of followup | None |

| Setting | • All study settings | None |

| Study Design | • RCTs | • Non-RCTs |

- Selected systematic reviews will be considered as reference check sources of studies to be reviewed for possible inclusion (data will be abstracted from individual studies rather than from systematic reviews)
- Partial studies (limited course of treatment), outcome studies (lower dose), experimental treatment manipulations (dismantling)

Abbreviations: PICOTS = populations, interventions, comparators, outcomes, timing, settings, study design; PTSD = posttraumatic stress disorder; RCTs = randomized controlled trials; SUD = substance use disorder

### 2.2 Literature Search

Electronic databases were searched for evidence from August 1, 2021, to March 3, 2023. Literature databases searched included PTSDpubs (formerly PILOTS), Ovid® MEDLINE®, Cochrane CENTRAL, Embase®, the Cumulative Index to Nursing and Allied Health Literature
2. Methods

(CINAHL®, SCOPUS, and PsycINFO®. Search strategies were provided in Appendix A. The search strategies were developed and conducted by the Pacific Northwest Evidence-based Practice Center (EPC) librarian and peer reviewed by a NCPTSD librarian. A gray literature search was not conducted. Due to the nature of the project, a portal for submission of Supplemental Evidence And Data for Systematic review (SEADS) was not opened for this project.

PICOTS (Table 1) were used to determine eligibility for inclusion and exclusion of abstracts. One reviewer determined eligibility at the title/abstract review stage and a second investigator reviewed excluded records. For records included at the title/abstract review stage, full-text articles were retrieved and reviewed independently for eligibility by two reviewers. Disagreements were resolved by consensus of the team of investigators. A record of included studies is available in Appendix B and studies excluded at the full-text level with reasons for exclusion appear in Appendix C.

2.3 Data Abstraction

After studies were screened and deemed to meet inclusion criteria, study data were abstracted, including study design, year, setting, country, sample size, eligibility criteria, source(s) of funding, study characteristics, population characteristics, intervention characteristics, and study results (see Appendix D for a complete list of data elements abstracted). Data were abstracted into detailed evidence tables in Microsoft® Excel developed for the first report13 and revised for the 2020 and 2022 reports15,17 to include additional data elements such as study inclusion/exclusion criteria related to suicide and psychosis, proportion of participants with comorbidities at baseline (e.g., suicidal ideation/behavior, psychotic, personality, and anxiety disorder, and prior hospitalization), results for secondary PTSD outcomes at treatment arm-level, and results for suicide- or self-directed violence-related outcomes including suicidal ideation/behavior. These data elements were abstracted for all included studies and were provided in the evidence tables of the prior reports. In this current update, detailed data on inclusion and exclusion criteria were added to the database for all included studies, including quoted inclusion/exclusion criteria sections pasted directly from the publication.

For the last update,17 the evidence tables were restructured to ensure that future updates to the PTSD-Repository no longer required any hand searching and editing when transforming data from the Microsoft® Excel data tables into the PTSD-Repository online database, and that most, if not all, data integration processes could be automated using replicable syntax. The last update also added calculation of standardized effect sizes for newly included studies, provided the study reported the necessary data, and calculated standardized effect sizes are also provided in this update for newly added studies. Standardized effect size data for previously included studies will be added in future updates. All abstracted data were dual reviewed for accuracy and completeness. Evidence tables are available in Appendix E and Appendix F.

A separate evidence table was constructed to record risk of bias (RoB) assessments, described below. All studies were incorporated in the summarized results presented below, regardless of overall RoB rating.

2.4 Evidence Synthesis

The evidence tables are designed to enable a variety of syntheses that would be of interest to different stakeholders. Results from studies were not synthesized, but characteristics of included
2. Methods

studies including number of publications by year, study sample size, proportion of studies enrolling community versus military/veteran populations, and distribution of studies by PTSD assessment method, were summarized using simple counts and proportions.

2.5 Standardized Effect Size Calculation

Meta-analysis was not performed. To facilitate user syntheses, standardized effect sizes were calculated for continuous PTSD outcomes for newly included studies, provided the necessary data was reported in the study. Future updates will add calculated standardized effect sizes for all previously included studies. To facilitate comparison across studies and across outcomes, a within-arm effect size was calculated using the formula in Figure 2, as an analog of Cohen’s $d$. Hedge’s $g$ was used as the standardized effect size for between-arm comparisons. Hedge’s $g$ was calculated based on adjusted mean difference, if reported. Otherwise, it was calculated based on followup scores or change scores, with followup scores preferred. We preferred followup scores because they have been shown to be more conservative when combining randomized controlled trials (RCTs) compared to placebo when baseline scores show some evidence of imbalance. When baseline scores are balanced, the followup score and change score provide similar results. For studies not reporting standard deviation, it was calculated from 95 percent confidence interval whenever reported. All analyses were performed using R (version 4.1.0).

Figure 2. Within-arm effect size formula

$$d = \frac{Mean_{followup} - Mean_{baseline}}{s}$$

Where, $s = \sqrt{s_{baseline}^2 + s_{followup}^2 - 2 \times corr \times s_{baseline} \times s_{followup}}$

Assuming correlation = 0.5 and $N_{baseline} = N_{followup}$

2.6 Assessment of Methodological Risk of Bias of Individual Studies

Because previously-included studies from prior reports were assessed with an earlier version of Cochrane’s RoB assessment tool based on the AHRQ Methods Guide for Effectiveness and Comparative Effectiveness Review, we updated RoB assessments for all newly included RCTs in this report as well as all prior RCTs included in previous reports. All RCTs in this report are now assessed using Cochrane’s RoB 2 system, ensuring that all studies in the database now use the same, gold standard RoB 2 assessment. To clarify aspects of the RoB assessments, and to ensure transparency and ease of future updating, we included detailed definitions related to how RoB was assessed and clearly described cutoff values (e.g., for attrition) applied when implementing the Cochrane RoB 2 system. We also abstracted RoB-related data into additional columns to document the overall percent of primary PTSD outcome assessment data that was missing (i.e., overall attrition from measurement) and the percent primary PTSD outcome data in each arm of the study of missing that was missing (i.e., differential attrition from measurement). Appendix G contains RoB assessments: 60 newly
2. Methods

included studies assessed using RoB 2 (Appendix Table G-1); and 436 previously included studies assessed using RoB 2 (Appendix Table G-2).

2.7 Grading the Strength of Evidence for Major Comparisons and Outcomes

Strength of evidence was not assessed for this review.

2.8 Assessing Applicability

Applicability was not assessed for this review.

2.9 Peer Review and Public Commentary

Experts in the field of PTSD were invited to provide external peer review of this review and evidence tables. Comments and editorial review were also sought from the AHRQ Task Order Officer, an associate editor, and partners at NCPTSD. In addition, the draft report was posted on the AHRQ website for 4 weeks to elicit public comment. In response to reviewers’ comments, we revised text as needed and addressed all relevant reviewer comments in an associated disposition of comments report with the authors’ individual responses.
3. Results

3.1 Results of Literature Search

In this update we included 60 new studies\textsuperscript{21-80} published through March 3, 2023, bringing the total number of included studies in this report to 496 (in 784 publications). The literature flow diagram (Figure 3) summarizes the search and selection of articles performed previously in prior reports in addition to this update to provide a comprehensive overview of all included studies. Combining all database searches and other sources yielded 14,369 unique records. After review of abstracts and titles, 2,138 articles were selected for full-text review, and 496 studies were determined to meet inclusion criteria and were designated for data abstraction. Reasons for exclusion of studies were ineligible population, intervention, outcomes, study design, publication type, and foreign language articles. Appendix B contains the list of studies that met inclusion criteria; Appendix C lists studies excluded upon full-text review and reasons for exclusion.
3.1 Results, Results of Literature Search

Figure 3. Literature flow diagram (summary of all included studies)

- Records identified through database search (n=17,028)
- Additional records identified through other sources* (n=444)
- Records identified in database update search (n=18,636)

Records after duplicates removed (n=14,369)

Records screened (n=14,369) ➔ Records excluded (n=12,231)

Full-text articles assessed for eligibility (n=2,138) ➔ Full-text articles excluded, with reasons (n studies=1,354)
- Ineligible population, n=557
- Ineligible intervention, n=90
- Ineligible comparison, n=12
- Ineligible outcome, n=138
- Ineligible study design, n=216
- Ineligible publication type, n=331
- Non-English language, n=10

Studies included (n studies=496 in 784 publications)

*Other sources include prior reports, reference lists of relevant articles, systematic reviews, etc.
†In this update report, 60 new trials (in 62 publications) were included and 1 study included in the prior report was excluded.
3.2 Characteristics of Included Studies

Interventions were first classified by treatment focus: Posttraumatic stress disorder (PTSD), PTSD and substance use disorder (SUD), SUD, Active control, or Inactive control. In this classification, each arm was classified into a single category. Control arms were categorized based on the intervention and study design. Interventions without an active treatment component, such as waitlist or placebo, are coded as inactive control. Intervention arms being used to control for active components of another treatment are coded as Active control if there is expected to be some active effect but less than the main treatment (e.g., superiority trials). For example, for a trial comparing prolonged exposure versus psychoeducation, with a superiority design hypothesizing larger effect with prolonged exposure, the psychoeducation arm would be coded as Active control. Treatments for PTSD in trials with a noninferiority design will have both intervention arms coded as PTSD.

Treatments were classified by the intervention categories described in Table 2. These categories included pharmacologic treatments and five nonpharmacologic treatment categories, which are psychotherapy, nonpharmacologic biologic treatments, nonpharmacologic cognitive therapy, complementary and integrative health, and collaborative care, plus inactive control. Study arms coded as Active control for treatment focus above, are categorized corresponding to the actual components of the treatment for intervention category. Using the same example as above, the prolonged exposure arm (coded as PTSD for treatment focus above) would be categorized as psychotherapy, and the psychoeducation arm (coded as Active control for treatment focus) would also be categorized as psychotherapy. Each treatment arm was classified; an arm could have more than one intervention category because a treatment could include interventions falling into different categories. For example, a study that evaluated a combined psychotherapy and pharmacotherapy intervention versus waitlist would have the first arm classified as both psychotherapy and pharmacotherapy, and the second arm as inactive control.
### 3.2 Results, Characteristics of Included Studies

#### Table 2. Intervention categories with examples

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacotherapy</td>
<td>Medication</td>
<td>Antiadrenergic drugs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Antidepressants</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Antipsychotics</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Benzodiazepines</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Cannabinoids</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mood Stabilizers</td>
</tr>
<tr>
<td>Nonpharmacologic Biologic</td>
<td>Interventions that use a medical device or procedure of some kind.</td>
<td>Electroconvulsive therapy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hyperbaric oxygen therapy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Repetitive transcranial magnetic stimulation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stellate ganglion block</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Vagal nerve stimulation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Neurofeedback</td>
</tr>
<tr>
<td>Complementary and Integrative Health</td>
<td>Wide category of approaches that are considered to be outside the standard in the current practice of Western medicine.</td>
<td>Acupuncture</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clinical hypnosis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Meditation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Massage therapy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Natural products</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Tai chi/qi gong</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Yoga</td>
</tr>
</tbody>
</table>
### 3.2 Results, Characteristics of Included Studies

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychotherapy</td>
<td>Talk therapy with a licensed provider</td>
<td>Cognitive Processing Therapy, Eye Movement Desensitization and Reprocessing, Cognitive Behavioral Therapy, Narrative Exposure Therapy, Present-centered therapy, Prolonged Exposure</td>
</tr>
<tr>
<td>Nonpharmacologic Cognitive</td>
<td>Interventions that teach cognitive skills to improve attention.</td>
<td>Attention bias modification, Attention control training</td>
</tr>
<tr>
<td>Collaborative Care</td>
<td>Interventions in which integrated medical and mental health treatment is delivered in primary care, often by nurse managers.</td>
<td>Centrally assisted collaborative telecare, Three component model, Trauma-informed collaborative care</td>
</tr>
<tr>
<td>Other</td>
<td>Treatments that don’t fit into another category</td>
<td>Animal-assisted, Other physical activity and recreational therapies, Digital interventions not delivered by a licensed provider</td>
</tr>
<tr>
<td>Inactive Control</td>
<td>Interventions which are essentially inactive or are not presumed to have an effect on mental health symptoms</td>
<td>Waitlist, Placebo, Assessment only</td>
</tr>
</tbody>
</table>

*Table 2 intervention lists and categories adapted from the 2017 Department of Veterans Affairs/Department of Defense clinical practice guideline.84*
3.2.1 Overall Studies Included in the Evidence Tables

The data abstraction evidence tables (Appendix E and Appendix F) for this report present detailed information on study and population characteristics for the 496 total included studies. Across included studies, comorbid PTSD/SUD was the focus for 3 percent of treatment arms and less than 1 percent focused on SUD (Figure 4). Fifty-four percent of treatment arms addressed PTSD and 18 percent were Active Controls; 24 percent were Inactive control arms.

Figure 4. Summary of all included studies: distribution of treatment arms by treatment focus*

* Studies have more than one treatment arm.
Abbreviations: PTSD = posttraumatic stress disorder; SUD = substance use disorder
3.2.1 Results, Characteristics of Included Studies, Overall Studies Included in the Evidence Tables

The distribution of treatment arms by intervention category is shown in Figure 5. Psychotherapy was the most frequently studied treatment, employed in 46 percent of total treatment arms, followed by pharmacotherapy in 17 percent of treatment arms.

Figure 5. Summary of all included studies: distribution of treatment arms by intervention category*

* Studies have more than one treatment arm. Counts for these categories sum to greater than the total of 1,094 treatment arms in the included studies since some treatment arms combine multiple interventions of different categories. For example, one treatment arm could combine a psychotherapy treatment with a pharmacotherapy treatment. Thus each category would count for one within this single arm.
3.2.1 Results, Characteristics of Included Studies, Overall Studies Included in the Evidence Tables

Studies were grouped into ten study classes based on interventions studied. For studies in which the treatment arms were all the same category, or compared with a treatment arm categorized as inactive control, the study was categorized as the study class of the active treatment(s). For example, a study of prolonged exposure (psychotherapy) versus waitlist (inactive control) would be categorized as psychotherapy for the study class. The category Other study class includes studies of interventions classified as Other for intervention category. Studies in which the treatment arms were of different intervention categories were classified into a combination category for study class, for the most common combinations (i.e., psychotherapy and pharmacotherapy, and psychotherapy and complementary and integrative health [CIH]). Other combinations were grouped in the Other mixed study class.

Psychotherapy was the most commonly studied intervention (44% of studies), followed by pharmacotherapy interventions (19%), and combined psychotherapy and pharmacotherapy (7%) (Figure 6).

Figure 6. Summary of all included studies: distribution of included publications by study class

Other mixed includes studies in which the interventions studied were a combination other than psychotherapy & pharmacotherapy or psychotherapy & CIH (e.g., nonpharmacologic biologic & psychotherapy). Other study class includes studies of interventions classified as Other for intervention category.

Abbreviations: CIH = complementary and integrative health
3.2.1 Results, Characteristics of Included Studies, Overall Studies Included in the Evidence Tables

The publication dates of the included studies ranged from 1988 to partway through 2023 (Figure 7). Forty-two studies were published in 2021, the highest amount of any year. The number of studies published per year increased in the 2000s then again in the 2010s. Most studies of CIH interventions were published in the last ten years, a trend also observed with studies of nonpharmacologic biologic treatments.

Figure 7. Summary of all included studies: distribution of included publications by year*

* 2023 is a partial year (search date was through March 2023).
3.2.1 Results, Characteristics of Included Studies, Overall Studies Included in the Evidence Tables

The majority of studies (59%) were conducted in the United States (Figure 8), though it is important to note that inclusion eligibility required that the study was published in English.

Figure 8. Summary of all included studies: distribution of included studies by country

Multiple = study conducted in multiple countries. Only the eight countries with largest number of studies were included in this graph, studies conducted in the remaining countries are counted in “Other/Multiple”.

Abbreviations: U.K. = United Kingdom; U.S. = United States
3.2.1 Results, Characteristics of Included Studies, Overall Studies Included in the Evidence Tables

There was no restriction on sample size for study inclusion. Sample sizes across included studies ranged from 8 to 943 participants, with a total of 42,467 participants included in the database. The median sample size was 56 (interquartile range [IQR] 31 to 101). A little over half of studies (58%) had sample sizes in the range of 25 to 99 participants and a relatively small number of studies (15%) enrolled fewer than 25 participants (Figure 9).

Figure 9. Summary of all included studies: studies by sample size
3.2.1 Results, Characteristics of Included Studies, Overall Studies Included in the Evidence Tables

The sample mean age ranged from 18 to 71 years (median 40 years). Most studies were conducted in younger populations (Figure 10). The sample mean age was 30 to <45 years for 63 percent of studies, while about a quarter of studies had sample mean age from 45 to <60 years (23%); five percent of studies did not provide mean age for the sample.

Figure 10. Summary of all included studies: studies by mean age
3.2.1 Results, Characteristics of Included Studies, Overall Studies Included in the Evidence Tables

Most studies enrolled both female and male participants, at varying proportions (Figure 11). About a quarter of studies included only one sex: 14 percent (67 studies) included only female participants and 11 percent (56 studies) included only male participants. A small number (22 studies, 4%) did not report sex of the participants. Ten studies (2%) reported data for gender identity and/or sexual orientation of the sample.

Figure 11. Summary of all included studies: studies by participant sex

- **Sex not reported**: 22 studies
- **0%**: 56 studies
- **>0% to <25%**: 123 studies
- **25% to <50%**: 55 studies
- **50% to <75%**: 104 studies
- **75% to <100%**: 69 studies
- **100%**: 67 studies
Race and ethnicity data were abstracted according to U.S. Census categories. Because race and ethnicity data were reported in different ways (i.e., grouped into different, non-U.S. Census categories) across many studies, some data were not able to be abstracted because they could not be accurately grouped into U.S. Census categories. Additionally, race and ethnicity data were sometimes reported inconsistently or not reported across some studies. Over half of studies provided data on race that could be grouped into U.S. Census categories (57%), and just under a third provided data on both race and ethnicity (31%); data were not provided for race or ethnicity corresponding to U.S. Census categories in 42 percent of studies (Figure 12).

Figure 12. Summary of all included studies: studies reporting on race and ethnicity
3.2.1 Results, Characteristics of Included Studies, Overall Studies Included in the Evidence Tables

Slightly more studies enrolled participants from a community population (54% of studies) than from a military, veteran, or mixed population (Figure 13). Community samples may or may not include Active Duty Military or veteran participants, as many studies did not clarify these variables when describing community samples. The community population was predominant across trials of most treatment types (psychotherapy, pharmacologic, and nonpharmacologic biologic RCTs); however, for CIH, most studies (55%; 17 of 31 studies) were among veterans.

**Figure 13. Summary of all included studies: distribution of included studies by population type**

Mixed = Any combination of active duty military, veteran, and community based samples.
Abbreviations: CIH = complementary and integrative health; k = number of studies; NR = not reported

Only a small proportion of studies (8%, 39 studies) included any participants with subthreshold PTSD. However, studies including more than 20 percent of participants with subthreshold PTSD were excluded from the database according to inclusion/exclusion criteria (i.e., only those with more than 80% of participants with PTSD were included in the database and in this calculation). Most studies (78%) were conducted in the outpatient setting.
3.2.1 Results, Characteristics of Included Studies, Overall Studies Included in the Evidence Tables

Some studies targeted specific types of trauma (e.g., required participants to have experienced combat-related trauma or sexual assault), though in most cases other additional trauma types were allowed (i.e., most studies did not target specific types of trauma and included participants with a mix of trauma types). The distribution of included studies by trauma type are shown in Figure 14, with mixed trauma types being most prevalent among these study populations (51%), followed by combat-related trauma (15%).

**Figure 14. Summary of all included studies: distribution of included studies by trauma type**

- Mixed: 254
- Combat-related: 74
- Terrorism/political violence/forced displacement: 24
- Accidents: 12
- Natural or manmade disasters: 10
- Child sexual abuse: 7
- Rape/sexual assault: 7
- Intimate partner violence: 7
- MST: 4
- Illness/medical procedure: 3
- Other: 12
- NR: 82

Notes: Active Duty member reporting sexual assault outside of military was categorized as rape/sexual assault. Intimate partner violence includes domestic violence. Accidents includes motor vehicle accidents, transportation-related accidents, and accidents due to construction. Natural or manmade disasters includes tornadoes, hurricanes, wildfires, earthquake, drought, and chemical spills. Mixed indicates multiple trauma types were targeted/included (e.g., a study which included participants with either child sexual abuse or rape/sexual assault would be classified as mixed).

Abbreviations: NR = not reported; MST = military sexual trauma
3.2.2 Studies Added in This Update

Key characteristics for the 60 studies added in this update are described in Tables 3-5. Table 3 provides study and sample characteristics. Table 4 details characteristics of the interventions. Table 5 provides a list of outcomes for each of the studies. Additional information about these studies is included in the detailed data abstraction evidence tables in Appendix E.
### 3.2.2 Results, Characteristics of Included Studies, Studies Added in This Update

#### Table 3. Summary of newly included studies: study and sample characteristics

<table>
<thead>
<tr>
<th>Author, Year</th>
<th>Study Class</th>
<th>Sample Size</th>
<th>Countries</th>
<th>Clinical Setting</th>
<th>Military Status</th>
<th>Race/Ethnicity Reported</th>
<th>Trauma Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abdallah, 2022</td>
<td>Pharmacotherapy</td>
<td>158</td>
<td>U.S.</td>
<td>Outpatient clinic</td>
<td>Mixed</td>
<td>Race and Ethnicity data reported</td>
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<td>U.S.</td>
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<tr>
<td>Acierno, 2021</td>
<td>Psychotherapy</td>
<td>136</td>
<td>U.S.</td>
<td>Outpatient clinic</td>
<td>Veteran</td>
<td>Race and Ethnicity data reported</td>
<td>MST</td>
</tr>
<tr>
<td>Alon, 2022</td>
<td>Nonpharmacologic cognitive</td>
<td>60</td>
<td>Israel</td>
<td>Other</td>
<td>Community</td>
<td>Not reported</td>
<td>Mixed</td>
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<tr>
<td>Baig, 2022</td>
<td>Psychotherapy &amp; pharmacotherapy</td>
<td>20</td>
<td>U.S.</td>
<td>Outpatient clinic</td>
<td>Veteran</td>
<td>Race and Ethnicity data reported</td>
<td>Combat-related</td>
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<tr>
<td>Bisson, 2022</td>
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<td>U.K.</td>
<td>Outpatient clinic</td>
<td>Community</td>
<td>Race data reported</td>
<td>Mixed</td>
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<td>U.K.</td>
<td>Outpatient clinic</td>
<td>Community</td>
<td>Not reported</td>
<td>Terrorism/political violence/forced displacement</td>
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<td>20</td>
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<td>Mixed</td>
<td>NR</td>
<td>Race data reported</td>
<td>Mixed</td>
</tr>
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<td>Bryant, 2023</td>
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<td>Australia</td>
<td>Outpatient clinic</td>
<td>Community</td>
<td>Race data reported</td>
<td>Mixed</td>
</tr>
<tr>
<td>Dell, 2022</td>
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<td>138</td>
<td>Australia</td>
<td>Mixed</td>
<td>Not reported</td>
<td>Mixed</td>
<td></td>
</tr>
<tr>
<td>Devilly, 1999</td>
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<td>23</td>
<td>Australia</td>
<td>Outpatient clinic</td>
<td>Community</td>
<td>Not reported</td>
<td></td>
</tr>
<tr>
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<td>192</td>
<td>U.S.</td>
<td>Outpatient clinic</td>
<td>Mixed</td>
<td>Race and Ethnicity data reported</td>
<td>Combat-related</td>
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<td>Veteran</td>
<td>Not reported</td>
<td>Combat-related</td>
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<tr>
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<td>49</td>
<td>U.S.</td>
<td>Outpatient clinic</td>
<td>Community</td>
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<td>NR</td>
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<td>28</td>
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<td>Outpatient clinic</td>
<td>Community</td>
<td>Race data reported</td>
<td>Mixed</td>
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<tr>
<td>ElBarazi, 2022</td>
<td>Psychotherapy &amp; pharmacotherapy</td>
<td>150</td>
<td>Egypt</td>
<td>Outpatient clinic</td>
<td>Community</td>
<td>Not reported</td>
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### 3.2.2 Results, Characteristics of Included Studies, Studies Added in This Update

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<th>Countries</th>
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### 3.2.2 Results, Characteristics of Included Studies, Studies Added in This Update

<table>
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<th>Sample Size</th>
<th>Countries</th>
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<th>Military Status</th>
<th>Race/Ethnicity Reported</th>
<th>Trauma Type</th>
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Abbreviations: CIH = complementary and integrative health; MST = military sexual trauma; NR = not reported; U.K. = United Kingdom; U.S. = United States.
### Table 4. Summary of newly included studies: intervention characteristics

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<tr>
<th>Author, Year</th>
<th>Intervention Group*</th>
<th>Treatment Name</th>
<th>Treatment Focus</th>
<th>Intervention Categorization</th>
<th>Intervention Format</th>
<th>Intervention Delivery Method</th>
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*Each intervention group (study arm) is labeled with a letter (A, B, C) and listed in a separate row, therefore studies are listed in multiple rows. Abbreviations: CBT = cognitive behavioral therapy; CBTi = cognitive behavioral therapy for insomnia; CIH = complementary and integrative health; CPT = cognitive processing therapy; EMDR = eye movement desensitization and reprocessing; FORNET = Forensic Offender Rehabilitation narrative exposure therapy; NA = not applicable; PE = prolonged exposure; PTSD = posttraumatic stress disorder; rTMS = repetitive transcranial magnetic stimulation; STAIR = Skills Training in Affect and Interpersonal Regulation; TAU = treatment as usual
### 3.2.2 Results, Characteristics of Included Studies, Studies Added in This Update

**Table 5. Newly included studies: Type of PTSD outcomes and other reported outcomes**

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Abbreviations: CAPS = Clinician-Administered PTSD Scale; CMS = Civilian Mississippi Scale for PTSD; IES = Impact of Event Scale; MPSS = Modified PTSD Symptom Scale; N = No, data element was not reported for the study; PCL = PTSD Checklist; PDS = Posttraumatic Diagnostic Scale; PSS-I = PTSD Symptom Scale-Interview; PSS-SR = PTSD Symptom Scale-Self-Report; PTSD = posttraumatic stress disorder; Y = Yes, outcome was reported for the study.

Note: cells containing “Y” are shaded green.
3.2.2 Results, Characteristics of Included Studies, Studies Added in This Update

Among the 60 newly included studies, the treatment focus of the interventions was mostly PTSD (57% of treatment arms); 3 arms (2%) focused on comorbid PTSD/SUD, or SUD. Twenty-one percent of treatment arms were an active control while the remaining 19 percent were inactive control arms (Figure 15).

The distribution of treatment arms by intervention category is shown in Figure 16. Psychotherapy was employed in almost half of the treatment arms (48%); other treatments employed included pharmacotherapy (8%), nonpharmacologic biologic interventions (8%), and CIH (8%).

**Figure 15. Summary of newly included studies: distribution of treatment arms by treatment focus***

*Studies have more than one treatment arm.
Abbreviations: PTSD = posttraumatic stress disorder; SUD = substance use disorder.
3.2.2 Results, Characteristics of Included Studies, Studies Added in This Update

Figure 16. Summary of newly included studies: distribution of treatment arms by intervention

*Studies have more than one treatment arm. Counts for these categories sum to greater than the total number of treatment arms in the included studies since some treatment arms combine multiple interventions of different categories. For example, one treatment arm could combine a psychotherapy treatment with a pharmacotherapy treatment. Thus each category would count for one within this single arm.
Almost all the studies (45/60, 75%) examined interventions within a single category versus a control. The predominant intervention studied was psychotherapy treatments (40%), with the remainder of studies classified as CIH (10%), nonpharmacologic biologic (8%), psychotherapy & pharmacotherapy (8%), other study class (7%), pharmacotherapy (5%), nonpharmacologic cognitive (3%), collaborative care (2%), and other mixed (12%) (Figure 17).

**Figure 17. Summary of newly included studies: distribution by study class***

Abbreviations: CIH = complementary and integrative health.
3.2.2 Results, Characteristics of Included Studies, Studies Added in This Update

A total of 6,122 participants were enrolled in the newly included studies, with sample sizes ranging from 20 to 916. The median sample size was 60 (IQR 35 to 136) and most studies (53%) had sample sizes between 25 and 99 participants (Figure 18). There were four studies with over 200 participants. Participants were drawn from the community population in 53 percent of studies, veterans in 22 percent of studies, and Active Duty military in two studies (3%); 12 studies (20%) were in a mixed population (Figure 19). Nearly half of the studies (53%) were conducted in the U.S. Other countries in which at least five percent of studies were conducted are Australia, Israel, The Netherlands, and U.K. (3 studies each).

Figure 18. Summary of newly included studies: distribution of studies by sample size
3.2.2 Results, Characteristics of Included Studies, Studies Added in This Update

Figure 19. Summary of newly included studies: distribution of studies by population type

<table>
<thead>
<tr>
<th>Population Type</th>
<th>Number of Studies</th>
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<tr>
<td>Veteran</td>
<td>13</td>
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<tr>
<td>Mixed</td>
<td>12</td>
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<td>Active Duty Military</td>
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<tr>
<td>Not Reported</td>
<td>1</td>
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</table>
3.2.2 Results, Characteristics of Included Studies, Studies Added in This Update

The sample mean age ranged from 21 to 56 years. Most studies were conducted in younger populations (Figure 20). The sample mean age was 30 to <45 years for 68 percent of studies, while one-fifth of studies had sample mean age from 45 to <60 years (12 studies, 20%). No studies had a sample mean age 60 years or higher, and five percent of studies did not provide mean age for the sample (3 studies).

Figure 20. Summary of newly included studies: studies by mean age
3.2.2 Results, Characteristics of Included Studies, Studies Added in This Update

Most studies enrolled both female and male participants, at varying proportions (Figure 21). Eighteen percent of studies included only one sex: 15 percent (9 studies) included only female participants and 3 percent (2 studies) included only male participants. Three studies (5%) reported data for gender identity and/or sexual orientation of the sample.

Figure 21. Summary of newly included studies: studies by participant sex

<table>
<thead>
<tr>
<th>% Female Sex</th>
<th>Number of Studies</th>
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<tbody>
<tr>
<td>0%</td>
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<tr>
<td>&gt;0% to &lt;25%</td>
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<tr>
<td>25% to &lt;50%</td>
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<tr>
<td>100%</td>
<td>9</td>
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</tbody>
</table>
3.2.2 Results, Characteristics of Included Studies, Studies Added in This Update

Over half of studies reported data on race that could be grouped into U.S. Census categories (58%), and 38 percent provided both race and ethnicity data; data were not provided for race or ethnicity corresponding to U.S. Census categories in 40 percent of the studies (Figure 22).

Figure 22. Summary of newly included studies: studies reporting on race and ethnicity

![Bar chart showing the number of studies reporting on race and ethnicity data.]

- Race and Ethnicity data reported: 23 studies
- Only race data reported: 12 studies
- Only ethnicity data reported: 1 study
- Neither reported: 24 studies
Seven studies limited inclusion to participants who had experienced specific trauma types, and 16 did not provide information on trauma types (Figure 23). The largest number of studies allowed mixed trauma types (32 studies, 53%).

Notes: Active Duty member reporting sexual assault outside of military was categorized as rape/sexual assault. Accidents include motor vehicle accidents, transportation-related accidents, and accidents due to construction. Mixed indicates multiple trauma types were targeted/included (e.g., a study which included participants with either child sexual abuse or rape/sexual assault would be classified as mixed).
The measure most frequently used to assess continuous PTSD outcomes was the Clinician-Administered PTSD Scale (CAPS), used in 40 percent of studies (Figure 24). Approximately the same number of studies used the PTSD Checklist (PCL) (39%), 7 percent assessed outcomes using the Posttraumatic Diagnostic Scale (PDS), and 6 percent used the Impact of Event Scale (IES).

**Figure 24. Summary of newly included studies: PTSD measures used to assess continuous PTSD outcomes**

*Studies may have used more than one measure to assess PTSD outcomes.

**Abbreviations:** CAPS = Clinician-Administered PTSD Scale; CMS = Civilian Mississippi Scale for PTSD; IES = Impact of Event Scale; MPSS = Modified PTSD Symptom Scale; PCL = PTSD Checklist; PDS = Posttraumatic Diagnostic Scale; PSS-I = PTSD Symptom Scale - Interview; PSS-SR = PTSD Symptom Scale – Self-Report; PTSD = posttraumatic stress disorder.
3.2.2 Results, Characteristics of Included Studies, Studies Added in This Update

Among other (non-PTSD) outcomes (Figure 25), depression was the most commonly assessed (60% of studies), followed by anxiety (33%), quality of life (13%) and function (12%).

Figure 25. Summary of newly included studies: non-PTSD outcomes reported*

*Studies may have reported more than one other outcome type.
Abbreviations: PTSD = posttraumatic stress disorder
3.3 Results, Risk of Bias Assessment

3.3 Risk of Bias Assessment

Risk of bias (RoB) was assessed using Cochrane’s RoB 2 tool, as described in the Methods section. Detailed RoB ratings are presented in Appendix G.

In this update, 60 newly included studies were assessed using Cochrane’s RoB 2 tool for trials (Table 6). The overall risk of bias was assessed as high for 67 percent of studies, some concerns for 17 percent of studies, and low for 17 percent (Figure 26). Studies were rated as high risk of bias mainly due to missing outcome data or measurement of the outcome.

Figure 26. Risk of bias rating for newly included studies (RoB 2 methods)
### 3.3 Results, Risk of Bias Assessment

**Table 6. Newly included studies: risk of bias ratings using Cochrane RoB 2 methods (k=60)**

<table>
<thead>
<tr>
<th>Category of Bias</th>
<th>Bias Due to Randomization (Cochrane) or Selection Bias (AHRQ)</th>
<th>Bias Due to Deviations From Intended Interventions (Cochrane) or Performance Bias (AHRQ)</th>
<th>Bias Due to Missing Outcome Data (Cochrane) or Attrition Bias (AHRQ)</th>
<th>Risk of Bias in Measurement of the Outcome (Cochrane) or Detection Bias (AHRQ)</th>
<th>Bias in Selection of Reported Result (Cochrane) or Reporting Bias (AHRQ)</th>
<th>Overall ROB</th>
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<td>Abdallah, 2022</td>
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3.3 Results, Risk of Bias Assessment

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<td>Yi, 2022</td>
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<td>High</td>
<td>Low</td>
<td>High</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>Youssef, 2022</td>
<td>High</td>
<td>High</td>
<td>Some Concerns</td>
<td>Some Concerns</td>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>Zaccari, 2022a</td>
<td>High</td>
<td>High</td>
<td>High</td>
<td>Low</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Zemestani, 2022</td>
<td>Some Concerns</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
</tr>
</tbody>
</table>

Abbreviations: AHRQ = Agency for Healthcare Research and Quality; ROB = risk of bias
3.3 Results, Risk of Bias Assessment

Note: cells are shaded corresponding to the value: “High” shaded in red, “Some Concerns” in yellow, and “Low” in green.
3.3 Results, Risk of Bias Assessment

All 496 included studies now have RoB 2 assessments: 60 newly included studies (Appendix G-1), plus the 436 previously included studies (Appendix G-2). Of previously included studies, 82 studies were assessed in the previous update, and the remaining 354 were completed in this update.

Across all 496 included studies, RoB was rated as high for 60 percent, some concerns for 27 percent, and low for 14 percent (Figure 27). Figure 28 shows the risk of bias ratings as a percentage of the total studies within each study class. In all study classes, the majority of studies were rated as high risk of bias. Complementary and integrative health had the highest proportion of studies rated as high risk of bias (65%). Similar proportions of studies were rated as high risk of bias in psychotherapy (61%), pharmacotherapy (62%), and other (61%) study classes. Most study classes had between 20 and 30 percent of studies assessed as some concerns (range 23% to 32%). About a quarter of studies (26%) in the psychotherapy and pharmacotherapy study class were rated as low risk of bias, with nonpharmacologic biologic having the next highest proportion of studies with this rating (17%). For studies in all other study classes, 12 to 14 percent were rated as low risk of bias.

Figure 27. Risk of bias rating for all included studies assessed using Cochrane RoB 2 methods
3.3 Results, Risk of Bias Assessment

Figure 28. Risk of bias ratings for all included studies using Cochrane RoB 2 methods by study class

Abbreviations: CIH = complementary and integrative health; k = number of studies
4. Discussion

4.1 Summary and Implications

This report is updated to include detailed data extraction and risk of bias assessments for 60 recently published randomized controlled trials (RCTs) of posttraumatic stress disorder (PTSD) treatments for those with PTSD and comorbid PTSD/substance use disorder (SUD). The updated evidence tables are being used by the National Center for PTSD (NCPTSD) to update the PTSD-Repository, a publicly available trials database accessible at https://ptsd-va.data.socrata.com/ and from the NCPTSD homepage (https://www.ptsd.va.gov/ptsdrepository/index.asp). A total of 496 RCTs are now included with detailed data abstraction and risk of bias (RoB) assessment. RoB assessments were conducted using Cochrane’s RoB 2 tool for trials for the 60 new trials and 436 previously included studies, completing the transition to RoB 2 assessments for all included studies.

The PTSD-Repository serves a variety of clinical, research, and policy purposes, and its recent expansion and release as a Web-based, interactive database is designed to serve a broad range of stakeholders including patients, providers, researchers, and policymakers. As part of these dissemination efforts to a broad range of stakeholders, data visualizations and data stories are available as curated, accessible summaries of key findings from PTSD-Repository trials. These summaries explain how to use the PTSD-Repository data and focus on topics such as “Who Has Been Studied”? These resources provide an accurate, standardized, and up-to-date source for PTSD trial data that can be used in a variety of contexts such as serving as source data for systematic reviews to examine the efficacy of various treatments, quickly informing mental health or government organizations when they are asked to respond to media requests about the state of research on a particular intervention, providing a source of reliable information for researchers identifying research gaps or writing background/rationale sections of grants, and many other purposes. Other such databases in related fields of traumatic brain injury and depression have served these and other purposes and have been used as the basis for numerous publications and grant-funded studies.

Estimated standardized effect sizes for continuous PTSD outcomes were added for newly included studies in this update and in the previous 2022 update. Future updates will include calculated standardized effect sizes for all previously included studies. This will facilitate comparison across trials. However, users of these data are cautioned to carefully consider which studies are appropriate to compare, as the PTSD-Repository includes a diverse group of trials in terms of populations, interventions, comparators, outcomes, timing, and settings studied.

This work developing and updating the evidence tables was undertaken with guidance from NCPTSD and Technical Expert Panels (TEPs). These discussions emphasized how to scope the project, which data elements and studies to abstract and include in future updates, how to maintain data accuracy and relevance in large evidence tables, how to update and conduct risk of bias assessments, and potential next steps for the PTSD-Repository. The TEPs and NCPTSD recommended regular updates in order to keep the PTSD-Repository updated with the most current trial data. Ongoing discussions with the TEPs and NCPTSD have also highlighted the importance of developing a process to refine variable definitions, add variables, adjust the scope (e.g., add studies targeting comorbidities or those including participants meeting a broader definition of PTSD or subthreshold PTSD), and revise data management processes to ensure fluid integration into the Web-based database. Examples of these revisions include recent
4. Discussion

Updates to the ways that suicide-related variables were abstracted and coded, the addition of detailed inclusion/exclusion criteria for each study, and the current process of updating RoB assessments using the newly available, pilot-tested Cochrane RoB 2 tool for randomized trials.

The 60 new included studies identified for this update were published from August 1, 2021 through March 3, 2023. Combined with the first three reports, this overarching project includes studies dating back to 1988.15

The evidence tables (Appendix E and Appendix F) for this report are extensive and far more detailed than typical systematic review evidence tables, reflecting the objective of displaying detailed data elements in a data repository that is designed to be formatted for public availability. We devoted considerable time and attention to developing standard conventions for recording data (e.g., abbreviations, data formatting) and data abstraction instructions to ensure consistent and comprehensive reporting of the many elements of study data being abstracted for this repository. This update includes detailed data from 60 newly published studies of treatments for PTSD or comorbid PTSD and SUDs as well as calculated standardized effect size estimates for PTSD outcomes reported in these trials. Future updates will include calculated standardized effect sizes for the entire body of evidence. We also updated risk of bias assessment using Cochrane’s RoB 2 tool for trials to assess the newly included studies and 354 previously included studies, to provide RoB 2 assessments for all 496 included studies.

Variations in study designs and approaches to reporting presented many challenges to the data abstraction process. For example, some studies reported difference in change from baseline between groups, while others only reported within-group change from baseline or endpoint difference between groups. In some instances, the RCT may have analyzed a primary outcome other than PTSD, such as anxiety or sleep outcomes. However, provided that a study analyzed and reported an overall PTSD outcome, the study was included in the evidence tables. In some instances, distinguishing harms from negative outcomes (e.g., unintended adverse consequences of treatment vs. lack in efficacy of the intervention) was challenging because certain variables (e.g., increased suicidal ideation/behavior) were classified as an outcome in some studies, and as an adverse event in others. To standardize our approach for data entry, suicide attempts and completion were always abstracted as harms; where appropriate data was provided, additional information on other suicide-related data and self-harm was abstracted as outcomes. Many studies of both pharmacologic and nonpharmacologic interventions did not report details about adverse events.

For some data elements, standardization was not possible, and our data abstraction was guided by what the study reported and how the study reported the data (e.g., labeling of control interventions as placebo, usual care, minimal intervention, active placebo, etc.; gender categories and/or sexual orientation; race/ethnicity; current or historical substance use disorder or depression; clinically meaningful response; loss of diagnosis as an outcome); we report qualitative details related to study descriptions of such elements in the evidence tables in columns with the ‘details’ label (Appendix E and Appendix F). Akin to other data elements reported differently across studies, results and effect sizes were inconsistently reported and reported using different statistics in the included studies; therefore, we had to use a variety of methods to calculate comparable, standardized effect sizes depending on data availability across the diverse group of studies, as described in the methods. Lastly, gaps in reporting of certain data elements resulted in many evidence table cells listing ‘not reported’ (NR). Similar gaps in reporting of RoB-related elements also were apparent, particularly in earlier studies. Recognition


4. Discussion

of these gaps may help future researchers to report study methods and results more comprehensively.

Finally, there are also some limitations to the RoB assessment in this report: RoB was assessed by one person and checked for accuracy by another person rather than by a dual independent review and consensus process. This leads to the possibility that systematic differences between raters might be reflected in the ratings. However, the process of updating the RoB assessment to Cochrane’s RoB 2 tool for all RCTs included in the database is now complete. Therefore, all studies include the same, gold standard Cochrane RoB 2 assessment, RoB can be compared across studies since all are now assessed using the same RoB methods, and we have provided RoB summary statistics across all included studies.

4.2 Next Steps

The completion of this project signifies the end of the fourth phase of work and expansion of the PTSD-Repository evidence tables. In this phase, we added newly published RCTs, completed the process of updating all studies to the Cochrane RoB 2 system, added qualitative reporting on inclusion and exclusion criteria for all studies, and continued calculating standard effect sizes for the included studies. The NCPTSD created the Web-based, searchable, interactive PTSD-Repository database, and the current project updates and expands the evidence tables that serve as the foundation for that work.86,90,91

In addition to updates to include newly published RCTs, future additions to the evidence tables have been explored and recommended by the TEP. These future additions could include reporting outcomes for PTSD symptom clusters, item-level data, individual participant-level data, subgroup analyses (e.g., to provide data on what works for whom), participant populations with >20 percent subthreshold PTSD, broader PTSD diagnostic criteria applied for inclusion, interventions designed to prevent PTSD or treat comorbid PTSD and other disorders such as depression, nonrandomized trials that control for important confounders, and qualitative and quantitative synthesis of key outcome data. We base these suggestions on our interaction with the evidence base, the TEP, and NCPTSD.

The PTSD-Repository can (1) serve as a data source for future systematic reviews, meta-analyses, or other cross-study comparisons; (2) help identify research gaps to determine future research priorities; (3) encourage researchers to adopt standard data elements in research and reporting; (4) serve as a source for clinicians seeking information on effectiveness of interventions for patients with particular demographics or exposures; (5) provide the public a source to search for evidence on interventions they or their loved ones are considering; (6) provide policymakers with an up-to-date accounting of evidence to respond to inquiries; and (7) augment and inform the use of existing patient education tools such as PTSD mobile applications11 or the online PTSD Treatment Decision Aid.12 The TEP highlighted how adding variables, outcomes, subpopulations, updated RoB 2 assessment, and other studies in the future could be useful to researchers, policymakers, clinicians, and patients and help achieve the aforementioned goals of developing this database. This report and future updates aim to aid in the dissemination of the PTSD-Repository. We plan to continue to provide data for all types of potential PTSD-Repository users, so that content can be developed to support ease and accuracy of use, such as updated data dictionaries and data stories that provide both information on how to use the PTSD-Repository as well as summaries of key findings from PTSD-Repository data. The TEP comments compiled during the initial and continuation stages of this project provide a guide for future work in updating the evidence tables of the PTSD-Repository.


# Abbreviations and Acronyms

<table>
<thead>
<tr>
<th>Acronym or Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>AHRQ</td>
<td>Agency for Healthcare Research and Quality</td>
</tr>
<tr>
<td>CAPS</td>
<td>Clinician-Administered PTSD Scale</td>
</tr>
<tr>
<td>CBT</td>
<td>cognitive behavioral therapy</td>
</tr>
<tr>
<td>CBTi</td>
<td>cognitive behavioral therapy for insomnia</td>
</tr>
<tr>
<td>CER</td>
<td>comparative effectiveness review</td>
</tr>
<tr>
<td>CIH</td>
<td>complementary and integrative health</td>
</tr>
<tr>
<td>CMS</td>
<td>Civilian Mississippi Scale for PTSD</td>
</tr>
<tr>
<td>CPG</td>
<td>clinical practice guideline</td>
</tr>
<tr>
<td>CPT</td>
<td>Cognitive Processing Therapy</td>
</tr>
<tr>
<td>DoD</td>
<td>Department of Defense</td>
</tr>
<tr>
<td>DSM</td>
<td>Diagnostic and Statistical Manual of Mental Disorders</td>
</tr>
<tr>
<td>EMDR</td>
<td>Eye Movement Desensitization and Reprocessing</td>
</tr>
<tr>
<td>EPC</td>
<td>evidence-based practice center</td>
</tr>
<tr>
<td>FORNET</td>
<td>Forensic Offender Rehabilitation narrative exposure therapy</td>
</tr>
<tr>
<td>ICD</td>
<td>International Statistical Classification of Diseases and Related Health Problems</td>
</tr>
<tr>
<td>IES</td>
<td>Impact of Event Scale</td>
</tr>
<tr>
<td>IQR</td>
<td>Interquartile range</td>
</tr>
<tr>
<td>ITT</td>
<td>intent-to-treat</td>
</tr>
<tr>
<td>k</td>
<td>number of studies</td>
</tr>
<tr>
<td>KQ</td>
<td>Key Question</td>
</tr>
<tr>
<td>MPSS</td>
<td>Modified PTSD Symptom Scale</td>
</tr>
<tr>
<td>MST</td>
<td>military sexual trauma</td>
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<tr>
<td>N</td>
<td>No, data element was not reported for the study</td>
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<tr>
<td>NA</td>
<td>not applicable</td>
</tr>
<tr>
<td>NCPTSD</td>
<td>National Center for Posttraumatic Stress Disorder</td>
</tr>
<tr>
<td>NR</td>
<td>not reported</td>
</tr>
<tr>
<td>PCL</td>
<td>PTSD Checklist</td>
</tr>
<tr>
<td>PDS</td>
<td>Posttraumatic Diagnostic Scale</td>
</tr>
<tr>
<td>PE</td>
<td>Prolonged Exposure</td>
</tr>
<tr>
<td>PICOTS</td>
<td>populations, interventions, comparators, outcomes, timing, settings, study design</td>
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<tr>
<td>PSS-I</td>
<td>PTSD Symptom Scale-Interview</td>
</tr>
<tr>
<td>PSS-SR</td>
<td>PTSD Symptom Scale-Self-Report</td>
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<tr>
<td>PTSD</td>
<td>posttraumatic stress disorder</td>
</tr>
<tr>
<td>PTSD-Repository</td>
<td>PTSD Trials Standardized Data Repository</td>
</tr>
<tr>
<td>RCT</td>
<td>randomized controlled trial</td>
</tr>
<tr>
<td>RoB</td>
<td>risk of bias</td>
</tr>
<tr>
<td>rTMS</td>
<td>repetitive transcranial magnetic stimulation</td>
</tr>
<tr>
<td>SEADS</td>
<td>Supplemental Evidence And Data for Systematic Review</td>
</tr>
<tr>
<td>STAIR-EMDR</td>
<td>Skills Training in Affective and Interpersonal Regulation-eye movement desensitization and reprocessing</td>
</tr>
<tr>
<td>SUD</td>
<td>substance use disorder</td>
</tr>
<tr>
<td>Acronym or Abbreviation</td>
<td>Definition</td>
</tr>
<tr>
<td>------------------------</td>
<td>------------</td>
</tr>
<tr>
<td>TAU</td>
<td>treatment as usual</td>
</tr>
<tr>
<td>TBI</td>
<td>traumatic brain injury</td>
</tr>
<tr>
<td>TEP</td>
<td>Technical Expert Panel</td>
</tr>
<tr>
<td>U.K.</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>U.S.</td>
<td>United States</td>
</tr>
<tr>
<td>VA</td>
<td>U.S. Department of Veterans Affairs</td>
</tr>
<tr>
<td>VA/DoD CPG</td>
<td>Department of Veterans Affairs/Department of Defense clinical practice guideline</td>
</tr>
<tr>
<td>WET</td>
<td>Written Exposure Therapy</td>
</tr>
<tr>
<td>Y</td>
<td>Yes, outcome was reported for study</td>
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</tbody>
</table>
Appendix Table of Contents

Appendix A. Literature Search Strategies ................................................................................................. A-1
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Appendix A. Literature Search Strategies

Database: Ovid MEDLINE®, Ovid MEDLINE® In-Process & Other Non-Indexed Citations

**Pharmacologic interventions**

1. stress disorders, post-traumatic/
2. ("posttraumatic stress disorder" or "post traumatic stress disorder" or PTSD).ti,ab.
3. 1 or 2
4. exp Drug Therapy/ or dt.fs. or (medication* or pharmacologic* or pharmaco-therap* or pharmacotherap*).ti,ab.
5. (drug* adj2 (therap* or treatment*)).ti,ab. or exp Adrenergic alpha-Antagonists/ or Sympatholytics/ or Doxazosin/ or Prazosin/
6. ("adrenergic alpha antagonist*" or "adrenergic receptor block*" or "alpha adrenergic antagonist*" or "alpha block*" or antiadrenergic* or doxazosin or prazosin or sympatholytic* or terazosin).ti,ab. or exp Antipsychotic Agents/
7. exp Benzodiazepines/ or ("anti-psychotic*" or antipsychotic* or FGA* or SGA* or aripiprazole or asenapine or brexipiprazole or cariprazine or chlorpromazine or clozapine or fluphenazine or haloperidol or iloperidone or loxapine or lurasidone or olanzapine or paliperidone or perphenazine or pimozide or quetiapine or risperidone or thioridazine or thiothixene or trifluoperazine or ziprasidone).ti,ab.
8. (alprazolam or benzodiazepine* or benzodiazepinone* or chlordiazepoxide or clonazepam or clorazepate or diazepam or estazolam or flurazepam or lorazepam or midazolam or oxazepam or quazepam or temazepam or triazolam).ti,ab. or exp Monoamine Oxidase Inhibitors/
9. ("monoamine oxidase" adj2 inhibitor*) or MAOI or isocarboxazid or phenelzine or selegiline or tranylcypromine).ti,ab.
10. carbamazepine/ or clonidine/ or lithium/ or pregabalin/ or valproic acid/ or exp Anticonvulsants/ or exp Antimanic Agents/
11. exp Cyclohexanecarboxylic Acids/ or (anticonvuls* or carbamazepine or clonidine or divalproex or gabapentin or lamotrigine or lithium or oxcarbazepine or pregabalin or tiagabine or topiramate or valproate or "valproic acid").ti,ab.
12. exp "hypnotics and sedatives"/ or exp anti-anxiety agents/ or ("anti anxiety" or antianxiety or buspironne or diphenhydramine or eszopiclone or guanfacine or hydroxyzine or hypnotic* or ramelteon or sedative* or suvorexant or tasimelteon or zaleplon or zolpidem or zopiclone).ti,ab.
13. (antidepressant* or "anti-depressant*" or "selective serotonin" or (serotonin adj3 reuptake) or SNRI* or SSRI* or tricyclic or amitriptyline or amoxapine or bupropion or citalopram or clomipramine or desipramine or desvenlafaxine or doxepin or duloxetine or escitalopram or fluoxetine or fluvoxamine or hydroxyzine or imipramine or levomilnacipran or maprotiline or milnacipran or mirtazapine or nefazodone or norlndiploline or paroxetine or protriptyline or sertraline or trazadone or trimipramine or venlafaxine or vilazodone or vortioxetine).ti,ab. or exp Antidepressive Agents/
14. exp Amphetamines/ or (amphetamine or armodafanil or atomoxetine or dextemethylphenidate or dextroamphetamine or lisdexamphetamine or MDMA or methamphetamine or methylphenidate or modafanil).ti,ab.
15. exp Steroids/ or (DHEA or hydrocortisone or steroid*).ti,ab. or exp Cannabinoids/
16. Cannabinoids/ or Medical Marijuana/ or (cannabi* or marijuana or tetrahydrocannabinol or
THC).ti,ab.
17. ketamine/ or ketamine.ti,ab. or Propranolol/ or propranolol.ti,ab.
18. 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17
19. 3 and 18
20. exp Randomized Controlled Trials as Topic/ or exp Randomized Controlled Trial/
21. double-blind method/ or random allocation/ or single-blind method/ or Placebos/
22. (random* or control* or trial or sham or placebo* or blind* or dummy* or
mask*).ti,ab,kw.
23. 20 or 21 or 22
24. 19 and 23
25. ("20220929" or 2022093* or 20221* or 2023*).ed,ez.
26. 24 and 25

Nonpharmacologic interventions
1. stress disorders, post-traumatic/ or ("posttraumatic stress disorder" or "post traumatic
stress disorder" or PTSD).ti,ab.
2. exp Psychotherapy/ or exp Complementary Therapies/ or exp Convulsive Therapy/
3. Hyperbaric Oxygenation/ or Transcranial Magnetic Stimulation/ or exp Rehabilitation/
4. exp Dietary Supplements/
5. exp "Delivery of Health Care, Integrated"/ or exp Self-Help Groups/ or exp peer group/
6. exp social support/ or exp Telemedicine/ or telephone/ or exp cell phone/
7. (therap* or psychotherap* or counsel* or nonpharma* or non-pharma* or ("alternative
medicine" or acupuncture or "animal assist*" or art or "cell phone" or "cognitive
behavior*" or CBT or complementary or dance or drama or electroconvulsive or ECT
or exercise or "eye movement desensitization and reprocessing" or EMDR or family or
"hyperbaric oxygen*" or integrated or meditation or "mind body" or mindfulness or
music or "prolonged exposure" or relaxation or "seeking safety" or "self help" or "tai
chi" or "t'ai chi" or "text messag*" or "transcranial magnetic stimulation" or TMS or
yoga)).ti,ab.
8. 2 or 3 or 4 or 5 or 6 or 7
9. 1 and 8
10. exp Randomized Controlled Trials as Topic/ or exp Randomized Controlled Trial/ or
double-blind method/ or random allocation/ or single-blind method/ or Placebos/ or
(random* or control* or trial or sham or placebo* or blind* or dummy* or
mask*).ti,ab,kw.
11. 9 and 10
12. ("20220929" or 2022093* or 20221* or 2023*).ed,ez.
13. 11 and 12

Database: PTSDpubs (formerly PILOTS)
(MAINSUBJECT.EXACT("PTSD") OR MAINSUBJECT.EXACT("PTSD (DSM-III-R)") OR
MAINSUBJECT.EXACT("PTSD (DSM-III)") OR MAINSUBJECT.EXACT("PTSD (DSM-
IV)") OR MAINSUBJECT.EXACT("PTSD (DSM-5)") OR
MAINSUBJECT.EXACT("Complex PTSD") OR MAINSUBJECT.EXACT("PTSD (ICD-11)")
OR MAINSUBJECT.EXACT("PTSD (ICD-10)") OR MAINSUBJECT.EXACT("PTSD (ICD-9)") OR (ptsd OR "posttraumatic stress disorder" OR "post-traumatic stress disorder") AND (MAINSUBJECT.EXACT("Randomized Clinical Trial") OR ti(random* OR control* OR trial))

Database: APA PsycInfo®
1. exp posttraumatic stress disorder/ or ("post traumatic stress disorder" or "posttraumatic stress disorder" or PTSD).ti,ab.
2. exp treatment/ or exp stimulation/ or exp electroconvulsive shock/ or exp TELEMEDICINE/ or exp counseling/ or exp support groups/ or (therap* or psychotherap* or counsel* or nonpharma* or non-pharma*).ti,ab. or ("alternative medicine" or acupuncture or "animal assist**" or art or "cell phone" or "cognitive behavior**" or CBT or complementary or dance or drama or electroconvulsive or ECT or exercise or "eye movement desensitization and reprocessing" or EMDR or family or "hyperbaric oxygen**" or integrated or meditation or "mind body" or mindfulness or music or "prolonged exposure" or relaxation or "seeking safety" or "self help" or "tai chi" or "tai ji" or "text messag**" or "transcranial magnetic stimulation" or TMS or yoga).ti,ab.
3. treatment effectiveness evaluation/ or Treatment Outcomes/ or followup studies/ or (random* or control* or trial or sham or placebo* or blind* or dumm* or mask*).ti,ab.
4. 1 and 2 and 3
5. ("20220929" or 2022093* or 20221* or 2023*).up.
6. 4 and 5

Database: EBM Reviews – Cochrane Central Register of Controlled Trials
1. Stress Disorders, Post-Traumatic/ or ("posttraumatic stress disorder" or "post traumatic stress disorder" or ptsd).ti,ab.
2. (dt or pc or rh or th).fs. or exp treatment outcome/ or exp therapeutics/ or (treatment or therap* or intervention*).ti,ab,kw.
3. 1 and 2
4. limit 3 to medline records
5. 3 not 4
6. ("20220929" or 2022093* or 20221* or 2023*).up.
7. 5 and 6

Database: Elsevier® Embase
('posttraumatic stress disorder'/exp/mj OR 'posttraumatic stress disorder'/exp OR 'posttraumatic stress disorder':ab,ti OR 'post traumatc stress disorder':ab,ti OR 'ptsd':ab,ti) AND [randomized controlled trial]/lim AND ('randomized controlled trial'/exp OR 'randomized controlled trial') AND [embase]/lim NOT ([embase]/lim AND [medline]/lim) AND [28-09-2022]/sd NOT [03-03-2023]/sd

Database: EBSCO® CINAHL
S2 ( (MM "Stress Disorders, Post-Traumatic") OR ( AB "post traumatic
stress disorder" OR AB "posttraumatic stress disorder" OR AB "ptsd" ) OR
( TI "post traumatic stress disorder" OR TI "posttraumatic stress
disorder" OR TI "ptsd" ) ) AND ( (TI random* or AB random* or PT
clinical trial or PT randomized controlled trial) )
S1 ( (MM "Stress Disorders, Post-Traumatic") OR ( AB "post traumatic
stress disorder" OR AB "posttraumatic stress disorder" OR AB "ptsd" ) OR
( TI "post traumatic stress disorder" OR TI "posttraumatic stress
disorder" OR TI "ptsd" ) ) AND ( (TI random* or AB random* or PT
clinical trial or PT randomized controlled trial))

Database: Elsevier® Scopus
(( TITLE ( ( random* OR control* OR trial* OR sham* OR placebo* OR blind* ) ) ) ) AND ( TITLE-ABS-KEY ( ( "post traumatic stress disorder" OR "posttraumatic stress disorder" OR "ptsd" ) ) ) ) AND LOAD-DATE > 20220928 AND ( LIMIT-TO ( PUBYEAR , 2023 ) OR LIMIT-TO ( PUBYEAR , 2022 ) )
### Appendix B. List of Included Studies


36. Bell AN, Moss D, Kallmeyer RJ. Healing the neurophysiological roots of trauma: a controlled study examining loreta z-score neurofeedback and HRV biofeedback for chronic PTSD. NeuroRegulation. 2019;6(2):54-70. doi: 10.15540/ner.6.2.54.


Appendix C. List of Excluded Studies

Table C-1. Key to exclusion codes

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<thead>
<tr>
<th>Exclusion Code</th>
<th>Exclusion Reason</th>
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<td>Ineligible population</td>
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<td>Ineligible intervention</td>
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<td>5</td>
<td>Ineligible comparison</td>
</tr>
<tr>
<td>6</td>
<td>Ineligible outcome</td>
</tr>
<tr>
<td>8</td>
<td>Ineligible study design</td>
</tr>
<tr>
<td>9</td>
<td>Ineligible publication type (including systematic reviews)</td>
</tr>
<tr>
<td>11</td>
<td>Not English language article</td>
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</tbody>
</table>


29. Actrn. A Randomised Controlled Trial of Cognitive Behavioural Therapy for Insomnia (CBT-I) and Imagery Rehearsal Therapy (IRT) for Ex-Service Personnel with Insomnia and Nightmares in the Context of Posttraumatic Stress Disorder (PTSD) and Obstructive Sleep Apnoea (OSA).


32. Actrn. IMPACT - Intervention to Manage PTSD And Comorbidities after Trauma Study.

33. Actrn. A feasibility and efficacy cross over clinical trial of reinforcing subconscious re framing of past and present programs to reduce symptoms of Post Traumatic Stress Disorder (PTSD).


1174. Stirman SW. Seven-day intensive cognitive therapy for PTSD is as effective as weekly cognitive therapy and more effective than weekly supportive therapy. Evidence based mental health. 2015;18(1):21-0. PMID: CN-02125835 NEW. Exclusion: 9.


Appendix D. Data Abstraction and Risk of Bias Elements

Data abstraction and Risk of Bias 2 (RoB 2) elements were abstracted for all 496 studies.

**Study Identifiers**
1. PTSDpubs ID
2. Author, Year
3. study_id
4. Citation
5. ClinicalTrials ID
6. PMID
7. PubMed Link
8. Funding Source

**Secondary Studies**
1. Secondary Study Author & Year
2. Secondary Study Citation
3. Secondary Study Relationship
4. Secondary Study PMID
5. Secondary Study PTSDpubs ID

**Inclusion-Exclusion Criteria**
1. Study-reported inclusion and exclusion criteria

**Study Characteristics**
1. Study Publication Year
2. Study Class
3. Countries
4. Site Type
5. Clinical Setting
6. Study Design
7. Subscale/Symptom Cluster Data
8. Subgroup Analysis
9. Providers Have Grad Degrees
10. Intervention Includes Group Therapy
11. Allowed PTSD Psychotherapy Co-Intervention
12. Allowed Other Psychotherapy Co-Intervention
13. Allowed Psychotropic Med Co-Intervention
14. Patients with Suicidality Excluded
15. Suicide- and Self-Directed Violence-Related Inclusion and Exclusion Criteria
16. Psychotic Disorder- and Symptom-Related Inclusion and Exclusion Criteria
17. Suicide or Self-Harm Related Outcomes
Sample Characteristics

1. N Randomized
2. N Randomized Detail
3. PTSD Criteria Met at Baseline Percent
4. PTSD Criteria Met at Baseline Detail
5. PTSD Severity at Baseline Definition
6. PTSD Severity at Baseline Mean
7. PTSD Severity at Baseline Standard Deviation
8. PTSD Severity at Baseline Detail
9. PTSD Severity at Baseline 2 Definition
10. PTSD Severity at Baseline 2 Mean
11. PTSD Severity at Baseline 2 Standard Deviation
12. PTSD Severity at Baseline 2 Detail
13. Duration of Symptoms/Diagnosis Mean
14. Duration of Symptoms/Diagnosis Sample Characteristics: Standard Deviation
15. Duration of Symptoms/Diagnosis Detail
16. Active Duty Military Percent
17. Veteran Percent
18. Service-Connected Veteran Percent
19. Community Percent
20. Military Status
21. Military Status qualitative values
22. Age Mean
23. Age Standard Deviation
24. Age Detail
25. Female Percent
26. Female Detail
27. Male Percent
28. Race/Ethnicity Reported
29. Race, White
30. Race, Black
31. Race, AIAN
32. Race, Asian
33. Race, NHPI
34. Race, Other
35. Race Detail
36. Ethnicity Hispanic
37. Ethnicity Hispanic Detail
38. Ethnicity Hispanic Detail
39. Percent Treatment-naïve
40. Percent Treatment-naïve Detail
41. Percent with Depression
42. Percent with Depression Detail
43. SUD Substance Class
44. SUD Specific Substance Target
45. Current SUD Inclusion/Exclusion Criteria
46. Percent with Any SUD Detail
47. Percent with TBI History
48. Percent with TBI History Detail
49. Suicide- or Self-Directed Violence-Related Definition
50. Suicide- or Self-Directed Violence-Related Percent
51. Suicide- or Self-Directed Violence-Related Detail
52. Psychotic Disorder or Symptom-Related Definition
53. Psychotic Disorder or Symptom-Related Percent
54. Psychotic Disorder or Symptom-Related Detail
55. Personality Disorder Definition
56. Personality Disorder Percent
57. Personality Disorder Detail
58. Anxiety Disorder Definition
59. Anxiety Disorder Percent
60. Anxiety Disorder Detail
61. Prior Inpatient Hospitalization Percent
62. Prior Inpatient Hospitalization Percent Detail
63. Trauma Type
64. Trauma Detail
65. Number of Trauma Types Mean
66. Number of Trauma Types Standard Deviation
67. Number of Trauma Types Detail
68. Trauma Events Mean
69. Trauma Events Standard Deviation
70. Trauma Events Detail

**Study Interventions**

1. study_id_arm
2. Intervention Group
3. Arm N Randomized
4. Arm N Randomized Detail
5. Treatment Name
6. Standardized Treatment Name
7. Treatment Description
8. Treatment Focus
9. Treatment Focus Subclass
10. Intervention Categorization: Psychotherapy
11. Intervention Categorization: Psychotherapy Subclass
12. Intervention Categorization: Pharmacotherapy
13. Intervention Categorization: Pharmacotherapy Subclass
14. Intervention Categorization: CIH
15. Intervention Categorization: CIH Subclass
16. Intervention Categorization: Nonpharmacologic Biologic
17. Intervention Categorization: Nonpharmacologic Cognitive Therapy
18. Intervention Categorization: Collaborative Care
19. Intervention Categorization: Other
20. Intervention Details: Format
21. Intervention Details: Delivery Method
22. Intervention Details: Dose
23. Intervention Details: Session Length
24. Intervention Details: Frequency
25. Intervention Details: Treatment Duration
26. Intervention Details: Treatment Duration Detail
27. Intervention Details: Treatment Completion Definition
28. Intervention Details: Completed Psychotherapy Percent
29. Intervention Details: Completed Psychotherapy Percent Detail
30. Intervention Details: Treatment Adherence Definition
31. Intervention Details: Adhered Pharmacotherapy Percent
32. Intervention Details: Adhered Pharmacotherapy Percent Detail
33. Intervention Details: Psychotherapy Sessions Completed Mean
34. Intervention Details: Psychotherapy Sessions Completed Standard Deviation
35. Intervention Details: Psychotherapy Sessions Completed Detail
36. Intervention Details: Dose at Study End Point Mean
37. Intervention Details: Dose at Study End Point Standard Deviation
38. Intervention Details: Dose at Study End Point Detail

**PTSD Continuous Outcomes**

1. PTSD Outcome Measure Detail
2. PTSD Outcome Measure
3. Outcome Assessment Type
4. Analysis Type
5. Method for Handling Missing Data
6. Statistical Analysis Method
7. Adjusted Variables in Statistical Analysis
8. Cluster Randomized Trial
9. ICC
10. Follow-up Assessment Point
11. Arm 1 Designation
12. Arm 1 Baseline Assessment: N Completed Outcome Measurement
13. Arm 1 Baseline N Completed Outcome Measurement Detail
14. Arm 1 Baseline Assessment: Measure Score Mean
15. Arm 1 Baseline Assessment: Measure Score Standard Deviation
16. Arm 1 Baseline Assessment: Measure Score SD Calculated Indicator
17. Arm 1 Baseline Assessment: Measure Score Other Measure of Variance Type
18. Arm 1 Baseline Assessment: Measure Score Other Measure of Variance Value or Lower Bound
19. Arm 1 Baseline Assessment: Measure Score Other Measure of Variance Upper Bound
20. Arm 1 Baseline Assessment: Measure Score Detail
21. Arm 1 Follow-up Assessment: N Completed Outcome Measurement
22. Arm 1 Follow-up Assessment: N Completed Outcome Measurement Detail
23. Arm 1 Follow-up Assessment: Measure Score Mean
24. Arm 1 Follow-up Assessment: Measure Score Standard Deviation
25. Arm 1 Follow-up Assessment: Measure Score SD Calculated Indicator
26. Arm 1 Follow-up Assessment: Measure Score Other Measure of Variance Type
27. Arm 1 Follow-up Assessment: Measure Score Other Measure of Variance Value or Lower Bound
28. Arm 1 Follow-up Assessment: Measure Score Other Measure of Variance Upper Bound
29. Arm 1 Follow-up Assessment: Measure Score Adjusted Indicator
30. Arm 1 Follow-up Assessment: Measure Score Detail
31. Arm 1 Within-Group Change: Score Difference 1 Detail
32. Arm 1 Within-Group Change: Score Difference 1
33. Arm 1 Within-Group Change: Score Difference 1 Calculated Indicator
34. Arm 1 Within-Group Change: Score Difference 1 Standard Deviation
35. Arm 1 Within-Group Change: Score Difference 1 SD Calculated Indicator
36. Arm 1 Within-Group Change: Score Difference 1 95% CI Lower Bound
37. Arm 1 Within-Group Change: Score Difference 1 95% CI Upper Bound
38. Arm 1 Within-Group Change: Score Difference 1 p value
39. Arm 1 Within-Group Change: Score Difference 2 Detail
40. Arm 1 Within-Group Change: Score Difference 2
41. Arm 1 Within-Group Change: Score Difference 2 Calculated Indicator
42. Arm 1 Within-Group Change: Score Difference 2 Standard Deviation
43. Arm 1 Within-Group Change: Score Difference 2 SD Calculated Indicator
44. Arm 1 Within-Group Change: Score Difference 2 95% CI Lower Bound
45. Arm 1 Within-Group Change: Score Difference 2 95% CI Upper Bound
46. Arm 1 Within-Group Change: Score Difference 2 p value
47. Arm 1 Within-Group Change: EPC-calculated within arm effect size
48. Arm 1 Within-Group Change: Effect Size 1 Detail
49. Arm 1 Within-Group Change: Effect Size 1 Type
50. Arm 1 Within-Group Change: Effect Size 1
51. Arm 1 Within-Group Change: Effect Size 1 Type of Variance Measure
52. Arm 1 Within-Group Change: Effect Size 1 Variance Value or Lower Bound
53. Arm 1 Within-Group Change: Effect Size 1 Variance Upper Bound
54. Arm 1 Within-Group Change: Effect Size 1 p value
55. Arm 1 Within-Group Change: Effect Size 2 Detail
56. Arm 1 Within-Group Change: Effect Size 2 Type
57. Arm 1 Within-Group Change: Effect Size 2
58. Arm 1 Within-Group Change: Effect Size 2 Type of Variance Measure
59. Arm 1 Within-Group Change: Effect Size 2 Variance Value or Lower Bound
60. Arm 1 Within-Group Change: Effect Size 2 Variance Upper Bound
61. Arm 1 Within-Group Change: Effect Size 2 p value
62. Arm 2 Designation
63. Arm 2 Baseline Assessment: N Completed Outcome Measurement
64. Arm 2 Baseline Assessment: N Completed Outcome Measurement Detail
65. Arm 2 Baseline Assessment: Measure Score Mean
66. Arm 2 Baseline Assessment: Measure Score Standard Deviation
67. Arm 2 Baseline Assessment: Measure Score SD Calculated Indicator
68. Arm 2 Baseline Assessment: Measure Score Other Measure of Variance Type
69. Arm 2 Baseline Assessment: Measure Score Other Measure of Variance Value or Lower Bound
70. Arm 2 Baseline Assessment: Measure Score Other Measure of Variance Upper Bound
71. Arm 2 Baseline Assessment: Measure Score Detail
72. Arm 2 Follow-up Assessment: N Completed Outcome Measurement
73. Arm 2 Follow-up Assessment: N Completed Outcome Measurement Detail
74. Arm 2 Follow-up Assessment: Measure Score Mean
75. Arm 2 Follow-up Assessment: Measure Score Standard Deviation
76. Arm 2 Follow-up Assessment: Measure Score SD Calculated Indicator
77. Arm 2 Follow-up Assessment: Measure Score Other Measure of Variance Type
78. Arm 2 Follow-up Assessment: Measure Score Other Measure of Variance Value or Lower Bound
79. Arm 2 Follow-up Assessment: Measure Score Other Measure of Variance Upper Bound
80. Arm 2 Follow-up Assessment: Measure Score Adjusted Indicator
81. Arm 2 Follow-up Assessment: Measure Score Detail
82. Arm 2 Within-Group Change: Score Difference 1 Detail
83. Arm 2 Within-Group Change: Score Difference 1
84. Arm 2 Within-Group Change: Score Difference 1 Calculated Indicator
85. Arm 2 Within-Group Change: Score Difference 1 Standard Deviation
86. Arm 2 Within-Group Change: Score Difference 1 SD Calculated Indicator
87. Arm 2 Within-Group Change: Score Difference 1 95% CI Lower Bound
88. Arm 2 Within-Group Change: Score Difference 1 95% CI Upper Bound
89. Arm 2 Within-Group Change: Score Difference 1 p value
90. Arm 2 Within-Group Change: Score Difference 2 Detail
91. Arm 2 Within-Group Change: Score Difference 2
92. Arm 2 Within-Group Change: Score Difference 2 Calculated Indicator
93. Arm 2 Within-Group Change: Score Difference 2 Standard Deviation
94. Arm 2 Within-Group Change: Score Difference 2 SD Calculated Indicator
95. Arm 2 Within-Group Change: Score Difference 2 95% CI Lower Bound
96. Arm 2 Within-Group Change: Score Difference 2 95% CI Upper Bound
97. Arm 2 Within-Group Change: Score Difference 2 p value
98. Arm 2 Within-Group Change: EPC-calculated within arm effect size
99. Arm 2 Within-Group Change: Effect Size 1 Detail
100. Arm 2 Within-Group Change: Effect Size 1 Type
101. Arm 2 Within-Group Change: Effect Size 1
102. Arm 2 Within-Group Change: Effect Size 1 Type of Variance Measure
<p>| | |</p>
<table>
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<tr>
<td>103.</td>
<td>Arm 2 Within-Group Change: Effect Size 1 Variance Value or Lower Bound</td>
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<tr>
<td>104.</td>
<td>Arm 2 Within-Group Change: Effect Size 1 Variance Upper Bound</td>
</tr>
<tr>
<td>105.</td>
<td>Arm 2 Within-Group Change: Effect Size 1 p value</td>
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<tr>
<td>106.</td>
<td>Arm 2 Within-Group Change: Effect Size 2 Detail</td>
</tr>
<tr>
<td>107.</td>
<td>Arm 2 Within-Group Change: Effect Size 2 Type</td>
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<td>108.</td>
<td>Arm 2 Within-Group Change: Effect Size 2</td>
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<td>109.</td>
<td>Arm 2 Within-Group Change: Effect Size 2 Type of Variance Measure</td>
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<tr>
<td>110.</td>
<td>Arm 2 Within-Group Change: Effect Size 2 Variance Value or Lower Bound</td>
</tr>
<tr>
<td>111.</td>
<td>Arm 2 Within-Group Change: Effect Size 2 Variance Upper Bound</td>
</tr>
<tr>
<td>112.</td>
<td>Arm 2 Within-Group Change: Effect Size 2 p value</td>
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<tr>
<td>113.</td>
<td>Comparison Arms Designation</td>
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<tr>
<td>114.</td>
<td>Comparison Score Difference 1 Detail</td>
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<tr>
<td>115.</td>
<td>Comparison Score Difference 1 Adjusted Indicator</td>
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<tr>
<td>116.</td>
<td>Comparison Score Difference 1</td>
</tr>
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<td>117.</td>
<td>Comparison Score Difference 1 Calculated Indicator</td>
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<td>Comparison Score Difference 1 Standard Error</td>
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<td>Comparison Score Difference 1 SE Calculated Indicator</td>
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<td>Comparison Score Difference 1 95% CI Lower Bound</td>
</tr>
<tr>
<td>121.</td>
<td>Comparison Score Difference 1 95% CI Upper Bound</td>
</tr>
<tr>
<td>122.</td>
<td>Comparison Score Difference 1 p value</td>
</tr>
<tr>
<td>123.</td>
<td>Comparison Score Difference 2 Detail</td>
</tr>
<tr>
<td>124.</td>
<td>Comparison Score Difference 2 Adjusted Indicator</td>
</tr>
<tr>
<td>125.</td>
<td>Comparison Score Difference 2</td>
</tr>
<tr>
<td>126.</td>
<td>Comparison Score Difference 2 Calculated Indicator</td>
</tr>
<tr>
<td>127.</td>
<td>Comparison Score Difference 2 Standard Error</td>
</tr>
<tr>
<td>128.</td>
<td>Comparison Score Difference 2 SE Calculated Indicator</td>
</tr>
<tr>
<td>129.</td>
<td>Comparison Score Difference 2 95% CI Lower Bound</td>
</tr>
<tr>
<td>130.</td>
<td>Comparison Score Difference 2 95% CI Upper Bound</td>
</tr>
<tr>
<td>131.</td>
<td>Comparison Score Difference 2 p value</td>
</tr>
<tr>
<td>132.</td>
<td>EPC Calculated: Comparison Standardized Effect Size</td>
</tr>
<tr>
<td>133.</td>
<td>EPC Calculated: Comparison Standardized Effect Size Standard Error</td>
</tr>
<tr>
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<td>EPC Calculated: Comparison Standardized Effect Size 95% CI Lower Bound</td>
</tr>
<tr>
<td>135.</td>
<td>EPC Calculated: Comparison Standardized Effect Size 95% CI Upper Bound</td>
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<td>EPC Calculated: Comparison Standardized Effect Size Data Source</td>
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<td>Study Reported: Comparison Effect Size 1 Detail</td>
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<td>138.</td>
<td>Study Reported: Comparison Effect Size 1 Type</td>
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<td>Study Reported: Comparison Effect Size 1 Type of Variance Measure</td>
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<td>Study Reported: Comparison Effect Size 1 Variance Value or Lower Bound</td>
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<td>142.</td>
<td>Study Reported: Comparison Effect Size 1 Variance Upper Bound</td>
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<tr>
<td>143.</td>
<td>Study Reported: Comparison Effect Size 1 p value</td>
</tr>
</tbody>
</table>
PTSD Dichotomous Outcomes

1. Outcome Type
2. Definition number
3. Outcome definition
4. Method for Handling Missing Data
5. Analysis Type
6. Statistical Analysis Method
7. Adjusted Variables in Statistical Analysis
8. Assessment Point
9. Arm 1 Designation
10. Arm 1 Percent Achieved
11. Arm 1 Numerator for Percent Achieved
12. Arm 1 Denominator for Percent Achieved
13. Arm 2 Designation
14. Arm 2 Percent Achieved
15. Arm 2 Numerator for Percent Achieved
16. Arm 2 Denominator for Percent Achieved
17. Comparison Arms Designation
18. Comparison Effect Size 1 Detail
19. Comparison Effect Size 1 Type
20. Comparison Effect Size 1
21. Comparison Effect Size 1 Type of Variance Measure
22. Comparison Effect Size 1 Variance Value or Lower Bound
23. Comparison Effect Size 1 Variance Upper Bound
24. Comparison Effect Size 1 p value
25. Comparison Effect Size 2 Detail
26. Comparison Effect Size 2 Type
27. Comparison Effect Size 2
28. Comparison Effect Size 2 Type of Variance Measure
29. Comparison Effect Size 2 Variance Value or Lower Bound
30. Comparison Effect Size 2 Variance Upper Bound
31. Comparison Effect Size 2 p value
32. Additional Data Reported

Suicide Continuous Outcomes

1. Analysis Type
2. Assessment Point
3. Outcome Measure
4. Outcome Measure Definition
5. Arm 1 Intervention Designation
6. Arm 1 Baseline Measure Score Mean
7. Arm 1 Baseline Measure Score Standard Deviation
8. Arm 1 Baseline Measure Score Other Measure of Variance Type
9. Arm 1 Baseline Measure Score Other Measure of Variance Value or Lower Bound
10. Arm 1 Baseline Measure Score Other Measure of Variance Upper Bound
11. Arm 1 Baseline Measure Score Detail
12. Arm 1 Follow-up Measure Score Mean
13. Arm 1 Follow-up Measure Score Standard Deviation
14. Arm 1 Follow-up Measure Score Other Measure of Variance Type
15. Arm 1 Follow-up Measure Score Other Measure of Variance Value or Lower Bound
16. Arm 1 Follow-up Measure Score Other Measure of Variance Upper Bound
17. Arm 1 Follow-up Measure Score Detail
18. Arm 2 Intervention Designation
19. Arm 2 Baseline Measure Score Mean
20. Arm 2 Baseline Measure Score Standard Deviation
21. Arm 2 Baseline Measure Score Other Measure of Variance Type
22. Arm 2 Baseline Measure Score Other Measure of Variance Value or Lower Bound
23. Arm 2 Baseline Measure Score Other Measure of Variance Upper Bound
24. Arm 2 Baseline Measure Score Detail
25. Arm 2 Follow-up Measure Score Mean
26. Arm 2 Follow-up Measure Score Standard Deviation
27. Arm 2 Follow-up Measure Score Other Measure of Variance Type
28. Arm 2 Follow-up Measure Score Other Measure of Variance Value or Lower Bound
29. Arm 2 Follow-up Measure Score Other Measure of Variance Upper Bound
30. Arm 2 Follow-up Measure Score Detail
31. Comparison Arms Designation
32. Comparison Effect Size Detail
33. Comparison Effect Size Type
34. Comparison Effect Size
35. Comparison Effect Size 95% CI Lower Bound
36. Comparison Effect Size 95% CI Upper Bound
37. Comparison Effect Size p value
38. Continuous Outcome Measure Comments

**Suicide Dichotomous Outcomes**

1. Analysis Type
2. Assessment Point Category
3. Assessment Point
4. Outcome Measure
5. Outcome Measure Definition
6. Arm 1 Intervention Designation
7. Arm 1 Percent with outcome
8. Arm 1 Numerator for Percent
9. Arm 1 Denominator for Percent
10. Arm 2 Intervention Designation
11. Arm 2 Percent
12. Arm 2 Numerator for Percent
13. Arm 2 Denominator for Percent
14. Comparison Arms Designation
15. Comparison Effect Size Detail
16. Comparison Effect Size Type
17. Comparison Effect Size
18. Comparison Effect Size 95% CI Lower Bound
19. Comparison Effect Size 95% CI Upper Bound
20. Comparison Effect Size p value
21. Dichotomous Outcome Measure Comments

Other Outcomes
1. Outcome
2. Outcome Measure
3. Comparison
4. Follow-up Assessment in Weeks
5. Analysis Type
6. Effect Size 1 Detail
7. Effect Size 1 Type
8. Effect Size 1 Value
9. Effect Size 1 Type of Variance Measure
10. Effect Size 1 Other Measure of Variance Value or Lower Bound
11. Effect Size 1 Other Measure of Variance Upper Bound
12. Effect Size 1 p value
13. Effect Size 2 Detail
14. Effect Size 2 Type
15. Effect Size 2 Value
16. Effect Size 2 Type of Variance Measure
17. Effect Size 2 Other Measure of Variance Value or Lower Bound
18. Effect Size 2 Other Measure of Variance Upper Bound
19. Effect Size 2 p value

Harms
1. Arm
2. Serious Adverse Event Percent
3. Serious Adverse Event Detail
4. Withdrawal Due to Adverse Events Percent
5. Withdrawal Due to Adverse Events Detail
6. Attempted Suicide Percent
7. Attempted Suicide Detail
8. Completed Suicide Percent
9. Completed Suicide Detail
10. Harms Comment

Risk of Bias 2 Assessment Elements

1. 1.1) Was the allocation sequence random?
2. 1.2) Was the allocation sequence concealed until participants were enrolled and assigned to interventions?
3. 1.3) Did baseline differences between intervention groups suggest a problem with the randomization process?
4. RoB judgement
5. 2.1) Were ppts aware of their assigned intervention during the trial?
6. 2.2) Were carers and people delivering the interventions aware of participants' assigned intervention during the trial?
7. 2.3) (If Y, PY or NI to masking carers or ppts) were there deviations from the intended intervention that arose because of the trial context?
8. 2.4) (If Y, PY to previous question) were these deviations likely to have affected the outcome?
9. 2.5) (If Y, PY, NI to previous question) were these deviations from intended intervention balanced between groups?
10. 2.6) Was an appropriate analysis used to estimate the effect of assignment to intervention?
11. 2.7) (If N, PN, NI to previous question) Was there potential for a substantial impact (on the result) of the failure to analyse participants in the group to which they were randomized?
12. RoB judgement
13. 3.1) Were data for this outcome available for all, or nearly all, participants randomized?
14. 3.1 Detail) List overall % of missing outcome (ie, overall attrition) data
15. 3.2) (If N/PN/NI to previous question) Is there evidence that the result was not biased by missing outcome data?
16. 3.3) (If N/PN to previous question) Could missingness in the outcome depend on its true value?
17. 3.4) (If Y, PY, NI to previous question) Is it likely that missingness in the outcome depended on its true value?
18. 3.4 Detail) List % of missing outcome data (ie, differential attrition) in each group
19. RoB judgement
20. 4.1) Was the method of measuring the outcome inappropriate?
21. 4.2) Could measurement or ascertainment of the outcome have differed between intervention groups?
22. 4.3) (If N/PN/NI to both previous questions) Were outcome assessors aware of the intervention received by study participants?
23. 4.4) (If Y/PY/NI to previous question) Could assessment of the outcome have been influenced by knowledge of intervention received?
24. 4.5) (If Y/PY/NI to previous question) Is it likely that assessment of the outcome was influenced by knowledge of intervention received?
25. RoB judgement
26. 5.1) Were the data that produced this result analysed in accordance with a pre-specified analysis plan that was finalized before unblinded outcome data were available for analysis?
27. 5.2) Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple eligible outcome measurements (e.g. scales, definitions, time points) within the outcome domain?
28. 5.3) Is the numerical result being assessed likely to have been selected, on the basis of the results, from multiple eligible analyses of the data?
29. RoB judgement
30. RoB rating
Appendix E. Evidence Tables of New Included Studies

The evidence tables are shown in the associated Excel® file located at https://effectivehealthcare.ahrq.gov/products/ptsd-pharm-non-pharm-treatment/research:

Table E-1. Study identifiers of new included studies
Table E-2. Secondary studies of new included studies
Table E-3. Inclusion-exclusion criteria of new included studies
Table E-4. Study characteristics of new included studies
Table E-5. Sample characteristics of new included studies
Table E-6. Study interventions of new included studies
Table E-7. PTSD continuous outcomes of new included studies
Table E-8. PTSD dichotomous outcomes of new included studies
Table E-9. Suicide continuous outcomes of new included studies
Table E-10. Suicide dichotomous outcomes of new included studies
Table E-11. Other outcomes of new included studies
Table E-12. Harms of new included studies
Appendix F. Evidence Tables of Prior Report Studies

The evidence tables are shown in the associated Excel® file located at https://effectivehealthcare.ahrq.gov/products/ptsd-pharm-non-pharm-treatment/research:

- Table F-1. Study identifiers of prior report studies
- Table F-2. Secondary studies of prior report studies
- Table F-3. Inclusion-exclusion criteria of prior report studies
- Table F-4. Study characteristics of prior report studies
- Table F-5. Sample characteristics of prior report studies
- Table F-6. Study interventions of prior report studies
- Table F-7. Harms of prior report studies
Appendix G. Risk of Bias Assessment of Included Studies

The risk of bias (RoB) assessment is detailed in the associated Microsoft® Excel files located at https://effectivehealthcare.ahrq.gov/products/ptsd-pharm-non-pharm-treatment/research:
  Table G-1. RoB 2 assessment of new included studies
  Table G-2. RoB 2 assessment of prior report studies