Systematic Review

Pharmacologic and Nonpharmacologic Treatments for Posttraumatic Stress Disorder: 2022 Update of the PTSD-Repository Evidence Base

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This report is based on research conducted by the Pacific Northwest Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. 75Q80120D00006). The findings and conclusions in this document are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. Therefore, no statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

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

The information in this report is intended to help healthcare decision makers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of healthcare services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

A representative from AHRQ served as a Contracting Officer's Representative and reviewed the contract deliverables for adherence to contract requirements and quality. AHRQ did not directly participate in the literature search, determination of study eligibility criteria, data analysis, interpretation of data, or preparation or drafting of 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 comprehensive, science-based information on common, costly 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 EPC evidence reports and technology assessments will be helpful to health plans, providers, purchasers, government programs, and 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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Peer Reviewers

Prior to publication of the final evidence report, EPCs sought input from independent Peer Reviewers without financial conflicts of interest. However, the conclusions and synthesis of the scientific literature presented in this report do not necessarily represent the views of individual reviewers.

Peer Reviewers 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 nonfinancial conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential nonfinancial conflicts of interest identified.

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Pharmacologic and Nonpharmacologic Treatments for Posttraumatic Stress Disorder: An Update of the PTSD-Repository Evidence Base

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 and National Center for PTSD (NCPTSD) PTSD Trials Standardized Data Repository (PTSD-Repository).

Data sources. We searched PTSDpubs, Ovid® MEDLINE®, Cochrane CENTRAL, PsycINFO®, Embase®, CINAHL®, and Scopus® for eligible RCTs published from June 1, 2018, to January 26, 2022.

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 newly 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 and update RoB using the new RoB 2 tool over the next several annual updates.

Results. We added 48 new RCTs examining treatments for PTSD, for a total of 437 included studies published from 1988 to July 30, 2021. Among the 48 newly added RCTs, psychotherapy interventions were the most commonly employed (50%), followed by complementary and integrative health (17%). Approximately half of studies were conducted in the United States (46%), and enrolled community participants (52%) and participants with a mix of trauma types (48%). Studies typically had sample sizes ranging from 25 to 99 participants (69%). RoB was rated as high for 52 percent of studies, 31 percent were rated as low RoB, and the remaining studies were rated as having some concerns (15%).

Conclusions. This report updates the previous AHRQ report to include 48 recently published RCTs, for a total of 437 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 inform updates to the PTSD-Repository, a comprehensive database of PTSD trials.

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Executive Summary

Main Points

- This update adds 48 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[1] and National Center for PTSD (NCPTSD) PTSD Trials Standardized Data Repository (PTSD-Repository);[2] the new total of included RCTs is 437.
- Across the 48 newly published RCTs, the most commonly studied intervention was psychotherapy (50%), followed by complementary and integrative health (17%) and pharmacologic interventions (16%); 8 percent of studies used both pharmacologic and psychotherapeutic interventions.
- Almost half of studies were conducted in the United States (46%), or enrolled community participants (52%). Most studies had sample sizes in the range of 25 to 99 participants (69%), with a relatively small number of studies enrolling more than 200 participants (8%).
- The PTSD Checklist (PCL) and the Clinician-Administered PTSD Scale (CAPS) were measures most frequently used to assess continuous PTSD outcomes, used in 62% and 52% of studies, respectively. PTSD diagnostic change or clinically meaningful response was assessed in 58 percent of studies. Among non-PTSD outcomes, depression was the most commonly assessed (67% of studies).
- For studies added in this update, we abstracted data to calculate standardized effect sizes for continuous PTSD outcomes, and risk of bias (RoB) was assessed using the updated Cochrane RoB 2 tool for randomized trials. Of these 48 RCTs, 52 percent were rated as high RoB, 31 percent were rated as low RoB, and the remaining studies were rated as some concerns (15%). Note that, for previously included studies (n=389), RoB is being progressively reassessed using RoB 2 and will be provided in a future update, along with calculated standardized effect sizes.

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. This project builds upon our previous work;[1,3,4] the purpose of this report is to identify and abstract data from RCTs examining treatment for PTSD and comorbid PTSD/SUD to update the previous AHRQ report[1] which will inform the subsequent update and expansion of the PTSD-Repository (a publicly accessible clinical trials database maintained by the NCPTSD).[2] 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.[5] For this update, we searched PTSDpubs (formerly PILOTS), Ovid® MEDLINE®, Cochrane CENTRAL, PsycINFO®, Embase®, CINAHL®, and Scopus® for eligible RCTs published from June 1, 2018, to January 26, 2022. We dually reviewed citations from the literature search and potentially includable full-text articles for eligibility, resolving disagreement by consensus. One team member abstracted data from included RCTs published prior to July 30, 2021, into evidence tables developed for the last update[1] and a second reviewer checked for accuracy and completeness. Note that studies published after July 30, 2021 will be included in the next annual update. An investigator assessed RoB for newly added studies and a subset of the 389 studies previously included in the PTSD-Repository using Cochrane's RoB 2: A Revised Tool for Assessing Risk of Bias in Randomized Trials,[6] and a second reviewer checked for accuracy. Note that we do not provide summary statistics for RoB assessment of all 437 studies in this update, since we will not complete updated RoB assessment for all 389 studies from the previous report in this phase; complete RoB assessment using the updated Cochrane RoB 2 tool and summary statistics will be provided in future annual updates.

Results

In this update, we added 48 RCTs examining treatments for PTSD for a total of 437 included RCTs overall. The updated report now includes 125 pharmacologic studies (trials with at least one medication arm) and 312 nonpharmacologic studies (trials with no medication arms). Among the 48 newly added RCTs, psychotherapy interventions were the most commonly employed (50%), followed by complementary and integrative health (17%). Approximately half of studies were conducted in the United States (46%), enrolled community participants (52%) and participants with a mix of trauma types (48%). Studies typically had sample sizes ranging from 25 to 99 participants (69%). The PCL and the CAPS were measures most frequently used to assess continuous PTSD outcomes, used in 62% and 52% of studies, respectively. PTSD diagnostic change or clinically meaningful response were assessed in 58 percent of studies. Among non-PTSD outcomes, depression was the most commonly assessed (67% of studies).Of the 48 newly added RCTs, 52 percent were rated as high RoB, 15 percent were rated as some concerns, and 31 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 with comprehensive data, calculated standardized effect sizes for PTSD outcomes, and RoB assessment from 48 recently published trials. As with the previous AHRQ reports, 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) 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.

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Introduction

Background

Posttraumatic stress disorder (PTSD) is a prevalent disorder with significant negative impacts on health, quality of life, and healthcare utilization.[1] 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.[2-5] Individuals with PTSD are often more likely to experience other mental health comorbidities compared to those without, particularly substance use.[3] 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.[6,7]

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.[8] 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. However, heterogeneity of review methods, scope, and data presentation make it difficult to synthesize across reviews and have led to variation in conclusions.[9,10] Methodological differences, such as data coding approaches and combining treatment categories for analysis, further limit the comparability of findings.

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[11] or the online PTSD Treatment Decision Aid.[12] The Department of Veterans Affairs' National Center for PTSD (NCPTSD) partnered with the

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.[13-15] The purpose of this update review, and the two 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.[16] 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[13] identified 318 studies. The second report[15] 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. This update builds on the first two AHRQ reports by including newly published studies and adding standardized effect sizes for PTSD outcomes in all these new studies. Specifically, this report updates the database to include RCTs of PTSD interventions published from June 2018 through July 30, 2021 (studies published since the completion of the last update[15]).

While we pilot tested an expanded RoB process in the last update,[15] because of the recent release of a revised, pilot-tested, and broadly accepted Cochrane RoB 2 system that addressed concerns in previous RoB assessment methods, the sponsor and Technical Expert Panel for this project recommended switching to the Cochrane RoB 2 tool for RoB assessment in the PTSD-Repository. Thus, this update will use the newly available Cochrane RoB 2 tool to assess RoB for the newly included studies and a subset of the previously included studies. Future updates will expand RoB 2 assessment and calculated standardized effect sizes to previously included studies.

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[13] and expanded to include interventions targeting comorbid PTSD/SUD, as examined in CER No. 235.[15] 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:**

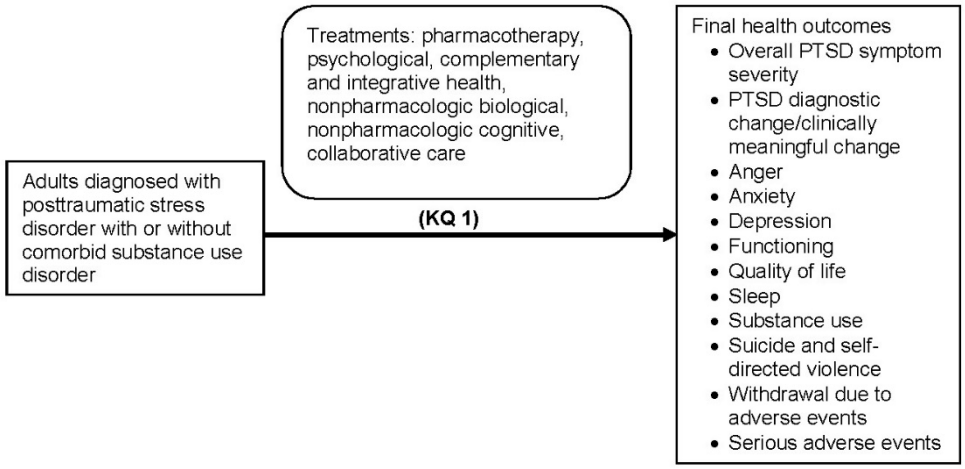
- Overall PTSD outcome, PTSD diagnostic change, PTSD clinically meaningful change
- Other outcomes – Anxiety, anger, depression, function, quality of life, sleep, substance use, suicide- and self-directed violence, withdrawal due to adverse events, serious adverse events

- **Timing:**
  - No limitation on study duration or length of followup
- **Settings:**
  - No limitation on study setting
- **Study Design:**
  - RCTs

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, 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

Methods

This report follows the methods suggested in the Agency for Healthcare Research and Quality (AHRQ) Methods Guide for Effectiveness and Comparative Effectiveness Reviews[17] 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[13] and the last update.[15] A protocol was published on the AHRQ website (https://effectivehealthcare.ahrq.gov/products/ptsd-repository-update/protocol). Notably, because this project focused both on updating the evidence base with new PTSD trials as well as updating risk of bias (RoB) assessment methods, two Technical Expert Panels (TEPs) were convened to provide guidance in these two areas. The Content TEP had expertise related to PTSD trials as well as expertise in substance use disorders, suicide prevention research, and issues related to diversity and inclusion in clinical trials. The RoB TEP had RoB assessment methods expertise and provided guidance related to the updated RoB assessment methods.

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.[15] We included treatments for 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.

Table 1. PICOTS: Inclusion and exclusion criteria

PICOTS	Include	Exclude
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) • Diagnosis of acute stress disorder • Studies that do not specify criteria used to diagnose PTSD • Sample population with <80% of participants diagnosed with PTSD (i.e., >20% with study-defined subthreshold PTSD), or if include comorbid SUD, <80% of participants diagnosed with comorbid PTSD/SUD
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. • Interventions such as waitlist/minimal attention, usual care, placebo, or other minimally-active treatment (e.g., education or attention control) are categorized as "Controls"	None
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

Literature Search

Electronic databases were searched for evidence from June 1, 2018, to April 12, 2021, containing 18 months of overlap with the last database search for the last update.[15] An updated literature search was conducted January 26, 2022, and new literature published before July 30,

2021 that met inclusion criteria was incorporated into the final report. Note that studies meeting inclusion criteria but published after July 30, 2021 will be included in the next annual update due to limited time and resources. These studies are listed in Appendix C.

Literature databases searched included PTSDpubs (formerly PILOTS), Ovid® MEDLINE®, Cochrane CENTRAL, Embase®, the Cumulative Index to Nursing and Allied Health Literature (CINAHL®), SCOPUS, and PsycINFO®. Search strategies are 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. Again, included studies published after July 30, 2021, are listed in Appendix C and studies excluded at the full-text level with reasons for exclusion appear in Appendix D.

Data Abstraction

After studies were screened and deemed to meet inclusion criteria, study data was 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 E for a complete list of data elements abstracted). Data were abstracted into detailed evidence tables in Microsoft® Excel developed for the first report[13] and revised for the last update[15] to include additional data elements: 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. For this update, the evidence table was restructured to ensure that future updates to the PTSD-Repository no longer required any hand searching and editing, and that most, if not all, data integration processes could be automated using replicable syntax. This update added calculation of standardized effect sizes for newly included studies, provided the study reported the necessary data. All abstracted data were dual reviewed for accuracy and completeness. Evidence tables are available in Appendix F.

A separate evidence table was constructed to record RoB assessments, described below. All studies regardless of overall RoB rating were incorporated in the summarized results presented below. Results from studies were not synthesized, but characteristics of included 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.

Standardized Effect Size Calculation

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 formula (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 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.[18] 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

$$d = \frac{Mean_{folow\ -up} - Mean_{baseline}}{s}$$

$$\text{Where, } s = \sqrt{s^2_{baseline} + s^2_{follow\ -up} - 2 \times corr \times s_{baseline} \times s_{follow\ -up}}$$

$$\text{Assuming correlation} = 0.5 \text{ and } N_{baseline} = N_{follow\ -up}$$

Assessment of Methodological Risk of Bias of Individual Studies

Risk of bias was assessed for all new randomized controlled trials (RCTs) added in this update using Cochrane's RoB 2 system. The decision to update the RoB assessments to align with the Cochrane RoB 2 assessment tool was informed by discussions with the sponsor, NCPTSD, and a TEP specifically focused on RoB assessments. This RoB-focused TEP highlighted the need for a final product that is accessible to a broad range of users; uses the current, pilot-tested, and gold standard RoB assessment tool; and emphasizes transparent and replicable abstraction of RoB-related data to facilitate updating as RoB assessment tools continue to evolve in the future. To augment and clarify aspects of the RoB assessments to ensure transparency and ease of future updating, we included detailed definitions related to how RoB was assessed. 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). Because previously-included studies from the last update[15] were assessed with an earlier version of Cochrane's RoB assessment tool based on the AHRQ Methods Guide for Effectiveness and Comparative Effectiveness Review,[19] we updated RoB assessments for a subset of RCTs previously included the PTSD-Repository in this report and plan to complete the transition to the Cochrane RoB 2 system for the remaining studies in future updates. Appendix G contains RoB assessments for newly included studies (Appendix Table G-1) and studies included in prior reports (Appendix Table G-2). Appendix Table G-3 provides updated RoB 2 assessments for 82 of the studies from the prior reports. This table will be updated with RoB 2 assessments of the remaining studies in future updates.

Grading the Strength of Evidence for Major Comparisons and Outcomes

Strength of evidence was not assessed for this review.

Assessing Applicability

Applicability was not assessed for this review.

Peer Review and Public Commentary

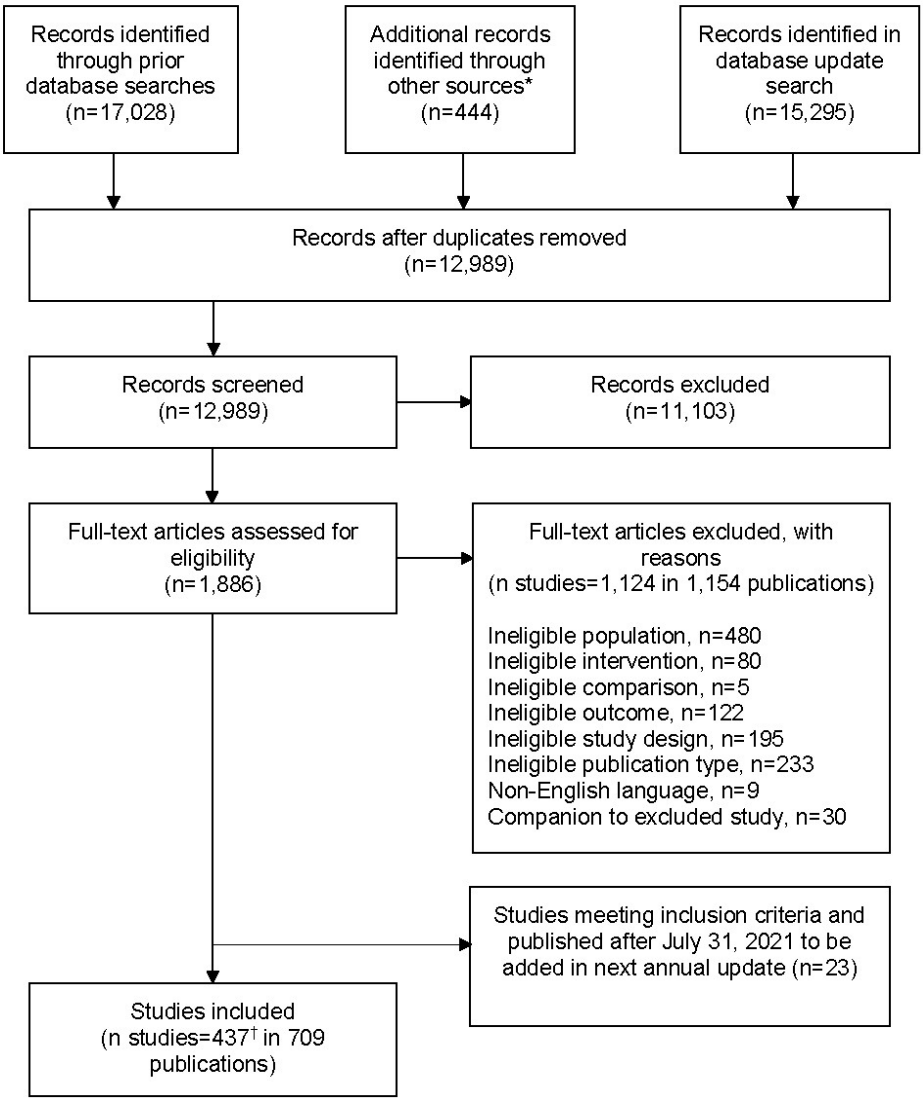
Experts in the field of PTSD were invited to provide external peer review of this review and evidence tables. Comments and editorial review were also sought from the AHRQ Task Order Officer, an associate editor, and partners at NCPTSD. The draft report was posted on the AHRQ website for 4 weeks to elicit 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. This report will be posted after the publication of the final evidence report on the AHRQ website.

Results

Results of Literature Search

In this update we included 48 new studies published through July 31, 2021 (in 47 publications), bringing the total number of included studies in this report to 437 (in 709 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 12,989 unique records. After review of abstracts and titles, 1,886 articles were selected for full-text review, and 437 studies were determined to meet inclusion criteria and were designated for data abstraction. An additional 23 studies were identified as eligible for inclusion, but were published after July 30, 2021, and will be included in the next annual update. These studies are listed in Appendix C. Reasons for exclusion of studies were ineligible population, intervention, outcomes, study design, publication type, and foreign language articles. Appendices B and C contain the list of studies that met inclusion criteria; Appendix B includes studies published before July 31, 2021 (incorporated into this review); Appendix C includes the list of studies published after July 31, 2021 (to be incorporated in the next annual update). Appendix D lists studies excluded upon full-text review and reasons for exclusion.

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



*Other sources include prior reports, reference lists of relevant articles, systematic reviews, etc.
†In this update report, 48 new studies (in 47 publications) were included.

Characteristics of Included Studies

Treatments were classified by the intervention categories described in Table 2. These categories included pharmacologic treatments and four nonpharmacologic treatment subtypes, which are nonpharmacologic biologic treatments, nonpharmacologic cognitive therapy, complementary and integrative health, and psychotherapeutic treatments. 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 vs. control intervention would have the first arm classified as both psychotherapy and pharmacotherapy, and the second arm as control.

Table 2. Intervention categories with examples*†

Category	Definition	Examples
Pharmacotherapy	Medication	Antiadrenergic drugs (e.g., clonidine, guanfacine, propranolol) Antidepressants (e.g., SSRIs, SNRIs, TCAs, MAOIs, other) Antipsychotics (first and second generation) Benzodiazepines Cannabinoids (e.g., cannabidiol, dronabinol, tetrahydrocannabinol) Mood Stabilizers (e.g., anticonvulsants, lithium) Psychostimulants (e.g., MDMA, amphetamine, methylphenidate, modafinil) Sedatives (e.g., diphenhydramine, eszopiclone) Steroids (e.g., dehydroepiandrosterone, hydrocortisone) Miscellaneous (e.g., D-cycloserine, ketamine, mifepristone, others)
Nonpharmacologic Biologic	Interventions that use a medical device or procedure of some kind.	Electroconvulsive therapy Hyperbaric oxygen therapy Repetitive transcranial magnetic stimulation Stellate ganglion block Vagal nerve stimulation
Complementary and Integrative Health	Wide category of approaches that are considered to be outside the standard in the current practice of Western medicine.	Acupuncture Clinical hypnosis Meditation (includes mindfulness and mantram) Massage therapy Tai chi/qi gong Yoga Other physical activity and recreational therapies Animal-assisted Natural products Creative therapies Relaxation (includes biofeedback/neurofeedback) Spirituality
Psychotherapy	Talk therapy with a licensed provider	Cognitive Processing Therapy COPE Eye Movement Desensitization and Reprocessing Cognitive Behavioral Therapy Narrative Exposure Therapy Present-centered therapy Prolonged Exposure Psychodynamic Therapy Seeking Safety Written Exposure Therapy
Nonpharmacologic Cognitive	Interventions that teach cognitive skills to improve attention.	Attention bias modification
Collaborative Care	Interventions in which integrated medical and mental health treatment is delivered in primary care, often by nurse managers.	Centrally assisted collaborative telecare Three component model Telemedicine Outreach for PTSD
Other	Treatments that don't fit into another category	Digital interventions not delivered by a licensed provider (e.g., internet-based CBT, PTSD Coach)
Control	Comparison conditions such as a placebo pill, waitlist, and treatment as usual.	Placebo Psychoeducation Sham Treatment as Usual Waitlist

*Table 2 intervention lists and categories adapted from the 2017 Department of Veterans Affairs/Department of Defense clinical practice guideline.[20]

†See Appendix I for full treatment coding guidance.

Abbreviations: CBT = cognitive behavioral therapy; COPE = Concurrent Treatment for PTSD and Substance Use Disorder Using Prolonged Exposure; MDMA = 3,4-methylenedioxy-methamphetamine; MAOI = monoamine oxidase inhibitor; PTSD =

posttraumatic stress disorder; SSRI = selective serotonin reuptake inhibitor; SNRI = serotonin and norepinephrine reuptake inhibitor; TCA = tricyclic antidepressant.

Key characteristics for the 48 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, and Table 5 provides a list of outcomes for each of the studies. Additional details about these studies are included in the detailed data abstraction evidence tables in Appendix F. The underlying data for figures in this section are provided additionally as tables in Appendix H.

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

Author, Year	Study Class	Sample Size	Countries	Clinical Setting	Military Status	Race/Ethnicity Reported	Trauma Type
Alsheikh Ali, 2020[21]	Psychotherapy	40	Jordan	Unclear	Community	Not Reported	Terrorism/political violence/forced displacement
Angelakis, 2020[22]	Psychotherapy	52	Australia	Outpatient clinic	Community	Race data reported	Mixed
Baekkelund, 2021[23]	Psychotherapy	89	Norway	Outpatient clinic	Community	Not Reported	Mixed
Beck, 2021[24]	CIH	74	Denmark	Outpatient clinic	Community	Not Reported	Mixed
Bellehsen, 2021[25]	CIH	40	U.S.	Outpatient clinic	Veteran	Race and Ethnicity data reported	Mixed
Bisson, 2020[26]	Psychotherapy	42	U.K.	Outpatient clinic	Veteran	Race data reported	Mixed
Bohus, 2020[27]	Psychotherapy	193	Germany	Outpatient clinic	Community	Not Reported	Mixed
Bonn-Miller, 2021[28]	Pharmacotherapy	80	U.S.	Outpatient clinic	Veteran	Race data reported	Mixed
Bormann, 2018[29]	CIH	173	U.S.	Outpatient clinic	Veteran	Race and Ethnicity data reported	Other
Boterhoven de Haan, 2020[30]	Psychotherapy	155	Australia; Germany; The Netherlands	Outpatient clinic	Community	Race data reported	Mixed
Bottche, 2021[31]	Psychotherapy	224	Egypt, Saudi Arabia, Algeria, Syria, Morocco, and Palestine	Other (internet)	Community	Not Reported	Mixed
Dadabayev, 2020[32]	Pharmacotherapy	21	U.S.	Outpatient clinic	Veteran	Race data reported	Other
Davis, 2020b[33]	Pharmacotherapy	78	U.S.	Outpatient clinic	Veteran	Race and Ethnicity data reported	Mixed
Davis, 2021[34]	Psychotherapy	92	U.S.	Outpatient clinic	Mixed	Race data reported	Mixed
Dunlop, 2021[35]	Pharmacotherapy	41	U.S.	Outpatient clinic	Community	Race and Ethnicity data reported	Mixed
Duran, 2020[36]	Psychotherapy	95	Brazil	Outpatient clinic	Community	Not Reported	Not Reported
Efendi, 2020[37]	Psychotherapy	90	Indonesia	Outpatient clinic	Community	Not Reported	Natural disaster
Farahimanesh, 2021[38]	Psychotherapy	60	Iran	Outpatient clinic	Community	Not Reported	Not Reported

Author, Year	Study Class	Sample Size	Countries	Clinical Setting	Military Status	Race/Ethnicity Reported	Trauma Type
Feder, 2021[39]	Pharmacotherapy	30	U.S.	Outpatient clinic	Community	Race and Ethnicity data reported	Mixed
Gallegos, 2020[40]	CIH	29	U.S.	Outpatient clinic	Community	Race and Ethnicity data reported	Intimate partner violence
Gray, 2021[41]	Psychotherapy	30	U.S.	Outpatient clinic	Mixed	Race and Ethnicity data reported	Mixed
Haynes, 2020[42]	Psychotherapy	43	U.S.	Outpatient clinic	Veteran	Race and Ethnicity data reported	Combat-related
Jain, 2020[43]	Psychotherapy	26	U.S.	Primary care clinic	Veteran	Race and Ethnicity data reported	Not Reported
Jalal, 2020[44]	Psychotherapy	30	South Africa	Mixed	Community	Not Reported	Not Reported
Jarero, 2019[45]	Psychotherapy	60	Mexico	Unclear/Not Reported	Community	Not Reported	Other
Johnson, 2020[46]	Psychotherapy	172	U.S.	Other	Community	Race and Ethnicity data reported	Intimate partner violence
Kearney, 2021[47]	Psychotherapy & CIH	184	U.S.	Outpatient clinic	Veteran	Race and Ethnicity data reported	Mixed
Kelly, 2021[48]	CIH	104	U.S.	Not Reported	Veteran	Race data reported	MST
Koch, 2020[49]	Psychotherapy	44	Germany	Outpatient clinic	Community	Not Reported	Mixed
Latif, 2021[50]	Psychotherapy	50	Pakistan	Other	Community	Not Reported	Intimate partner violence
Lehavot, 2021[51]	Other Mixed	102	U.S.	Other	Veteran	Race and Ethnicity data reported	Mixed
Litz, 2021[52]	Psychotherapy	122	U.S.	Unclear/Not Reported	Active Duty Military	Race data reported	Not Reported
McLean, 2020[53]	Psychotherapy	40	U.S.	Mixed	Mixed	Race and Ethnicity data reported	Not Reported
Meffert, 2021[54]	Psychotherapy	256	Kenya	Other	Community	Not Reported	Intimate partner violence
Mitchell, 2021[55]	Psychotherapy & Pharmacotherapy	90	Canada; Israel; U.S.	Unclear/Not Reported	Mixed	Race and Ethnicity data reported	Mixed
Moradi, 2021[56]	Nonpharmacologic cognitive	43	Iran	Other (home)	Community	Race data reported	Accidents
Nicholson, 2020[57]	Nonpharmacologic biologic	36	Canada	Unclear/Not Reported	Mixed	Not Reported	Mixed
Oprel, 2021[58]	Psychotherapy	149	The Netherlands	Outpatient clinic	Community	Not Reported	Mixed
Petrakis, 2020[59]	Psychotherapy & Pharmacotherapy	24	U.S.	Outpatient clinic	Veteran	Race and Ethnicity data reported	Not Reported

Author, Year	Study Class	Sample Size	Countries	Clinical Setting	Military Status	Race/Ethnicity Reported	Trauma Type
Rajan, 2020[60]	Psychotherapy	36	Sweden	Outpatient clinic	Community	Race data reported	Rape/sexual assault
Roullet, 2021[61]	Psychotherapy and Pharmacotherapy	66	France	Outpatient clinic	Community	Not Reported	Mixed
Sandahl, 2021[62]	Psychotherapy and Pharmacotherapy	219	Denmark	Outpatient clinic	Community	Not Reported	Mixed
Spangler, 2020[63]	Pharmacotherapy	75	U.S.	Unclear/Not Reported	Mixed	Race data reported	Not Reported
Sullivan, 2021[64]	Pharmacotherapy	245	U.S.	Outpatient clinic	Mixed	Race and Ethnicity data reported	Mixed
Tang, 2021[65]	Nonpharmacologic biologic	28	Canada	Mixed	Community	Not Reported	Not Reported
Wheeler, 2020 Study 1[66]	CIH	30	U.K.	Other	Veteran	Not Reported	Not Reported
Wheeler, 2020 Study 2[66]	CIH	25	U.K.	Other	Veteran	Not Reported	Not Reported
Youngstedt, 2021[67]	CIH	71	U.S.	Other (home)	Veteran	Not Reported	Combat-related

Abbreviations: CIH = complementary and integrative health; MST = military sexual trauma.

Table 4. Summary of newly included studies: intervention characteristics

Author, Year	Intervention Group*	Treatment Name	Treatment Focus	Intervention Categorization	Intervention Format	Intervention Delivery Method
Alsheikh Ali, 2020[21]	A	Group counseling	PTSD	Psychotherapy	Group	In Person
Alsheikh Ali, 2020[21]	B	No treatment	Control	Control	NA	NA
Angelakis, 2020[22]	A	Cognitive Processing Therapy	PTSD	Psychotherapy	Individual	In Person
Angelakis, 2020[22]	B	Behavioral Activation/Cognitive Processing Therapy	PTSD	Psychotherapy	Individual	In Person
Angelakis, 2020[22]	C	Cognitive Processing Therapy/Behavioral Activation	PTSD	Psychotherapy	Individual	In Person
Baekkelund, 2021[23]	A	Stabilization group treatment	PTSD	Psychotherapy	Group	In person
Baekkelund, 2021[23]	B	Waiting period	Control	Control	NA	In person
Beck, 2021[24]	A	Trauma-focused music and imagery	PTSD	Psychotherapy + CIH	Individual	In Person
Beck, 2021[24]	B	TAU	PTSD	Psychotherapy + Control	Individual	In Person
Bellehsen, 2021[25]	A	Transcendental meditation	PTSD	CIH	Mixed	In person
Bellehsen, 2021[25]	B	TAU	Control	Control	NA	NA
Bisson, 2020[26]	A	Multimodular motion-assisted memory desensitization and reconsolidation	PTSD	Psychotherapy	Individual	In Person
Bisson, 2020[26]	B	Waiting list	Control	Control	NA	NA
Bohus, 2020[27]	A	DBT-PTSD	PTSD	Psychotherapy	Individual	In person
Bohus, 2020[27]	B	CPT	PTSD	Psychotherapy	Individual	In person
Bonn-Miller, 2021[28]	A	High THC	PTSD	Pharmacotherapy	Individual	In person
Bonn-Miller, 2021[28]	B	High CBD	PTSD	Pharmacotherapy	Individual	In person
Bonn-Miller, 2021[28]	C	THC+CBD	PTSD	Pharmacotherapy	Individual	In person
Bonn-Miller, 2021[28]	D	Placebo	Control	Control	Individual	In person
Bormann, 2018[29]	A	Mantram repetition	PTSD	CIH	Individual	In Person

Author, Year	Intervention Group*	Treatment Name	Treatment Focus	Intervention Categorization	Intervention Format	Intervention Delivery Method
Bormann, 2018[29]	B	PCT	PTSD	Psychotherapy	Individual	In Person
Boterhoven de Haan, 2020[30]	A	Imagery rescripting	PTSD	Psychotherapy	Individual	In person
Boterhoven de Haan, 2020[30]	B	EMDR	PTSD	Psychotherapy	Individual	In person
Bottche, 2021[31]	A	Internet-based CBT (regular length)	PTSD	Psychotherapy	Individual	Mixed: technology assisted and written
Bottche, 2021[31]	B	Brief internet-based CBT	PTSD	Psychotherapy	Individual	Mixed: technology assisted and written
Dadabayev, 2020[32]	A	Ketamine	PTSD	Pharmacotherapy	Individual	In person
Dadabayev, 2020[32]	B	Ketorolac	Control	Pharmacotherapy	Individual	In person
Davis, 2020bDavis, 2020b[33]	A	Mirtazapine	PTSD	Pharmacotherapy	Individual	In Person
Davis, 2020bDavis, 2020b[33]	B	Placebo	Control	Control	Individual	In Person
Davis, 2021[34]	A	Mindfulness-based CBCT	PTSD	Psychotherapy	Mixed	In Person
Davis, 2021[34]	B	CBCT with communication skills training	PTSD	Psychotherapy	Mixed	In Person
Dunlop, 2021[35]	A	Vortioxetine	PTSD	Pharmacotherapy	Individual	In person
Dunlop, 2021[35]	B	Placebo	Control	Control	Individual	In person
Duran, 2020[36]	A	PE	PTSD	Psychotherapy	Individual	In Person
Duran, 2020[36]	B	TBCT	PTSD	Psychotherapy	Individual	In Person
Efendi, 2020[37]	A	Trauma-focused Cognitive Behavioral Therapy	PTSD	Psychotherapy	Individual	In Person
Efendi, 2020[37]	B	Waitlist	Control	Other	NA	NA
Farahimanesh, 2021[38]	A	Competitive Memory Training	PTSD	Nonpharmacologic Cognitive Therapy	Individual	In Person
Farahimanesh, 2021[38]	B	Memory Specificity Training	PTSD	Nonpharmacologic Cognitive Therapy	Individual	In Person
Feder, 2021[39]	A	Ketamine	PTSD	Pharmacotherapy	Individual	In Person

Author, Year	Intervention Group*	Treatment Name	Treatment Focus	Intervention Categorization	Intervention Format	Intervention Delivery Method
Feder, 2021[39]	B	Placebo	Control	Pharmacotherapy	Individual	In Person
Gallegos, 2020[40]	A	MBSR	PTSD	CIH	Group	In Person
Gallegos, 2020[40]	B	Wellness Control	Control	Other	Individual	Phone
Gray, 2021[41]	A	Reconsolidation of Traumatic Memories	PTSD	Psychotherapy	Individual	In Person
Gray, 2021[41]	B	Waitlist	Control	Other	NA	NA
Haynes, 2020[42]	A	Cognitive Behavioral Social Rhythm Group Therapy	PTSD	Psychotherapy	Group	In Person
Haynes, 2020[42]	B	Group PCT	PTSD	Psychotherapy	Group	In Person
Jain, 2020[43]	A	STAIR-PC	PTSD	Psychotherapy	Individual	In Person
Jain, 2020[43]	B	TAU	Control	Other	Individual	In Person
Jalal, 2020[44]	A	CA-CBT	PTSD	Psychotherapy	Individual	In Person
Jalal, 2020[44]	B	AMR	PTSD	CIH	Individual	In Person
Jarero, 2019[45]	A	EMDR-PRECI	PTSD	Psychotherapy	Individual	In Person
Jarero, 2019[45]	B	Waitlist	Control	Control	NA	NA
Johnson, 2020[46]	A	HOPE therapy	PTSD	Psychotherapy	Individual	In Person
Johnson, 2020[46]	B	PCT+	PTSD	Psychotherapy	Individual	In Person
Kearney, 2021[47]	A	Loving kindness meditation	PTSD	CIH	Group	In Person
Kearney, 2021[47]	B	Cognitive Processing Therapy	PTSD	Psychotherapy	Group	In Person
Kelly, 2021[48]	A	Trauma Center Trauma-Sensitive Yoga	PTSD	CIH	Group	In Person
Kelly, 2021[48]	B	CPT	PTSD	Psychotherapy	Group	In Person
Koch, 2020[49]	A	Skills-Training of Affect Regulation-A Culture-sensitive Approach	PTSD	Psychotherapy	Group	In Person
Koch, 2020[49]	B	Waitlist	Control	Other	NA	NA
Latif, 2021[50]	A	Culturally adapted trauma-focused CBT-based guided self-help	PTSD	Psychotherapy	Individual	In Person

Author, Year	Intervention Group*	Treatment Name	Treatment Focus	Intervention Categorization	Intervention Format	Intervention Delivery Method
Latif, 2021[50]	B	Waitlist	Control	Other	NA	NA
Lehavot, 2021[51]	A	Delivery of Self Training and Education for Stressful Situations	PTSD	Control	Individual	Technology alone
Lehavot, 2021[51]	B	Phone monitoring	Control	Other	Individual	Phone
Litz, 2021[52]	A	Adaptive Disclosure	PTSD	Psychotherapy	Individual	In Person
Litz, 2021[52]	B	Cognitive Processing Therapy-Cognitive Therapy	PTSD	Psychotherapy	Individual	In Person
McLean, 2020[53]	A	Web-based prolonged exposure therapy	PTSD	Psychotherapy	Individual	Technology alone
McLean, 2020[53]	B	Present-centered therapy	PTSD	Psychotherapy	Individual	In Person
Meffert, 2021[54]	A	IPT + TAU	PTSD	Psychotherapy	Individual	In Person
Meffert, 2021[54]	B	Waitlist + TAU	PTSD	Control	NR	NA
Mitchell, 2021[55]	A	MDMA-assisted therapy	PTSD	Psychotherapy + Pharmacotherapy	Individual	In Person
Mitchell, 2021[55]	B	Placebo + therapy	PTSD	Psychotherapy + Control	Individual	In Person
Moradi, 2021[56]	A	Memory flexibility training (MemFlex)	PTSD	Nonpharmacologic Cognitive Therapy	Individual	Written
Moradi, 2021[56]	B	Waitlist	Control	Control	NA	NA
Nicholson, 2020[57]	A	Alpha-rhythm electroencephalogram neurofeedback (EEG-NFB)	PTSD	Nonpharmacologic Biologic	Individual	In person
Nicholson, 2020[57]	B	Sham control	Control	Control	Individual	In person
Oprel, 2021[58]	A	Prolonged exposure	PTSD	Psychotherapy	Individual	In Person
Oprel, 2021[58]	B	Intensive prolonged exposure	PTSD	Psychotherapy	Individual	In Person
Oprel, 2021[58]	C	Skills training in affective and interpersonal regulation + prolonged exposure	PTSD	Psychotherapy	Individual	In Person
Petrakis, 2020[59]	A	Zonisamide + CPT	PTSD+SUD	Psychotherapy + Pharmacotherapy	Individual	In Person

Author, Year	Intervention Group*	Treatment Name	Treatment Focus	Intervention Categorization	Intervention Format	Intervention Delivery Method
Petrakis, 2020[59]	B	Placebo + CPT	PTSD+SUD	Psychotherapy + Other	Individual	In Person
Rajan, 2020[60]	A	Modified Lifespan Integration	PTSD	Psychotherapy	Individual	In Person
Rajan, 2020[60]	B	Waitlist control	Control	Other	NA	NA
Roullet, 2021[61]	A	Propranolol + traumatic memory reactivation	PTSD	Psychotherapy + Pharmacotherapy	Individual	In Person
Roullet, 2021[61]	B	Placebo + traumatic memory reactivation	Control	Psychotherapy + Control	Individual	In Person
Sandahl, 2021[62]	A	Imagery rehearsal therapy + mianserin + TAU	PTSD	Psychotherapy + Pharmacotherapy	Individual	In Person
Sandahl, 2021[62]	B	Imagery rehearsal therapy + TAU	PTSD	Psychotherapy	Individual	In Person
Sandahl, 2021[62]	C	Mianserin + TAU	PTSD	Psychotherapy + Pharmacotherapy	Individual	In Person
Sandahl, 2021[62]	D	TAU	PTSD	Psychotherapy + Collaborative Care	Individual	In Person
Spangler, 2020[63]	A	Riluzole	PTSD	Pharmacotherapy	Individual	In Person
Spangler, 2020[63]	B	Placebo	Control	Control	Individual	In Person
Sullivan, 2021[64]	A	TNX-102 SL (cyclobenzaprine)	PTSD	Pharmacotherapy	Individual	In Person
Sullivan, 2021[64]	B	TNX-102 SL (cyclobenzaprine)	PTSD	Pharmacotherapy	Individual	In Person
Sullivan, 2021[64]	C	Placebo	Control	Control	Individual	In Person
Tang, 2021[65]	A	ECT + traumatic memory reactivation	PTSD	Psychotherapy + Nonpharmacologic Biologic	Individual	In Person
Tang, 2021[65]	B	ECT + neutral memory reactivation	Control	Nonpharmacologic Biologic + Control	Individual	In Person
Wheeler, 2020 Study 1[66]	A	Angling	PTSD	CIH	Group	In Person

Author, Year	Intervention Group*	Treatment Name	Treatment Focus	Intervention Categorization	Intervention Format	Intervention Delivery Method
Wheeler, 2020 Study 1[66]	B	Equine	PTSD	CIH	Group	In Person
Wheeler, 2020 Study 1[66]	C	Falconry	PTSD	CIH	Group	In Person
Wheeler, 2020 Study 2[66]	A	Angling	PTSD	CIH	Group	In Person
Wheeler, 2020 Study 2[66]	B	Waitlist	Control	Control	NA	NA
Youngstedt, 2021[67]	A	Bright light exposure	PTSD	CIH	Individual	In Person
Youngstedt, 2021[67]	B	Control treatment	Control	Control	Individual	In Person

*Each intervention group (study arm) is listed in a separate row, therefore studies are listed in multiple rows.

Abbreviations: AMR = applied muscle relaxation; CA-CBT = culturally adapted cognitive behavioral therapy; CBD = cannabidiol; CBCT = cognitive-behavioral conjoint therapy; CBSRT = Cognitive Behavioral Social Rhythm Group Therapy; CBT = cognitive behavioral therapy; CIH = complementary and integrative health; CPT = Cognitive Processing Therapy; DBT-PTSD = dialectical behavior therapy for PTSD; ECT = electroconvulsive therapy; EEG-NFB = electroencephalogram neurofeedback; EMDR = Eye Movement Desensitization and Reprocessing; HOPE = Helping to Overcome PTSD through Empowerment; IPT = Interpersonal Psychotherapy; MBSR = Mindfulness-based Stress Reduction; MDMA = 3,4-methylenedioxy-methamphetamine; NA = not applicable; NR = not reported; PCT = Present-Centered Therapy; PCT+ = Present-Centered Therapy; PE = Prolonged Exposure; PTSD = posttraumatic stress disorder; STAIR-PC = Skills Training in Affective and Interpersonal Regulation for PTSD treatment in primary care; SUD = substance use disorder; TAU = treatment as usual; TBCT = trial-based cognitive therapy; THC = tetrahydrocannabinol; TNX-102 = cyclobenzaprine hydrochloride.

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

Author, Year	PTSD Continuous Outcome Measure(s)	PTSD Diagnostic Change	PTSD Clinically Meaningful Response	Anger	Anxiety	Depression	Function	Quality of Life	Sleep	Substance Use	Suicide
Alsheikh Ali, 2020[21]	PCL	N	N	N	N	N	N	N	N	N	N
Angelakis, 2020[22]	CAPS, PCL	Y	Y	N	N	Y	N	N	N	N	Y
Baekkelund, 2021[23]	PSS-SR	N	N	N	N	N	Y	N	N	N	N
Beck, 2021[24]	HTQ	N	Y	N	N	N	N	N	N	N	N
Bellehsen, 2021[25]	CAPS, PCL	Y	Y	Y	Y	Y	N	Y	Y	N	N
Bisson, 2020[26]	CAPS, PCL	N	N	N	Y	Y	Y	Y	Y	N	N
Bohus, 2020[27]	CAPS, PCL	Y	Y	N	N	Y	Y	N	N	N	N
Bonn-Miller, 2021[28]	CAPS, PCL	N	N	N	Y	Y	Y	N	Y	N	Y
Bormann, 2018[29]	CAPS, PCL	Y	Y	Y	N	Y	Y	Y	Y	N	N
Boterhoven de Haan, 2020[30]	CAPS, IES	N	N	Y	N	Y	Y	N	N	N	N
Bottche, 2021[31]	PDS	N	N	N	Y	Y	N	Y	N	N	N
Dadabayev, 2020[32]	IES	N	N	N	N	N	N	N	N	N	N
Davis, 2020b[33]	CAPS, SI-PTSD, DTS	N	Y	N	N	Y	N	N	Y	N	N
Davis, 2021[34]	CAPS, PCL	N	N	Y	Y	Y	N	N	N	N	N
Dunlop, 2021[35]	CAPS, PCL	N	Y	N	N	Y	N	N	N	N	Y
Duran, 2020[36]	DTS	Y	N	N	Y	Y	N	N	N	N	N
Efendi, 2020[37]	No continuous outcome measure	Y	N	N	N	Y	N	N	N	N	N
Farahimanesh, 2021[38]	PCL	N	N	N	N	Y	N	N	N	N	N
Feder, 2021[39]	CAPS	N	Y	N	N	Y	N	N	N	N	Y
Gallegos, 2020[40]	PCL	N	N	N	N	N	N	N	N	N	N

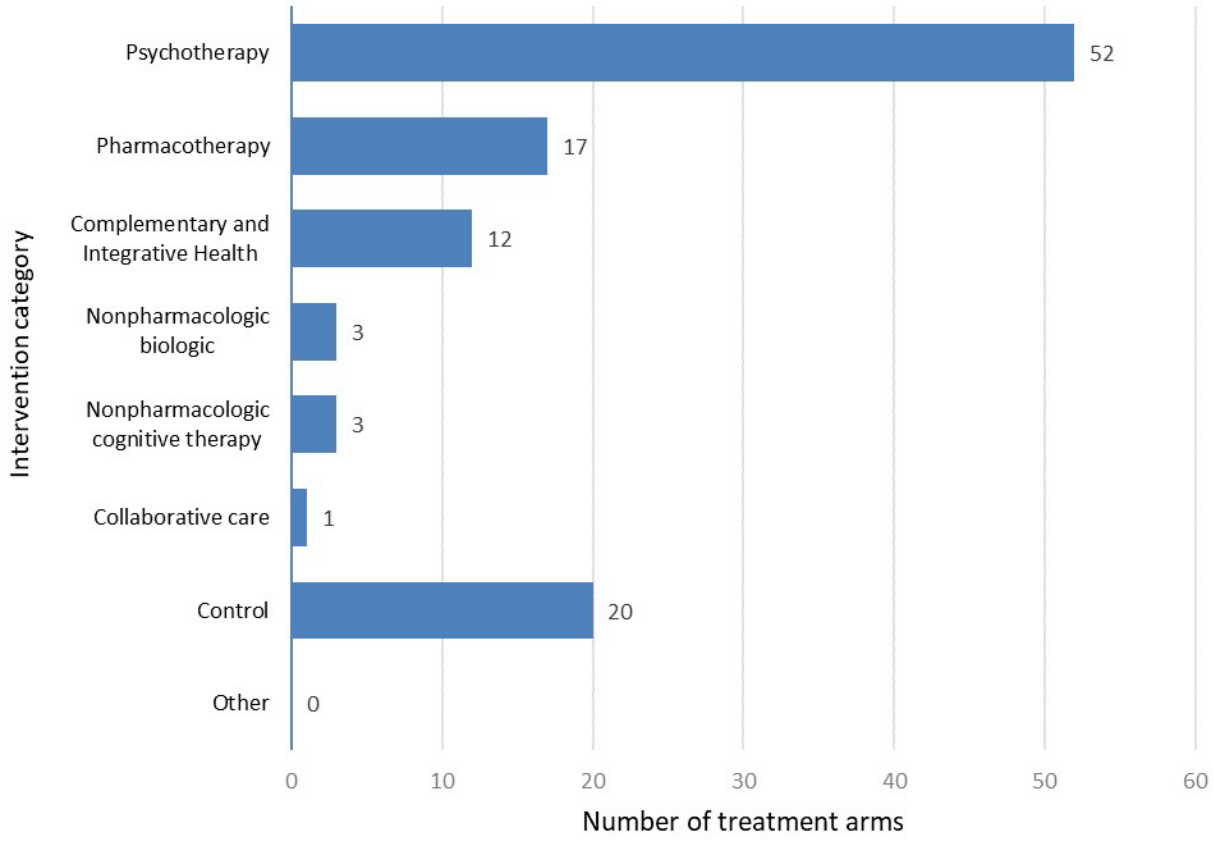
Author, Year	PTSD Continuous Outcome Measure(s)	PTSD Diagnostic Change	PTSD Clinically Meaningful Response	Anger	Anxiety	Depression	Function	Quality of Life	Sleep	Substance Use	Suicide
Gray, 2021[41]	PSS-I, PCL	N	Y	N	N	N	N	N	N	N	N
Haynes, 2020[42]	CAPS, PCL	N	Y	N	N	Y	N	N	Y	N	N
Jain, 2020[43]	PCL	N	Y	N	N	Y	Y	N	N	N	N
Jalal, 2020[44]	PCL	N	N	N	Y	Y	N	N	N	N	N
Jarero, 2019[45]	PCL	N	N	N	Y	Y	N	N	N	N	N
Johnson, 2020[46]	CAPS	Y	Y	N	N	Y	N	Y	N	N	N
Kearney, 2021[47]	CAPS	Y	Y	N	N	Y	N	N	N	N	N
Kelly, 2021[48]	CAPS, PCL	N	Y	N	N	N	N	N	N	N	N
Koch, 2020[49]	PCL	N	N	Y	N	N	N	N	N	N	N
Latif, 2021[50]	IES	N	N	N	Y	Y	Y	N	N	N	N
Lehavot, 2021[51]	PCL	N	Y	N	N	N	N	N	N	N	N
Litz, 2021[52]	CAPS, PCL	N	Y	N	N	Y	N	Y	N	N	N
McLean, 2020[53]	CAPS, PCL	N	Y	N	N	Y	N	Y	N	N	N
Meffert, 2021[54]	PCL	Y	N	N	N	Y	Y	N	N	N	N
Mitchell, 2021[55]	CAPS	Y	Y	N	N	Y	Y	N	N	N	Y
Moradi, 2021[56]	PCL	N	Y	N	N	Y	N	N	N	N	N
Nicholson, 2020[57]	CAPS	Y	N	N	N	N	N	N	N	N	N
Oprel, 2021[58]	CAPS, PCL	Y	Y	N	N	N	N	N	N	N	N
Petrakis, 2020[59]	CAPS, PCL	N	N	N	N	N	N	N	N	Y	N
Rajan, 2020[60]	IES, NSESSS	Y	N	N	N	N	Y	N	N	N	N
Roullet, 2021[61]	PCL	Y	N	N	N	Y	N	N	N	N	N
Sandahl, 2021[62]	HTQ	Y	N	N	Y	Y	Y	Y	Y	N	N
Spangler, 2020[63]	CAPS, PCL	N	N	N	Y	Y	Y	N	N	N	N
Sullivan, 2021[64]	CAPS	N	N	N	N	N	Y	N	N	N	N
Tang, 2021[65]	CAPS, MPSS	N	N	N	N	N	N	N	N	N	N
Wheeler, 2020 Study 1[66]	PCL	N	N	N	N	N	N	N	N	N	N

Author, Year	PTSD Continuous Outcome Measure(s)	PTSD Diagnostic Change	PTSD Clinically Meaningful Response	Anger	Anxiety	Depression	Function	Quality of Life	Sleep	Substance Use	Suicide
Wheeler, 2020 Study 2[66]	PCL	N	N	N	Y	Y	Y	N	N	N	N
Youngstedt, 2021[67]	CAPS, PCL	N	Y	N	Y	Y	N	N	Y	N	N

Abbreviations: CAPS = Clinician-Administered PTSD Scale; DTS = Davidson Trauma Scale; HTQ = Harvard Trauma Questionnaire; IES = Impact of Event Scale; MPSS = Modified PTSD Symptom Scale; N = No, data element was not reported for the study; NSESSS = National Stressful Events Survey PTSD Short 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; SI-PTSD = Structured Interview for PTSD; Y = Yes, outcome was reported for the study.

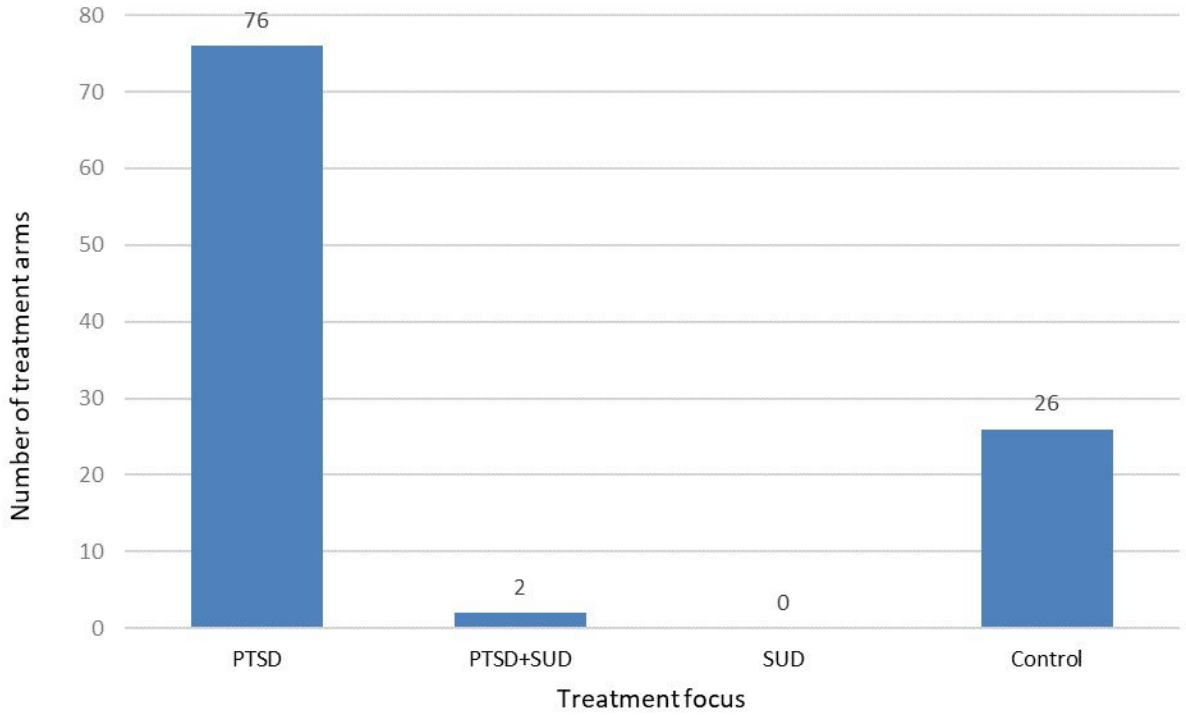
The distribution of treatment arms by intervention category is shown in Figure 4. Psychotherapy was employed in half of the treatment arms (50%); other treatments employed were pharmacotherapy (16%), Complementary and Integrative Health (CIH) (12%), and nonpharmacologic biologic interventions (3%). The treatment focus of the interventions was mostly posttraumatic stress disorder (PTSD) (73% of treatment arms); comorbid PTSD/substance use disorder (SUD) was the focus for two treatment arms (2%) and 25 percent were non-therapeutic control arms (Figure 5).

Figure 4. Summary of newly included studies: distribution of treatment arms by intervention category*



*Studies have more than one treatment arm, and a treatment arm may include multiple intervention categories. See Appendix H for underlying data table.

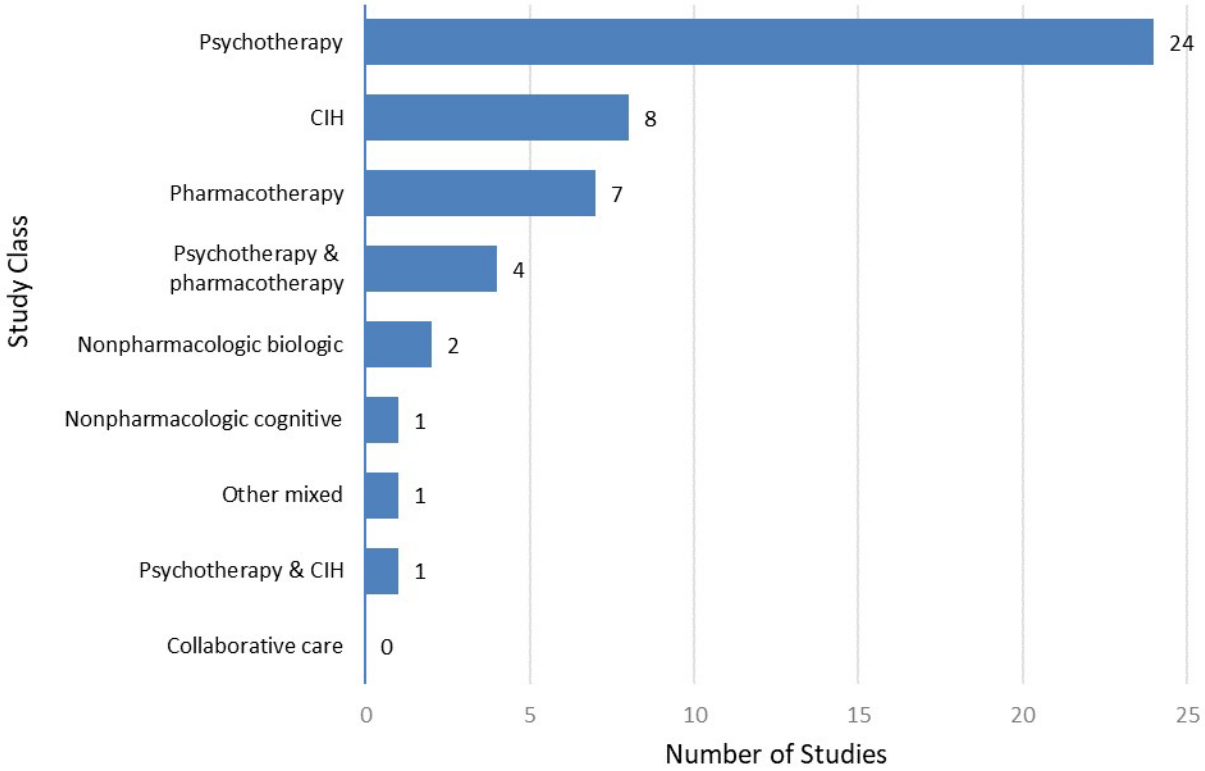
Figure 5. Summary of newly included studies: distribution of treatment arms by treatment focus*



*Studies have more than one treatment arm. See Appendix H for underlying data table.
Abbreviations: PTSD = posttraumatic stress disorder; SUD = substance use disorder.

Almost all the studies (42/48, 88%) examined interventions within a single category versus a control, predominantly psychotherapy treatments (50%) (Figure 6). The remainder of studies were classified as pharmacotherapy (15%), CIH (17%), nonpharmacologic biologic (4%), or psychotherapy & pharmacotherapy (8%).

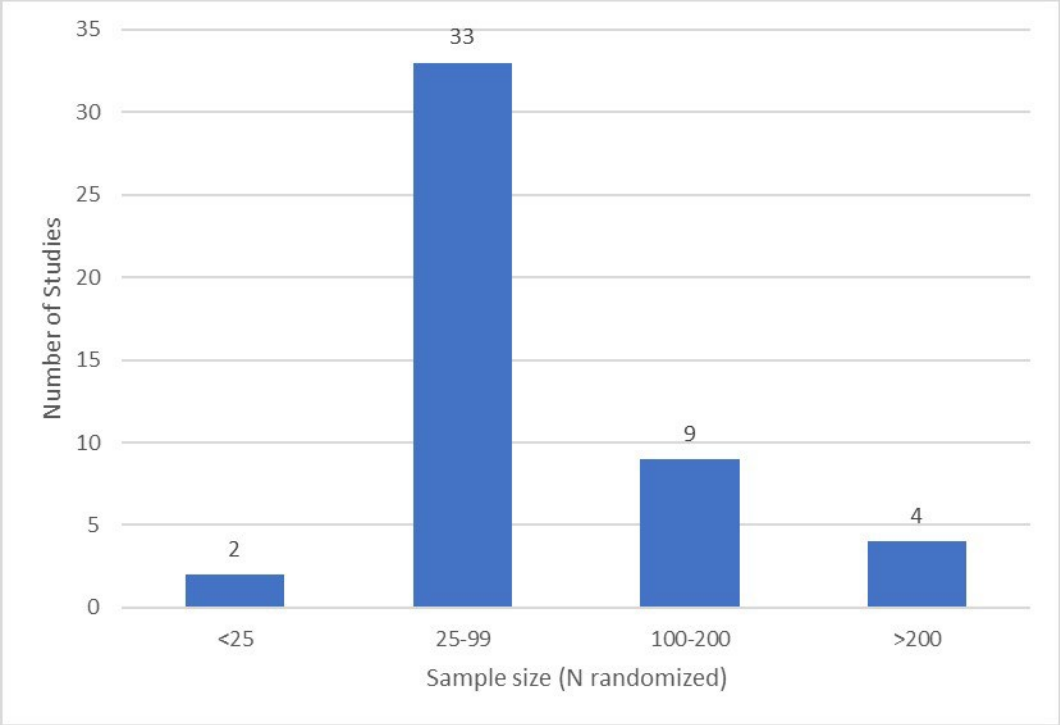
Figure 6. Summary of newly included studies: distribution of study class*



*See Appendix H for underlying data table.
Abbreviations: CIH = complementary and integrative health.

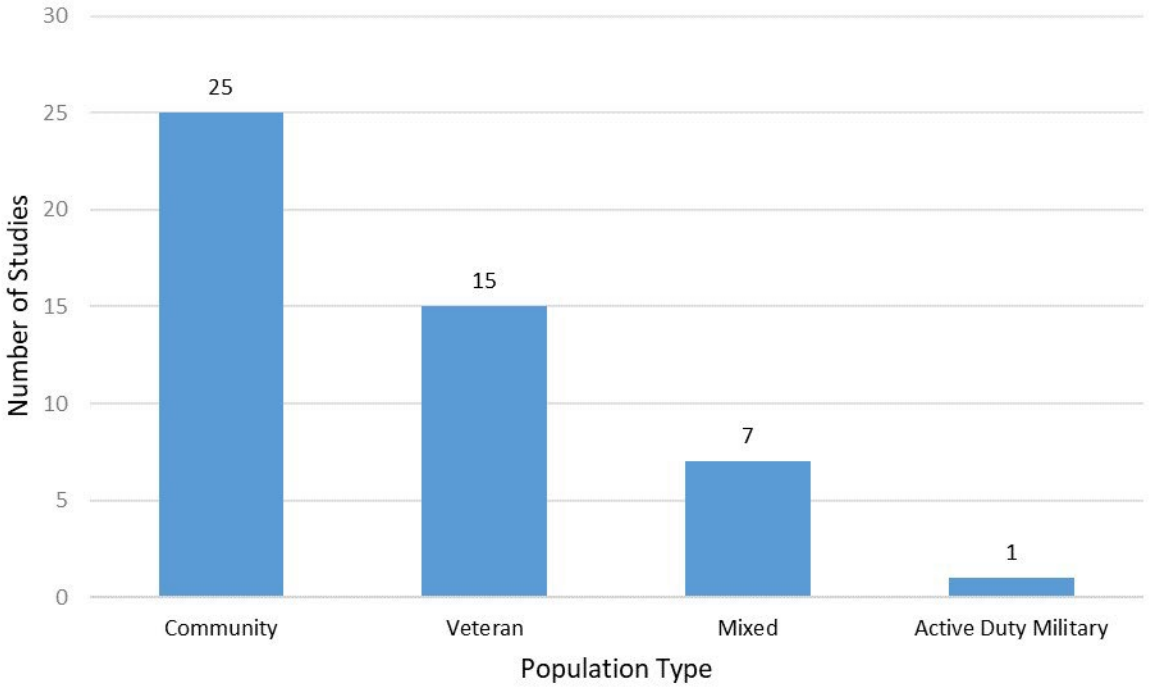
Across these studies, sample size ranged from 21 to 256 participants. Most studies (69%) had sample sizes between 25 and 99 participants (Figure 7). There were four studies with over 200 participants. Participants were drawn from the community population in 52 percent of studies, veterans in 31 percent of studies, and active duty military in one study (3%); seven studies (15%) were in a mixed population (Figure 8). Nearly half of the studies (22/48, 46%) were conducted in the U.S. Other countries in which more than one study was conducted are the United Kingdom (3 studies), Canada (2 studies), Germany (2 studies), and Iran (2 studies).

Figure 7. Summary of newly included studies: distribution of studies by sample size*



*See Appendix H for underlying data table.

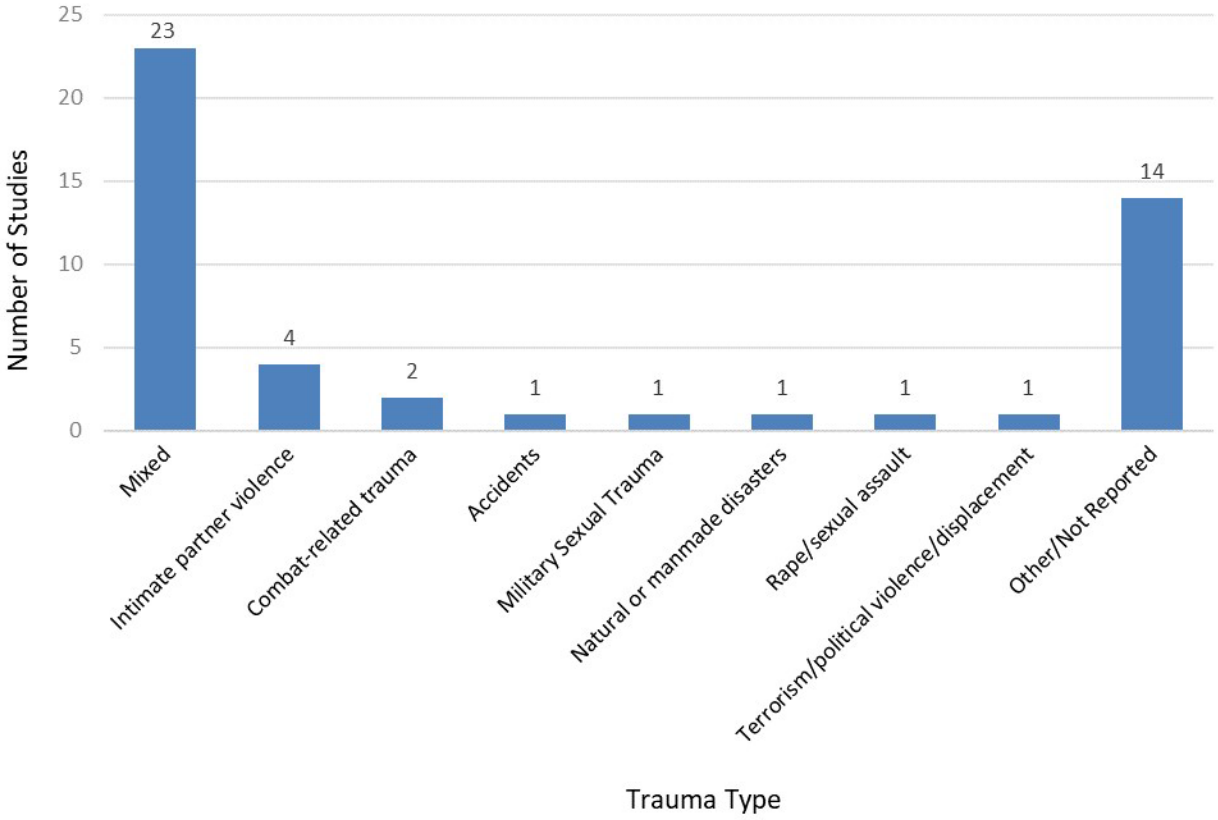
Figure 8. Summary of newly included studies: distribution of studies by population type*



*See Appendix H for underlying data table.

Eleven studies limited inclusion to participants who had experienced specific trauma types, and 11 did not provide information on trauma types (Figure 9). The largest number of studies allowed "mixed" trauma types (23 studies, 48%).

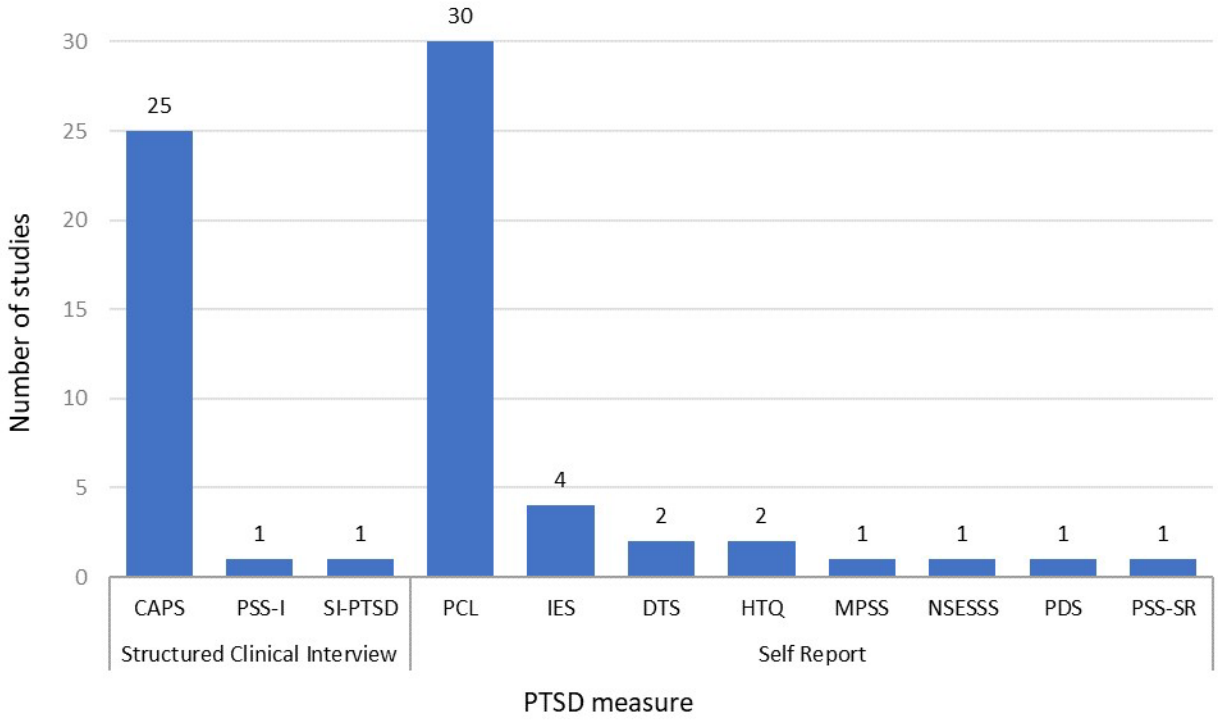
Figure 9. Summary of newly included studies: distribution of studies by trauma type*



*See Appendix H for underlying data table.
Notes: Active duty member reporting sexual assault outside of military was categorized as rape/sexual assault. Intimate partner violence includes domestic violence. Accidents include motor vehicle accidents, transportation-related accidents, and accidents due to construction. Natural or manmade disasters include 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).

The measure most frequently used to assess continuous PTSD outcomes was the PTSD Checklist (PCL), used in 62 percent of studies (Figure 10). More than half of studies used the Clinician-Administered PTSD Scale (CAPS) (52%), and 11 percent assessed outcomes using the Impact of Event Scale (IES) (Figure 10).

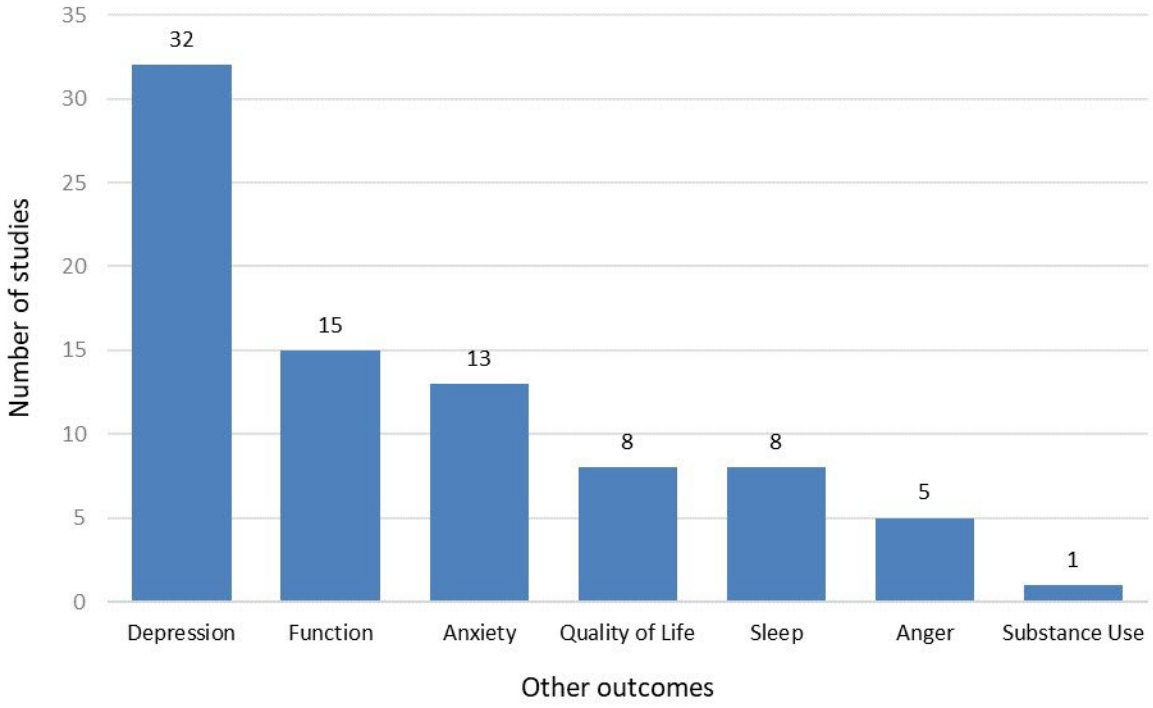
Figure 10. Summary of newly included studies: PTSD measures used to assess continuous PTSD outcomes*



*Studies may have used more than one measure to assess PTSD outcomes. One study did not assess a continuous PTSD outcome and is not shown in this graph. See Appendix H for underlying data table.
Abbreviations: CAPS = Clinician-Administered PTSD Scale; DTS = Davidson Trauma Scale; HTQ = Harvard Trauma Questionnaire; IES = Impact of Event Scale; MPSS = Modified PTSD Symptom Scale; NSESSS = National Stressful Events Survey PTSD Short Scale; PCL = PTSD Checklist; PSS-I = PTSD Symptom Scale - Interview; PSS-SR = PTSD Symptom Scale – Self-Report; PTSD = posttraumatic stress disorder; SI-PTSD = Structured Interview for PTSD.

Among other (non-PTSD) outcomes (Figure 11), depression was the most commonly assessed (67% of studies), followed by function (31%) and anxiety (27%). None of the studies added in this update assessed substance use outcomes.

Figure 11. Summary of newly included studies: non-PTSD outcomes reported*



***See Appendix H for underlying data table.**
Abbreviations: PTSD = posttraumatic stress disorder

Risk of Bias Assessment

Risk of bias (RoB) was assessed for newly included studies and a subset of previously included studies using Cochrane's RoB 2 tool, as described in the Methods section. Detailed RoB ratings from the last update that used the Agency for Healthcare Research and Quality (AHRQ) Risk of Bias tool are presented separately from RoB ratings of newly included studies to differentiate the assessment tools used for each subgroup of studies (Appendix G). Table 6 presents a summary of RoB 2 ratings for all newly included studies. Table 7 provides a summary of the original RoB ratings from the prior reviews.[15]

In this update, 48 new studies were assessed using Cochrane's RoB 2 tool for trials. These newly included 48 studies resulted in the following RoB assessments: 52 percent of studies were rated as high RoB, 15 percent as some concerns, and 31 percent as low. Studies were rated as high RoB mainly for RoB of bias due to missing outcome data or measurement of the outcome. These results are presented in Table 6.

The previously included 389 studies assessed using AHRQ methods resulted in the following RoB assessments, as described in the last update: 34 percent of studies were rated as high RoB, 60 percent as medium, and 6 percent as low. Studies were rated as high RoB mainly for poor reporting of randomization methods, allocation concealment, and masking of outcome assessor (Table 7). In addition, over half of the studies rated as high RoB did not conduct intent to treat

analyses (57%), reported over 20 percent overall attrition (54%), and lacked provider and patient masking (74% and 71% respectively).

Because we used different tools to assess RoB for the previously included studies (n=389) and the newly included studies (n=48), readers should be wary of combining RoB results across these 2 groups of studies. While technically possible to compare assessments across the Cochrane RoB and RoB2 tools, the systems do result in different ratings. Updated RoB assessment of all studies using the new Cochrane RoB 2 tool has been started (see Appendix G) and will be completed in future updates. Currently, Appendix G contains updated RoB 2 for 82 of the previously included studies.

Table 6. Newly included studies: risk of bias ratings using Cochrane RoB 2 methods (n=48)

Category of Bias	Bias Due to Randomization (Cochrane) or Selection Bias (AHRQ)	Bias Due to Deviations From Intended Interventions (Cochrane) or Performance Bias (AHRQ)	Bias Due to Missing Outcome Data (Cochrane) or Attrition Bias (AHRQ)	Risk of Bias in Measurement of the Outcome (Cochrane) or Detection Bias (AHRQ)	Bias in Selection of Reported Result (Cochrane) or Reporting Bias (AHRQ)	Overall ROB
Alsheikh Ali, 2020[21]	Some concerns	Low	High	High	Low	High
Angelakis, 2020[22]	Low	Low	Low	Low	Low	Low
Baekkelund, 2021[23]	Low	Low	Low	Low	Low	Low
Beck, 2021[24]	Low	Low	High	Some concerns	Low	High
Bellehsen, 2021[25]	Low	Low	Low	Low	Low	Low
Bisson, 2020[26]	Low	Low	Low	Low	Low	Low
Bohus, 2020[27]	Low	Low	Some concerns	Low	Low	Some concerns
Bonn-Miller, 2021[28]	Low	Low	Low	High	Low	High
Bormann, 2018[29]	Low	Low	Low	Low	Low	Low
Boterhoven de Haan, 2020[30]	Low	Low	Low	Low	Low	Low
Bottche, 2021[31]	Low	Low	High	Some concerns	Low	High
Dadabayev, 2020[32]	Low	Low	Low	Low	Low	Low
Davis, 2020b[33]	Low	Low	Low	Low	Low	Low
Davis, 2021[34]	Some concerns	Low	High	Low	Low	High
Dunlop, 2021[35]	Low	Low	Low	Low	Low	Low
Duran, 2020[36]	Low	Low	High	Some concerns	Low	High
Efendi, 2020[37]	Some concerns	Low	Low	High	Low	High
Farahimanesh, 2021[38]	Some concerns	Low	Low	Some concerns	Low	Some concerns
Feder, 2021[39]	Low	Low	Low	Low	Low	Low
Gallegos, 2020[40]	Low	Low	High	Low	Low	High
Gray, 2021[41]	Low	Low	Low	Low	Low	Low
Haynes, 2020[42]	Low	Low	Some concerns	Low	Low	Some concerns
Jain, 2020[43]	Low	Low	Low	High	Low	High
Jalal, 2020[44]	Some concerns	Low	High	High	Low	High
Jarero, 2019[45]	Low	Low	Low	High	Low	High
Johnson, 2020[46]	Low	Low	Low	Low	Low	Low
Kearney, 2021[47]	Low	Low	Some concerns	Low	Low	Some concerns
Kelly, 2021[48]	Low	Low	High	Low	Low	High
Koch, 2020[49]	Low	Low	High	High	Low	High

Category of Bias	Bias Due to Randomization (Cochrane) or Selection Bias (AHRQ)	Bias Due to Deviations From Intended Interventions (Cochrane) or Performance Bias (AHRQ)	Bias Due to Missing Outcome Data (Cochrane) or Attrition Bias (AHRQ)	Risk of Bias in Measurement of the Outcome (Cochrane) or Detection Bias (AHRQ)	Bias in Selection of Reported Result (Cochrane) or Reporting Bias (AHRQ)	Overall ROB
Latif, 2021[50]	Some concerns	Low	Low	High	Low	High
Lehavot, 2021[51]	Some concerns	Low	High	High	Low	High
Litz, 2021[52]	Low	Low	High	Some concerns	Low	High
McLean, 2020[53]	Low	Low	High	Low	Low	High
Meffert, 2021[54]	Some concerns	Low	Low	Low	Low	Some concerns
Mitchell, 2021[55]	Low	Low	Low	Low	Low	Low
Moradi, 2021[56]	Low	Low	Low	High	Low	High
Nicholson, 2020[57]	Low	Low	Low	Low	Low	Low
Oprel, 2021[58]	Low	Low	High	Low	Low	High
Petrakis, 2020[59]	Low	Low	Low	High	Low	High
Rajan, 2020[60]	Low	Low	Low	Low	Low	Low
Roullet, 2021[61]	Low	Low	Low	High	Low	High
Sandahl, 2021[62]	Low	Low	Low	Low	Low	Low
Spangler, 2020[63]	Some concerns	Low	Low	Low	Low	Some concerns
Sullivan, 2021[64]	Low	Low	High	Low	Low	High
Tang, 2021[65]	Some concerns	Low	Low	High	Low	High
Wheeler, 2020 Study 1[66]	Some concerns	Low	High	High	Low	High
Wheeler, 2020 Study 2[66]	Some concerns	High	High	Some concerns	Low	High
Youngstedt, 2021[67]	Some concerns	Low	Low	Low	Low	Some concerns

Abbreviations: AHRQ = Agency for Healthcare Research and Quality; RoB = risk of bias

Table 7. Studies assessed as having high risk of bias using AHRQ methods (n=139 out of 389 studies assessed with these methods)

Domain	Criterion	Yes	No	Unclear
Selection Bias	**Randomization Adequate?**	18%	5%	77%
	Allocation Concealment Adequate?	15%	4%	81%
	Groups Similar at Baseline?	33%	30%	38%
	ITT?	36%	57%	8%
Performance Bias	**Care Provider Masked?**	10%	74%	16%
	Patient Masked?	18%	71%	11%
Detection Bias	**Outcome Assessor Masked?**	29%	27%	45%
Attrition	**Overall Attrition <20%?**	36%	54%	10%
	Differential Attrition <15%?	55%	31%	14%

Abbreviations: AHRQ = Agency for Healthcare Research and Quality; ITT = intent-to-treat

Discussion

Summary and Implications

This report is updated to include detailed data extraction and risk of bias assessments for 48 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 437 RCTs are now included with detailed data abstraction and risk of bias (RoB) assessment. RoB assessments for the 48 new trials were conducted using Cochrane's RoB 2 tool for trials[68] and RoB for studies added in previous reports are in the process of being updated using this new RoB assessment tool.

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?"[69]

The evidence tables in this report will be used to populate the database underlying the Web-based, interactive PTSD-Repository. 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[70] and depression[71,72] have served these and other purposes and have been used as the basis for numerous publications and grant-funded studies.

Estimating standardized effect sizes for continuous PTSD outcomes across the studies was added for newly included studies in this 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 updates to the ways that suicide-related variables were abstracted and coded, and the current process of updating RoB assessments using the newly available, pilot-tested Cochrane RoB 2 tool for randomized trials.

The 48 new included studies identified for this update were published from June 1, 2018 through July 30, 2021 (the first review[15] included studies dating back to 1988).

The evidence tables (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 48 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. We also updated risk of bias assessment using Cochrane's RoB 2[68] tool for trials to assess the newly included studies and a subset of previously included studies. Future updates will expand these to all previously included studies; adding calculated standardized effect sizes and RoB2 study assessments.

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. 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 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 were also apparent, particularly in earlier studies. Recognition 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. First, 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 or by research groups might be reflected in the ratings. Most importantly, the process of updating the RoB assessment to Cochrane's RoB 2 tool for trials is still in progress, and therefore summary statistics across all included studies are not possible due to the different assessment methods. These will be updated and assessed on the same scale in future update reports, allowing for a more robust examination of RoB domains across the studies.

Next Steps

The completion of this project signifies the end of the second update and expansion of the PTSD-Repository evidence tables. 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. As part of this update, we were able to take into account this interactive Web resource and ensure that the PTSD-Repository evidence tables developed by our team were able to be more seamlessly integrated with the Web-based PTSD-Repository databases.[69,73,74] The goal of this evidence table restructuring was to ensure that future updates no longer required any hand searching and editing, and that most, if not all, data integration processes could be automated using replicable syntax. The current evidence tables into which our team abstracts data are far more conducive to this automated process, though it is likely that future updates will continue to revise and refine this process.

In addition to updates to include newly published RCTs, future additions to the evidence tables have been explored and recommended by the Content TEP. These future additions could include reporting outcomes for PTSD symptom clusters, item-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, qualitative reporting on inclusion and exclusion criteria, and qualitative and quantitative synthesis of key outcome data. We base these suggestions on our interaction with the evidence base, the Content and RoB TEPs, and NCPTSD.

Many of the recommendations by the Content and RoB TEPs and NCPTSD emphasized the potential uses for the PTSD-Repository and utility of expanding inclusion criteria for studies, while prioritizing ease of use for a range of potential stakeholders. As described, 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 applications[11] or the online PTSD Treatment Decision Aid.[12] The Content TEP highlighted how adding variables, outcomes, subpopulations, RoB 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 Content and RoB 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.

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Abbreviations and Acronyms

Acronym or Abbreviation	Definition
AHRQ	Agency for Healthcare Research and Quality
AMR	applied muscle relaxation
CA-CBT	culturally adapted cognitive behavioral therapy
CAPS	Clinician-Administered PTSD Scale
CBCT	cognitive-behavioral conjoint therapy
CBD	cannabidiol
CBSRT	Cognitive Behavioral Social Rhythm Group Therapy
CBT	cognitive behavioral therapy
CD	compact disc
CER	comparative effectiveness review
CIDI	Composite International Diagnostic Interview
CIH	complementary and integrative health
COPE	Concurrent Treatment for PTSD and Substance Use Disorder Using Prolonged Exposure
CPG	clinical practice guideline
CPT	Cognitive Processing Therapy
DBT-PTSD	dialectical behavior therapy for PTSD
DoD	Department of Defense
DSM	Diagnostic and Statistical Manual of Mental Disorders
DTS	Davidson Trauma Scale
DVD	digital video disc
ECT	electroconvulsive therapy
EMDR	Eye Movement Desensitization and Reprocessing
EPC	evidence-based practice center
HOPE	Helping to Overcome PTSD through Empowerment
HTQ	Harvard Trauma Questionnaire
ICBT	Integrated Cognitive Behavioral Therapy
ICD	International Statistical Classification of Diseases and Related Health Problems
IES	Impact of Event Scale
IPT	Interpersonal Psychotherapy
IRT	Imagery Rehearsal Training
ITT	intent-to-treat
KQ	Key Question
MAOI	monoamine oxidase inhibitor
MBSR	Mindfulness-based Stress Reduction
MDMA	3,4-methylenedioxy-methamphetamine
MINI	Mini-International Neuropsychiatric Interview
MPSS	Modified PTSD Symptom Scale
MST	military sexual trauma
N	No, data element was not reported for the study
NA	not applicable

Acronym or Abbreviation	Definition
NCPTSD	National Center for Posttraumatic Stress Disorder
NET	Narrative Exposure Therapy
NR	not reported
NSESSS	National Stressful Events Survey PTSD Short Scale
PC-PTSD	Primary Care PTSD Screen
PCL	PTSD Checklist
PCT	Present-Centered Therapy
PCT+	Present-Centered Therapy
PDS	Posttraumatic Diagnostic Scale
PE	Prolonged Exposure
PICOTS	Population, Intervention, Comparator, Outcomes, Timing, Setting, and Study design
PSS-I	PTSD Symptom Scale-Interview
PSS-SR	PTSD Symptom Scale-Self-Report
PTSD	posttraumatic stress disorder
RCT	randomized controlled trial
RoB	risk of bias
RTM	Reconsolidation of Traumatic Memories
rTMS	repetitive transcranial magnetic stimulation
SCID	structured clinical interview for the DSM
SEADS	Supplemental Evidence And Data for Systematic Review
SI-PTSD	Structured Interview for PTSD
SNRI	serotonin and norepinephrine reuptake inhibit
SSRI	selective serotonin reuptake inhibitor
STAIR	Skills Training in Affective and Interpersonal Regulation
STAIR-PC	Skills Training in Affective and Interpersonal Regulation for PTSD treatment in primary care
SUD	substance use disorder
TAU	treatment as usual
TBCT	trial-based cognitive therapy
TBI	traumatic brain injury
TCA	tricyclic antidepressant
tDSC	transcranial direct current stimulation
TEP	Technical Expert Panel
TF-CBT	trauma-focused cognitive behavioral therapy
THC	tetrahydrocannabinol
TMS	transcranial magnetic stimulation
TNX-102	cyclobenzaprine hydrochloride
VA	U.S. Department of Veterans Affairs
VA/DoD CPG	Department of Veterans Affairs/Department of Defense clinical practice guideline
WET	Written Exposure Therapy
Y	Yes, outcome was reported for study

Appendix Table of Contents

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. exp Drug Therapy/
4. dt.fs.
5. (medication* or pharmacologic* or pharmaco-therap* or pharmacotherap*).ti,ab.
6. (drug* adj2 (therap* or treatment*)).ti,ab.
7. exp Adrenergic alpha-Antagonists/ or Sympatholytics/ or Doxazosin/ or Prazosin/
8. ("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.
9. exp Antipsychotic Agents/
10. ("anti-psychotic*" or antipsychotic* or FGA* or SGA* or aripiprazole or asenapine or brexpiprazole 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.
11. exp Benzodiazepines/
12. (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.
13. exp Monoamine Oxidase Inhibitors/
14. (("monoamine oxidase" adj2 inhibitor*) or MAOI or isocarboxazid or phenelzine or selegiline or tranylcypromine).ti,ab.
15. carbamazepine/ or clonidine/ or lithium/ or pregabalin/ or valproic acid/
16. exp Anticonvulsants/
17. exp Antimanic Agents/
18. exp Cyclohexanecarboxylic Acids/
19. (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.
20. exp "hypnotics and sedatives"/ or exp anti-anxiety agents/
21. ("anti anxiety" or antianxiety or buspirone or diphenhydramine or eszopiclone or guanfacine or hydroxizine or hypnotic* or ramelteon or sedative* or suvorexant or tasimelteon or zaleplon or zolpidem or zopiclone).ti,ab.
22. exp Antidepressive Agents/
23. (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 hydroxizine or imipramine or levomilnacipran or maprotiline or milnacipran or mirtazapine or nefazodone or

nortriptyline or paroxetine or protriptyline or sertraline or trazadone or trimipramine or venlafaxine or vilazodone or vortioxetine).ti,ab.
24. exp Amphetamines/
25. (amphetamine or armodafanil or atomoxetine or dexmethylphenidate or dextroamphetamine or lisdexamphetamine or MDMA or methamphetamine or methylphenidate or modafanil).ti,ab.
26. exp Steroids/
27. (DHEA or hydrocortisone or steroid*).ti,ab.
28. exp Cannabinoids/
29. Cannabis/
30. Medical Marijuana/
31. (cannabi* or marijuana or tetrahydrocannabinol or THC).ti,ab.
32. ketamine/
33. ketamine.ti,ab.
34. Propranolol/
35. propranolol.ti,ab.
36. exp Randomized Controlled Trials as Topic/
37. exp Randomized Controlled Trial/
38. double-blind method/ or random allocation/ or single-blind method/
39. Placebos/
40. (random* or control* or trial or sham or placebo* or blind* or dumm* or mask*).ti,ab,kw.
41. (1 or 2) and (or/3-35)
42. 41 and (or/36-40)
43. (201806$ or 201807$ or 201908$ or 201809$ or 20181$ or 2019$ or 2020$ or 2021$).dt,dp.
44. ("2018 06 $" or "2018 07 $" or "2018 08 $" or "2018 09 $" or "2018 10 $" or "2018 11 $" or "2018 12 $" or "2019 $" or "2020 $" or "2021 $").dt,dp.
45. ("2018 jun $" or "2018 jul $" or "2018 aug $" or "2018 sep $" or "2018 oct $" or "2018 nov $" or "2018 dec $").dt,dp.
46. or/43-45
47. 42 and 46
48. limit 42 to yr="2019 -Current"
49. 47 or 48

Nonpharmacologic interventions

1. stress disorders, post-traumatic/
2. ("posttraumatic stress disorder" or "post traumatic stress disorder" or PTSD).ti,ab.
3. th.fs.
4. exp Psychotherapy/
5. exp Complementary Therapies/
6. exp Convulsive Therapy/
7. Hyperbaric Oxygenation/
8. Transcranial Magnetic Stimulation/
9. exp Rehabilitation/
10. exp Dietary Supplements/

11. exp "Delivery of Health Care, Integrated"/
12. exp Self-Help Groups/
13. exp peer group/
14. exp social support/
15. exp Telemedicine/
16. telephone/ or exp cell phone/
17. (therap* or psychotherap* or counsel* or nonpharma* or non-pharma*).ti,ab.
18. ("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.
19. exp Randomized Controlled Trials as Topic/
20. exp Randomized Controlled Trial/
21. double-blind method/ or random allocation/ or single-blind method/
22. (random* or control* or trial or sham or blind* or dumm* or mask*).ti,ab,kw.
23. (1 or 2) and (or/3-18)
24. 23 and (or/19-22)
25. (201806$ or 201807$ or 201908$ or 201809$ or 20181$ or 2019$ or 2020$ or 2021$).dt,dp.
26. ("2018 06 $" or "2018 07 $" or "2018 08 $" or "2018 09 $" or "2018 10 $" or "2018 11 $" or "2018 12 $" or "2019 $" or "2020 $" or "2021 $").dt,dp.
27. ("2018 jun $" or "2018 jul $" or "2018 aug $" or "2018 sep $" or "2018 oct $" or "2018 nov $" or "2018 dec $").dt,dp.
28. or/25-27
29. 24 and 28
30. limit 24 to yr="2019 -Current"
31. 29 or 30

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))
Additional limits: Scholarly Journals

Database: PsycINFO

1. exp posttraumatic stress disorder/
2. ("post traumatic stress disorder" or "posttraumatic stress disorder" or PTSD).ti,ab.
3. exp treatment/

4. exp stimulation/
5. exp electroconvulsive shock/
6. exp TELEMEDICINE/
7. exp counseling/
8. exp support groups/
9. (therap* or psychotherap* or counsel* or nonpharma* or non-pharma*).ti,ab.
10. ("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.
11. (1 or 2) and (or/3-10)
12. treatment effectiveness evaluation/
13. Treatment Outcomes/
14. followup studies/
15. (random* or control* or trial or sham or placebo* or blind* or dumm* or mask*).ti,ab.
16. 11 and (or/12-15)
17. limit 16 to english language
18. limit 17 to human
19. limit 18 to yr="2018 -Current"

Database: EBM Reviews - Cochrane Central Register of Controlled Trials

1. Stress Disorders, Post-Traumatic/
2. ("posttraumatic stress disorder" or "post traumatic stress disorder" or "ptsd").ti,ab.
3. (dt or pc or rh or th).fs.
4. exp treatment outcome/ or exp therapeutics/
5. (treatment or therap* or intervention*).ti,ab,kw.
6. (1 or 2) and (3 or 4 or 5)
7. limit 6 to medline records
8. 6 not 7
9. 2019$.yr,up.
10. (201807$ or 201808$ or 201809$ or 20181$).yr,up.
11. 9 or 10
12. 8 and 11
13. limit 12 to yr="2018 -Current"

Database: Elsevier® Embase

Embase: ('posttraumatic stress disorder'/exp/mj OR 'posttraumatic stress disorder':ab,ti OR 'post traumatic stress disorder':ab,ti OR 'ptsd':ab,ti) AND [randomized controlled trial]/lim AND 'randomized controlled trial'/de AND [embase]/lim NOT ([embase]/lim AND [medline]/lim)

Database: EBSCO® CINAHL

S1 (MM "Stress Disorders, Post-Traumatic+")
S2 AB "post traumatic stress disorder" OR AB "posttraumatic stress disorder" OR AB "ptsd"
S3 TI "post traumatic stress disorder" OR TI "posttraumatic stress disorder" OR TI "ptsd"
S4 S1 OR S2 OR S3
S5 (TI random* or AB random* or PT clinical trial or PT randomized controlled trial)
S6 S4 AND S5

Database: Elsevier® Scopus

Scopus: (TITLE-ABS-KEY ("post traumatic stress disorder" OR "posttraumatic stress disorder" OR "ptsd")) AND (TITLE (random* OR control* OR trial* OR sham* OR placebo* OR blind*)) AND (LIMIT-TO (LANGUAGE , "English"))

Appendix B. List of Included Studies

New included studies:

1. Clarifications to measures, analyses, and findings in trial of stellate ganglion block treatment for posttraumatic stress disorder symptoms. JAMA Psychiatry. 2020;77(9):982. doi: 10.1001/jamapsychiatry.2020.1829. PMID: 32609314.
2. Alpert E, Hayes AM, Barnes JB, et al. Predictors of dropout in cognitive processing therapy for PTSD: an examination of trauma narrative content. Behav Ther. 2020 Sep;51(5):774-88. doi: 10.1016/j.beth.2019.11.003. PMID: 32800305.
3. Alsheikh Ali ASS. Efficiency of intervention counseling program on the enhanced psychological well-being and reduced post-traumatic stress disorder symptoms among Syrian women refugee survivors. Clin Pract Epidemol Ment Health. 2020;16(Suppl-1):134-41. doi: 10.2174/1745017902016010134. PMID: 33029190.
4. Angelakis S, Weber N, Nixon RDV. Comorbid posttraumatic stress disorder and major depressive disorder: the usefulness of a sequential treatment approach within a randomised design. J Anxiety Disord. 2020 12;76:102324. doi: 10.1016/j.janxdis.2020.102324. PMID: 33137600.
5. Baekkelund H, Karlsrud I, Hoffart A, et al. Stabilizing group treatment for childhood-abuse related PTSD: a randomized controlled trial. Eur J Psychotraumatol. 2021 Jan 22;12(1):1859079. doi: 10.1080/20008198.2020.1859079. PMID: 33537118.
6. Beck BD, Meyer SL, Simonsen E, et al. Music therapy was noninferior to verbal standard treatment of traumatized refugees in mental health care: results from a randomized clinical trial. Eur J Psychotraumatol. 2021 Jul 6;12(1):1930960. doi: 10.1080/20008198.2021.1930960. PMID: 34285768.
7. Bellehsen M, Stoycheva V, Cohen BH, et al. A pilot randomized controlled trial of transcendental meditation as treatment for posttraumatic stress disorder in veterans. J Trauma Stress. 2021 Mar 18;18:18. doi: 10.1002/jts.22665. PMID: 33734493.
8. Berke DS, Carney JR, Rusowicz-Orazem L, et al. Parameters of aggressive behavior in a treatment-seeking sample of military personnel: a secondary analysis of three randomized controlled trials of evidence-based PTSD treatments. Behav Ther. 2021;52(1):136-48. doi: 10.1016/j.beth.2020.03.007. PMID: 33483111.
9. Bisson JI, van Deursen R, Hannigan B, et al. Randomized controlled trial of multi-modular motion-assisted memory desensitization and reconsolidation (3MDR) for male military veterans with treatment-resistant post-traumatic stress disorder. Acta Psychiatr Scand. 2020;142(2):141-51. doi: 10.1111/acps.13200. PMID: 32495381.
10. Bohus M, Kleindienst N, Hahn C, et al. Dialectical behavior therapy for posttraumatic stress disorder (DBT-PTSD) compared with cognitive processing therapy (CPT) in complex presentations of PTSD in women survivors of childhood abuse: a randomized clinical trial. JAMA Psychiatry. 2020 Jul 22;22:22. doi: 10.1001/jamapsychiatry.2020.2148. PMID: 32697288.
11. Bonn-Miller MO, Sisley S, Riggs P, et al. The short-term impact of 3 smoked cannabis preparations versus placebo on PTSD symptoms: A randomized cross-over clinical trial. PLoS One. 2021;16(3):e0246990. doi: 10.1371/journal.pone.0246990. PMID: 33730032.
12. Bormann JE, Thorp SR, Smith E, et al. Individual treatment of posttraumatic stress disorder using mantram repetition: a randomized clinical trial. Am J Psychiatry. 2018 Oct 1;175(10):979-88. doi: 10.1176/appi.ajp.2018.17060611. PMID: 29921143.

13. Boterhoven de Haan KL, Lee CW, Fassbinder E, et al. Imagery rescripting and eye movement desensitisation and reprocessing as treatment for adults with post-traumatic stress disorder from childhood trauma: randomised clinical trial. Br J Psychiatry. 2020 11;217(5):609-15. doi: 10.1192/bjp.2020.158. PMID: 32892758.

14. Bottche M, Wagner B, Vohringer M, et al. Is only one cognitive technique also effective? Results from a randomized controlled trial of two different versions of an internet-based cognitive behavioural intervention for post-traumatic stress disorder in Arabic-speaking countries. Eur J Psychotraumatol. 2021 Jul 15;12(1):1943870. doi: 10.1080/20008198.2021.1943870. PMID: 34345377.

15. Capone C, Tripp JC, Trim RS, et al. Comparing exposure- and coping skills based treatments on trauma-related guilt in veterans with co-occurring alcohol use and posttraumatic stress disorders. J Trauma Stress. 2020 08;33(4):603-9. doi: 10.1002/jts.22538. PMID: 32521096.

16. Dadabayev AR, Joshi SA, Reda MH, et al. Low dose ketamine infusion for comorbid posttraumatic stress disorder and chronic pain: a randomized double-blind clinical trial. Chronic Stress (Thousand Oaks). 2020 Jan-Dec;4:2470547020981670. doi: 10.1177/2470547020981670. PMID: 33426410.

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25. Gallegos AM, Heffner KL, Cerulli C, et al. Effects of mindfulness training on posttraumatic stress symptoms from a community-based pilot clinical trial among survivors of intimate partner violence. Psychol Trauma. 2020 Nov;12(8):859-68. doi: 10.1037/tra0000975. PMID: 32969703.

26. Galovski TE, Smith BN, Micol RL, et al. Interpersonal violence and head injury: the effects on treatment for PTSD. Psychol Trauma. 2021 Mar;13(3):376-84. doi: 10.1037/tra0000976. PMID: 33271049.

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Appendix C. List of Studies Meeting Inclusion Criteria Published After July 30, 2021

Studies published after July 31, 2021, to be included in next update:

1. Abdallah CG, Roache JD, Gueorguieva R, et al. Dose-related effects of ketamine for antidepressant-resistant symptoms of posttraumatic stress disorder in veterans and active duty military: a double-blind, randomized, placebo-controlled multi-center clinical trial. Neuropsychopharmacology. 2022 Jan 19;Online ahead of print:1-8. doi: 10.1038/s41386-022-01266-9. PMID: 35046508.
2. Acierno R, Jaffe AE, Gilmore AK, et al. A randomized clinical trial of in-person vs. home-based telemedicine delivery of prolonged exposure for PTSD in military sexual trauma survivors. J Anxiety Disord. 2021 Oct;83:102461. doi: 10.1016/j.janxdis.2021.102461. PMID: 34391978.
3. Brady F, Chisholm A, Walsh E, et al. Narrative exposure therapy for survivors of human trafficking: feasibility randomised controlled trial. BJPsych Open. 2021 Nov;7(6):e196. doi: 10.1192/bjo.2021.1029.
4. Bremner JD, Wittbrodt MT, Gurel NZ, et al. Transcutaneous cervical vagal nerve stimulation in patients with posttraumatic stress disorder (PTSD): a pilot study of effects on PTSD symptoms and interleukin-6 response to stress. J Affect Disord Rep. 2021 Dec;6:100190. doi: 10.1016/j.jadr.2021.100190. PMID: 34778863.
5. Brunet A, Sapkota RP, Guragain B, et al. Tackling the global problem of traumatic stress in low-income countries: a pilot clinical trial comparing reconsolidation therapy to paroxetine in Nepal. BMC Psychiatry. 2021 Sep 3;21(1):434. doi: 10.1186/s12888-021-03441-6. PMID: 34479508.
6. Echiverri-Cohen A, Spierer L, Perez M, et al. Randomized-controlled trial of response inhibition training for individuals with PTSD and impaired response inhibition. Behav Res Ther. 2021 Aug;143:103885. doi: 10.1016/j.brat.2021.103885. PMID: 34089923.
7. Fruchtman-Steinbok T, Keynan JN, Cohen A, et al. Amygdala electrical-finger-print (AmygEFP) neurofeedback guided by individually-tailored trauma script for post-traumatic stress disorder: proof-of-concept. Neuroimage Clin. 2021 Oct 15;32:102859. doi: 10.1016/j.nicl.2021.102859. PMID: 34689055.
8. Isserles M, Tendler A, Roth Y, et al. Deep transcranial magnetic stimulation combined with brief exposure for posttraumatic stress disorder: a prospective multisite randomized trial. Biol Psychiatry. 2021 Nov 15;90(10):721-8. doi: 10.1016/j.biopsych.2021.04.019. PMID: 34274108.
9. Khan A, Ullah F, Abid O, et al. Efficacy of cognitive behavioral therapy in post-traumatic stress disorder among spinal cord injury patients: a randomized controlled pilot study. J Evid Based Psychother. 2021 Sep;21(2):143-62. doi: 10.24193/jebp.2021.2.16.
10. Kobayashi I, Mellman TA, Cannon A, et al. Blocking the orexin system following therapeutic exposure promoted between session habituation, but not PTSD symptom reduction. J Psychiatr Res. 2021 Dec 14;145:222-9. doi: 10.1016/j.jpsychires.2021.12.027. PMID: 34933185.
11. Leem J, Cheong MJ, Lee H, et al. Effectiveness, cost-utility, and safety of neurofeedback self-regulating training in patients with post-traumatic stress disorder: a randomized controlled trial. Healthcare (Basel). 2021 Oct 11;9(10):1351. doi: 10.3390/healthcare9101351. PMID: 34683031.
12. Lehrner A, Hildebrandt T, Bierer LM, et al. A randomized, double-blind, placebo-controlled trial of hydrocortisone augmentation of prolonged exposure for PTSD in U.S. combat veterans. Behav Res Ther. 2021 Sep;144:103924. doi: 10.1016/j.brat.2021.103924. PMID: 34298438.

13. Norman SB, Capone C, Panza KE, et al. A clinical trial comparing trauma-informed guilt reduction therapy (TrIGR), a brief intervention for trauma-related guilt, to supportive care therapy. Depress Anxiety. 2022 Jan 25;Online ahead of print doi: 10.1002/da.23244. PMID: 35075738.

14. Pigeon WR, Crean HF, Cerulli C, et al. A randomized clinical trial of cognitive-behavioral therapy for insomnia to augment posttraumatic stress disorder treatment in survivors of interpersonal violence. Psychother Psychosom. 2022 Jan;91(1):50-62. doi: 10.1159/000517862. PMID: 34265777.

15. Ramakrishnan N, Lijffijt M, Green CE, et al. Neurophysiological and clinical effects of the NMDA receptor antagonist lanicemine (BHV-5500) in PTSD: a randomized, double-blind, placebo-controlled trial. Depress Anxiety. 2021 Nov;38(11):1108-19. doi: 10.1002/da.23194. PMID: 34254405.

16. Rauch SAM, Kim HM, Venners MR, et al. Change in posttraumatic stress disorder-related thoughts during treatment: do thoughts drive change when pills are involved? J Trauma Stress. 2021 Dec 31;Online ahead of print doi: 10.1002/jts.22762. PMID: 34973039.

17. Schnurr PP, Chard KM, Ruzek JI, et al. Comparison of prolonged exposure vs cognitive processing therapy for treatment of posttraumatic stress disorder among US veterans: a randomized clinical trial. JAMA Netw Open. 2022 Jan 4;5(1):e2136921. doi: 10.1001/jamanetworkopen.2021.36921. PMID: 35044471.

18. Sloan DM, Marx BP, Resick PA, et al. Effect of written exposure therapy vs cognitive processing therapy on increasing treatment efficiency among military service members with posttraumatic stress disorder: a randomized noninferiority trial. JAMA Netw Open. 2022 Jan 4;5(1):e2140911. doi: 10.1001/jamanetworkopen.2021.40911. PMID: 35015065.

19. Stein MB, Jain S, Simon NM, et al. Randomized, placebo-controlled trial of the angiotensin receptor antagonist losartan for posttraumatic stress disorder. Biol Psychiatry. 2021 Oct 1;90(7):473-81. doi: 10.1016/j.biopsych.2021.05.012. PMID: 34275593.

20. Steuwe C, Berg M, Beblo T, et al. Narrative exposure therapy in patients with posttraumatic stress disorder and borderline personality disorder in a naturalistic residential setting: a randomized controlled trial. Front Psychiatry 2021 Nov 26;12:765348. doi: 10.3389/fpsyt.2021.765348. PMID: 34899426.

21. Thierree S, Raulin-Briot M, Legrand M, et al. Combining trauma script exposure with rTMS to reduce symptoms of post-traumatic stress disorder: randomized controlled trial. Neuromodulation. 2021 Aug 17;Online ahead of print doi: 10.1111/ner.13505. PMID: 34403533.

22. Van Vliet NI, Huntjens RJC, Van DMK, et al. Phase-based treatment versus immediate trauma-focused treatment for post-traumatic stress disorder due to childhood abuse: randomised clinical trial. BJPsych Open. 2021 Nov;7(6):e211. doi: 10.1192/bjo.2021.1057.

23. Vera M, Oben A, Juarbe D, et al. A randomized clinical trial of prolonged exposure and applied relaxation for the treatment of Latinos with posttraumatic stress disorder. J Trauma Stress. 2021 Dec 31;Online ahead of print doi: 10.1002/jts.22773. PMID: 34973048.

Appendix D. List of Excluded Studies

Table D-1. Key to exclusion codes

Exclusion Code	Exclusion Reason
3	Ineligible population
4	Ineligible intervention
5	Ineligible comparison
6	Ineligible outcome
8	Ineligible study design
9	Ineligible publication type (including systematic reviews)
11	Not English language article
13	Companion to excluded study

New excluded studies:

1. Highlights. JAMA Psychiatry. 2020;77(2):109-. doi: 10.1001/jamapsychiatry.2019.2784. Exclusion: 9.
2. Repeated ketamine infusions reduce symptoms in patients with PTSD. Brown University Psychopharmacology Update. 2021;32(4):1-5. doi: 10.1002/pu.30700. Exclusion: 9.
3. Mirtazapine shows no benefit for veterans with PTSD. Brown University Psychopharmacology Update. 2021;32(2):7-. doi: 10.1002/pu.30681. Exclusion: 9.
4. Acierno R, Kauffman B, Muzzy W, et al. Behavioral activation and therapeutic exposure vs. cognitive therapy for grief among combat veterans: a randomized clinical trial of bereavement interventions. Am J Hosp Palliat Care. 2021 Dec;38(12):1470-8. doi: 10.1177/1049909121989021. PMID: 33504175. Exclusion: 3.
5. 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). http://www.who.int/trialsearch/Trial2.aspx?TrialID=ACTRN12619000642189. 2019 PMID: CN-01975153. Exclusion: 9.
6. Actrn. Pilot Study of Testing Group Psychological Help for Adult Syrian Refugees in Jordan. http://www.who.int/trialsearch/Trial2.aspx?TrialID=ACTRN12619000340134. 2019 PMID: CN-01970072. Exclusion: 9.
7. Actrn. Psychological Treatment of Posttraumatic Stress Disorder in Refugees. http://www.who.int/trialsearch/Trial2.aspx?TrialID=ACTRN12619000381189. 2019 PMID: CN-01970710. Exclusion: 9.
8. Actrn. IMPACT - Intervention to Manage PTSD And Comorbidities after Trauma Study. http://www.who.int/trialsearch/Trial2.aspx?TrialID=ACTRN12619000543189. 2019 PMID: CN-01972313. Exclusion: 9.
9. 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). http://www.who.int/trialsearch/Trial2.aspx?TrialID=ACTRN12619000603112. 2019 PMID: CN-01975397. Exclusion: 9.
10. Andersen TE, Ravn SL, Armfield N, et al. Trauma-focused cognitive behavioural therapy and exercise for chronic whiplash with comorbid posttraumatic stress disorder: a randomised controlled trial. Pain. 2021 Apr 1;162(4):1221-32. doi: 10.1097/j.pain.0000000000002117. PMID: 33086286. Exclusion: 4.

11. Andersson G, Olsson E, Ringsgard E, et al. Individually tailored internet-delivered cognitive-behavioral therapy for survivors of intimate partner violence: a randomized controlled pilot trial. Internet Interv. 2021 Sep 15;26:100453. doi: 10.1016/j.invent.2021.100453. PMID: 34584851. Exclusion: 3.

12. Astill Wright L, Barawi K, Simon N, et al. The reconsolidation using rewind study (RETURN): trial protocol. Eur J Psychotraumatol. 2021;12(1) doi: 10.1080/20008198.2020.1844439. Exclusion: 9.

13. Baas MAM, Stramrood CAI, Dijksman LM, et al. The optiMUM study: EMDR therapy in pregnant women with posttraumatic stress disorder after previous childbirth and pregnant women with fear of childbirth: design of a multicentre randomized controlled trial. Eur J Psychotraumatol. 2017 Feb 24;8(1):1293315. doi: 10.1080/20008198.2017.1293315. PMID: 28348720. Exclusion: 9.

14. Ballistrea L, Standifer M, Melillo C, et al. Technology based complementary and integrative health program for veteran dyads: a randomized control trial. Arch Phys Med Rehabil. 2019;100(10):e126. doi: 10.1016/j.apmr.2019.08.376. Exclusion: 9.

15. Bartel A. Examining change in objective and subjective neurocognitive performance following a randomized online trauma intervention. Dissertation Abstracts International: Section B: The Sciences and Engineering. 2021;82(12-B). Exclusion: 9.

16. Batki SL, Pennington DL, Lasher BA, et al. Topiramate treatment of alcohol use disorder in veterans with PTSD: preliminary analysis of a controlled trial. Alcohol Clin Exp Res. 2020;44:158A. doi: 10.1111/acer.14356. PMID: 25092377. Exclusion: 9.

17. Beksinska A, Jama Z, Kabuti R, et al. Prevalence and correlates of common mental health problems and recent suicidal thoughts and behaviours among female sex workers in Nairobi, Kenya. BMC Psychiatry. 2021 Oct 14;21(1):503. doi: 10.1186/s12888-021-03515-5. PMID: 34649544. Exclusion: 8.

18. Belleville G, Lebel J, Ouellet MC, et al. Resilient - an online multidimensional treatment to promote resilience and better sleep: a randomized controlled trial. Sleep Med. 2019;64:S214-S5. Exclusion: 9.

19. Bishop TM, Crean HF, Funderburk JS, et al. Initial session effects of brief cognitive behavioral therapy for insomnia: a secondary analysis of a small randomized pilot trial. Behav Sleep Med. 2021 Nov-Dec;19(6):769-82. doi: 10.1080/15402002.2020.1862847. PMID: 33410336. Exclusion: 3.

20. Bisson JI, van Gelderen M, Roberts NP, et al. Non-pharmacological and non-psychological approaches to the treatment of PTSD: results of a systematic review and meta-analyses. Eur J Psychotraumatol. 2020 Aug 24;11(1):1795361. doi: 10.1080/20008198.2020.1795361. PMID: 33029330. Exclusion: 9.

21. Bolsoni LM, Crippa JAS, Hallak JEC, et al. Effects of cannabidiol on symptoms induced by the recall of traumatic events in patients with posttraumatic stress disorder. Psychopharmacology (Berl). 2022 Jan 14;Online ahead of print doi: 10.1007/s00213-021-06043-y. PMID: 35029706. Exclusion: 6.

22. Boyd JE, O'Connor C, Protopopescu A, et al. An open-label feasibility trial examining the effectiveness of a cognitive training program, goal management training, in individuals with posttraumatic stress disorder. Chronic Stress (Thousand Oaks). 2019 Jan-Dec;3:2470547019841599. doi: 10.1177/2470547019841599. PMID: 32440592. Exclusion: 8.

23. Bragesjo M, Arnberg FK, Sarnholm J, et al. Condensed internet-delivered prolonged exposure provided soon after trauma: a randomised pilot trial. Internet Interv. 2021 Mar;23:100358. doi: 10.1016/j.invent.2020.100358. PMID: 33384946. Exclusion: 3.

24. Brenner LA, Forster JE, Stearns-Yoder KA, et al. Evaluation of an immunomodulatory probiotic intervention for veterans with co-occurring mild traumatic brain injury and posttraumatic stress disorder: a pilot study. Front Neurol. 2020;11 doi: 10.3389/fneur.2020.01015. PMID: 33192959. Exclusion: 6.

25. Bryant R, Kenny L, Joscelyne A, et al. Cognitive behaviour therapy for PTSD in police officers: a randomised controlled trial. Aust N Z J Psychiatry. 2021;55(SUPPL 1):41. Exclusion: 9.

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Appendix E. Data Abstraction and Risk of Bias Elements

Data abstraction elements were abstracted for all 427 studies. Risk of Bias 2 elements were abstracted for the 38 new included studies. Risk of Bias elements were abstracted for the 389 prior report 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

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 Sympton-Related Inclusion and Exclusion Criteria
17. Suicide or Self-Harm Related Outcomes
18. Diagnostic Assessment Type

19. Diagnostic Measure
20. Diagnostic Measure Detail
21. Study Comments

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-naive
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. NCPTSD 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: Nonpharm Biologic
17. Intervention Categorization: Nonpharm Cognitive Therapy
18. Intervention Categorization: Control
19. Intervention Categorization: Other
20. Intervention Categorization: Collaborative Care
21. Intervention Details: Format
22. Intervention Details: Delivery Method
23. Intervention Details: Dose
24. Intervention Details: Session Length
25. Intervention Details: Frequency
26. Intervention Details: Treatment Duration
27. Intervention Details: Treatment Duration Detail
28. Intervention Details: Treatment Completion Definition
29. Intervention Details: Completed Psychotherapy Percent
30. Intervention Details: Completed Psychotherapy Percent Detail
31. Intervention Details: Treatment Adherence Definition
32. Intervention Details: Adhered Pharmacotherapy Percent
33. Intervention Details: Adhered Pharmacotherapy Percent Detail
34. Intervention Details: Psychotherapy Sessions Completed Mean
35. Intervention Details: Psychotherapy Sessions Completed Standard Deviation
36. Intervention Details: Psychotherapy Sessions Completed Detail
37. Intervention Details: Dose at Study End Point Mean
38. Intervention Details: Dose at Study End Point Standard Deviation
39. 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

103. Arm 2 Within-Group Change: Effect Size 1 Variance Value or Lower Bound
104. Arm 2 Within-Group Change: Effect Size 1 Variance Upper Bound
105. Arm 2 Within-Group Change: Effect Size 1 p value
106. Arm 2 Within-Group Change: Effect Size 2 Detail
107. Arm 2 Within-Group Change: Effect Size 2 Type
108. Arm 2 Within-Group Change: Effect Size 2
109. Arm 2 Within-Group Change: Effect Size 2 Type of Variance Measure
110. Arm 2 Within-Group Change: Effect Size 2 Variance Value or Lower Bound
111. Arm 2 Within-Group Change: Effect Size 2 Variance Upper Bound
112. Arm 2 Within-Group Change: Effect Size 2 p value
113. Comparison Arms Designation
114. Comparison Score Difference 1 Detail
115. Comparison Score Difference 1 Adjusted Indicator
116. Comparison Score Difference 1
117. Comparison Score Difference 1 Calculated Indicator
118. Comparison Score Difference 1 Standard Error
119. Comparison Score Difference 1 SE Calculated Indicator
120. Comparison Score Difference 1 95% CI Lower Bound
121. Comparison Score Difference 1 95% CI Upper Bound
122. Comparison Score Difference 1 p value
123. Comparison Score Difference 2 Detail
124. Comparison Score Difference 2 Adjusted Indicator
125. Comparison Score Difference 2
126. Comparison Score Difference 2 Calculated Indicator
127. Comparison Score Difference 2 Standard Error
128. Comparison Score Difference 2 SE Calculated Indicator
129. Comparison Score Difference 2 95% CI Lower Bound
130. Comparison Score Difference 2 95% CI Upper Bound
131. Comparison Score Difference 2 p value
132. EPC Calculated: Comparison Standardized Effect Size
133. EPC Calculated: Comparison Indicator of Adjusted or Unadjusted Inputs
134. EPC Calculated: Comparison Standardized Effect Size Standard Error
135. EPC Calculated: Comparison Standardized Effect Size 95% CI Lower Bound
136. EPC Calculated: Comparison Standardized Effect Size 95% CI Upper Bound
137. EPC Calculated: Comparison Standardized Effect Size Data Source
138. Study Reported: Comparison Effect Size 1 Detail
139. Study Reported: Comparison Effect Size 1 Type
140. Study Reported: Comparison Effect Size 1
141. Study Reported: Comparison Effect Size 1 Type of Variance Measure
142. Study Reported: Comparison Effect Size 1 Variance Value or Lower Bound
143. Study Reported: Comparison Effect Size 1 Variance Upper Bound

144. Study Reported: Comparison Effect Size 1 p value
145. Study Reported: Comparison Effect Size 2 Detail
146. Study Reported: Comparison Effect Size 2 Type
147. Study Reported: Comparison Effect Size 2
148. Study Reported: Comparison Effect Size 2 Type of Variance Measure
149. Study Reported: Comparison Effect Size 2 Variance Value or Lower Bound
150. Study Reported: Comparison Effect Size 2 Variance Upper Bound
151. Study Reported: Comparison Effect Size 2 p value

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 1 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

Risk of Bias Assessment Elements

1. Selection Bias: Randomization adequate?
2. Selection Bias: Allocation concealment adequate?
3. Selection Bias: Groups similar at baseline?
4. Selection Bias: ITT analysis?
5. Performance Bias: Care providers masked?
6. Performance Bias: Patients masked?
7. Detection Bias: Outcome assessors masked?
8. Attrition: Overall attrition ≤20%?
9. Attrition: Differential attrition ≤15%?
10. Reporting Bias: Were all prespecified outcomes reported?
11. Reporting Bias: Method of Handling Dropouts
12. Other Considerations: Were outcome measures equal, valid, and reliable?
13. Other Considerations: Did study report adequate treatment fidelity based on measurement by independent raters?
14. Risk of Bias Rating
15. EPC Assessing Risk of Bias

Appendix F. Evidence Tables

The evidence tables are shown in the associated Excel® file at https://effectivehealthcare.ahrq.gov/products/management-infantile-epilepsy/research:

Table F-1. Study Identifiers
Table F-2. Secondary Studies
Table F-3. Study Characteristics
Table F-4. Sample Characteristics
Table F-5. Study Interventions
Table F-6. PTSD Continuous Outcomes
Table F-7. PTSD Dichotomous Outcomes
Table F-8. Suicide Continuous Outcomes
Table F-9. Suicide Dichotomous Outcomes
Table F-10. Other Outcomes
Table F-11. Harms

Appendix G. Risk of Bias Assessment of Included Studies

The risk of bias (RoB) assessment is detailed in the associated Microsoft® Excel files at https://effectivehealthcare.ahrq.gov/products/management-infantile-epilepsy/research:

Table G-1. RoB 2 Assessment of New Included Studies
Table G-2. RoB Assessment of Prior Report Studies
Table G-3. RoB2 Assessment of Prior Report Studies

Appendix H. Data for Figures in Characteristics of Included Studies

Table H-1. Distribution of treatment arms by intervention category* for studies added in this update: data table for Figure 4

Intervention Category	Number of Treatment Arms	Percent of Total Number of Treatment Arms
Other	0	0%
Control	20	19%
Collaborative care	1	1%
Nonpharmacologic cognitive therapy	3	3%
Nonpharmacologic biologic	3	3%
Complementary and integrative health	12	12%
Pharmacotherapy	17	16%
Psychotherapy	52	50%

*Studies have more than one treatment arm, and a treatment arm may include multiple intervention categories.

Table H-2. Distribution of treatment arms by treatment focus* for studies added in this update: data table for Figure 5

Treatment Focus	Number of Treatment Arms	Percent of Total Number of Treatment Arms
PTSD	76	73%
PTSD+SUD	2	2%
SUD	0	0%
Control	26	25%

*Studies have more than one treatment arm.
Abbreviations: PTSD = posttraumatic stress disorder; SUD = substance use disorder

Table H-3. Distribution of study class for studies added in this update: data table for Figure 6

Study Class	Number of Studies	Percent of Total Studies
Psychotherapy	24	50%
Complementary and integrative health	8	17%
Pharmacotherapy	7	15%
Psychotherapy and pharmacotherapy	4	8%
Nonpharmacologic biologic	2	4%
Nonpharmacologic cognitive	1	2%
Psychotherapy and complementary and integrative health	1	2%
Other mixed	1	2%
Collaborative care	0	0%

Table H-4. Distribution of studies added in this update by sample size: data table for Figure 7

Sample Size	Number of Studies	Percent of Total Studies
<25	2	4%
25-99	33	69%
100-200	9	19%
>200	4	8%

Table H-5. Distribution of studies added in this update by population type: data table for Figure 8

Population Type	Number of Studies	Percent of Total Studies
Community	25	52%
Veteran	15	31%
Mixed	7	15%
Active Duty Military	1	2%

Table H-6. Distribution of studies added in this update by trauma type: data table for Figure 9

Trauma Type	Number of Studies	Percent of Total Studies
Mixed	23	48%
Intimate partner violence	4	8%
Combat-related trauma	2	4%
Accidents	1	2%
Military Sexual Trauma	1	2%
Natural or manmade disasters	1	2%
Rape/sexual assault	1	2%
Terrorism/political violence/displacement	1	2%
Child sexual abuse	0	0%
Illness/medical procedure	0	0%
Other/Not Reported	14	29%

Table H-7. PTSD measures used to assess continuous PTSD outcomes* in studies added in this update: data table for Figure 10

Measure Type	Measure	Number of Studies	Percent of Total Studies
Structured Clinical Interview	CAPS	25	52%
	PSS-I	1	2%
	SI-PTSD	1	2%
Self Report	PCL	30	63%
	IES	4	8%
	DTS	2	4%
	HTQ	2	4%
	MPSS	1	2%
	NSESSS	1	2%
	PDS	1	2%
	PSS-SR	1	2%

*Studies may have used more than one measure to assess PTSD outcomes.
Abbreviations: CAPS = Clinician-Administered PTSD Scale; DTS = Davidson Trauma Scale; HTQ = Harvard Trauma Questionnaire; IES = Impact of Event Scale; MPSS = Modified PTSD Symptom Scale; NSESSS = National Stressful Events Survey PTSD Short Scale; PCL = PTSD Checklist; PSS-I = PTSD Symptom Scale - Interview; PSS-SR = PTSD Symptom Scale – Self-Report; PTSD = posttraumatic stress disorder; SI-PTSD = Structured Interview for PTSD

Table H-8. Other outcomes reported in studies added in this update: data table for Figure 11

Other Outcome Type	Number of Studies	Percent of Total Studies
Depression	32	67%
Function	15	31%
Anxiety	13	27%
Quality of Life	8	17%
Sleep	8	17%
Anger	5	10%
Substance Use	1	2%

Appendix I. Treatment Coding Guidance

Table I-1. Guidance for AHRQ coding of variables coded by NCPTSD*

Variable	Operationalization	Notes, FAQ, and Examples
Treatment Focus Subclass	For PTSD+SUD, record "integrated" or "not integrated" Integrated treatments for PTSD-SUD include interventions that *integrate* interventions for PTSD and SUD within one protocol delivered by one provider or are interventions for PTSD and SUD that are delivered simultaneously (within one therapy session) by one provider, to be distinguished from, for example, one treatment intended to address both conditions (e.g., pharmacotherapy), two treatments delivered simultaneously without clear integration or alignment by different providers (e.g., Relapse Prevention and TF-CBT with different therapists), or phased treatment (e.g., Relapse Prevention then TF-CBT)	Exemplars of integrated treatment: • COPE • Seeking Safety • ICBT • tobacco cessation integrated into ongoing PTSD treatment Examples of non-integrated treatments: • Topiramate or prazosin monotherapy (one treatment intended to address both conditions) • PE + topiramate (two treatments delivered simultaneously without clear integration)

Variable	Operationalization	Notes, FAQ, and Examples
NCPTSD Treatment Name	An edited treatment name, consolidating treatment name variations. Spell out each treatment name, no abbreviations. The goal of these more consistent names across treatments is to allow for easier identification and comparison of treatments Very common treatments that users may want to examine individually should retain their names such as PE, CPT, EMDR, WET, PCT, STAIR, IRT, IPT, RTM. But studies where there might just be one or two occurrences of a treatment could be changed to be more general such as TFCBT or CBT for the purpose of ensuring that they are captured in the broader category when data are summarized.	Do not specify details of the treatment such as format, delivery modality, dosing or etc. For example: • CPT by video = CPT • massed PE = PE • group PCT = PCT • Bilateral rTMS = TMS • high frequency TMS = TMS • Bupropion sustained release = buproprion *Do not specify if it is an adaptation such as a cultural adaptation, an adaptation for primary care, and adaptation for IPV survivors, etc.* *Retain* augmentation • E.g., risperidone augmentation should NOT be changed to risperidone (which implies monotherapy) Do not include TAU in treatment name • PE + TAU = PE For CBT with and without a trauma focus, may need to confirm within primary article Simplify control conditions as appropriate • Sham rTMS, tDCS = sham • Placebo augmentation = Placebo • Usual care = TAU When placebo medication is combined with another active treatment (e.g., PE + placebo), retain + placebo

Variable	Operationalization	Notes, FAQ, and Examples
Psychotherapy	Talk therapy with a licensed provider	Exemplars: • TF-CBT, PE, CPT, EMDR, NET, PCT Include specific psychotherapeutic interventions that may not be stand-alone treatments in clinical practice: • Imaginal exposure • In vivo exposure • Cognitive restructuring • Imagery rescripting
Psychotherapy Subclass	Enter Trauma-focused or Non-Trauma-focused Trauma-focused = "Any therapy that uses cognitive, emotional, or behavioral techniques to facilitate processing a traumatic experience and in which the trauma focus is a central component of the therapeutic process."[16]	Exemplars of trauma-focused psychotherapy: • CPT, PE, EMDR, NET, WET, COPE Exemplars of non-trauma-focused psychotherapy: • Present-centered therapy (PCT) • ICBT • Seeking Safety
Pharmacotherapy	Medication	Medication assisted psychotherapy arms should be coded as YES to Psychotherapy and YES to Pharmacotherapy Placebo medication arms are considered CONTROL
Pharmacotherapy Subclass	Category of medication	Examples: • SSRI • TCA
Complementary and Integrative Health (CIH)	Wide category of approaches that are considered to be outside the standard in the current practice of Western medicine.	Examples: • Acupuncture • Meditation • Natural products

Variable	Operationalization	Notes, FAQ, and Examples
CIH Subclass	Categories: • Acupuncture • Clinical hypnosis • Meditation • Massage therapy • Tai chi/qi gong • Yoga • Other physical activity and recreational therapies • Animal-assisted • Natural products • Creative therapies • Relaxation • Spirituality • Other	See subcodes list below this table for full definitions of categories. Meditation includes mindfulness and mantram Relaxation includes biofeedback/neurofeedback
Nonpharmacologic Biological	Interventions that use a medical device or procedure of some kind.	Exemplars: • TMS • stellate ganglion block Note: Sham conditions considered control, not non-pharmacologic biological
Nonpharmacologic Cognitive	Interventions that teach cognitive skills to improve attention.	Exemplars: • attention bias modification
Control	Comparison conditions such as a placebo pill, waitlist, and treatment as usual (i.e., when treatment as usual cannot be clearly defined as another specific treatment.)	Treatment should be *inactive* Exemplars: • Placebo • Sham Low dose medications like MDMA still considered active
Other	Treatments that don't better fit into another category	Exemplars: • Digital interventions not delivered by a licensed provider (e.g., internet-based CBT, PTSD Coach)
Collaborative Care	Interventions in which integrated medical and mental health treatment is delivered in primary care, often by nurse managers.	Example: • Centrally assisted collaborative telecare

Variable	Operationalization	Notes, FAQ, and Examples
Format	Enter individual, group, couples, or mixed • **Individual:** intervention delivered only in individual format • **Group:** intervention delivered only in group format • **Couples:** intervention delivered only in couples format • **Mixed:** Intervention delivered in 2+ formats	Code all arms, including non-psychotherapy arms
Delivery Method	Enter one of: • **In person:** Intervention delivered only in a face-to-face manner • **Phone**: Intervention delivered by phone only • **Video:** Intervention delivered by video teleconference only • **Technology alone**: Technology is the primary way that treatment is delivered; e.g., self-management • **Technology-assisted**: Self-management assisted by provider • **Written**: Intervention includes writing only • **Mixed:** Intervention includes 2+ forms of delivery	Examples of technology-assisted: • therapist-guided internet CBT • PTSD Coach mobile app with clinician support Tech-assisted does NOT include: • Virtual reality • DVDs and CDs

*These variables are coded at the study arm level.

CBT = cognitive behavioral therapy; CD = compact disc; CIH = complementary and integrative health; COPE = Concurrent Treatment for PTSD and Substance Use Disorder Using Prolonged Exposure; CPT = Cognitive Processing Therapy; DVD = digital video disc; EMDR = Eye Movement Desensitization and Reprocessing; FAQ = frequently asked question; ICBT = Integrated Cognitive Behavioral Therapy; IPT = Interpersonal Psychotherapy; IRT = Imagery Rehearsal Training; MDMA = 3,4-methylenedioxy-methamphetamine; NCPTSD = National Center for Posttraumatic Stress Disorder; NET = Narrative Exposure Therapy; PCT = Present-Centered Therapy; PE = Prolonged Exposure; PTSD = posttraumatic stress disorder; RTM = Reconsolidation of Traumatic Memories; rTMS = repetitive transcranial magnetic stimulation; SSRI = selective serotonin reuptake inhibitor; STAIR = Skills Training in Affect and Interpersonal Regulation; SUD = Substance Use Disorder; TAU = Treatment as usual; TCA = tricyclic antidepressant; tDSC = transcranial direct current stimulation; TF-CBT = trauma-focused cognitive behavioral therapy; TMS = transcranial magnetic stimulation; VA/DoD CPG = Department of Veterans Affairs/Department of Defense clinical practice guideline; WET = Written Exposure Therapy

Subcodes for Complementary and Integrative Health (CIH) Treatment Studies

1. **Acupuncture (https://www.va.gov/WHOLEHEALTH/professional-resources/Acupuncture.asp):** "Acupuncture is one of several techniques that make up the system of care provided by those trained in traditional medicine from China and other Asian countries. Acupuncture may refer to this whole system approach to health care or define the technique of acupuncture treatment. Most frequently we think of acupuncture as the penetration of thin needles into the body at acupuncture points to effect a change. Acupuncture is used to restore or maintain health."
2. **Clinical hypnosis (https://www.va.gov/WHOLEHEALTH/professional-resources/Clinical_Hypnosis.asp): "**Clinical Hypnosis is the process of (a) deliberately triggering a trance state and then (b) utilizing that state to encourage helpful cognitive, emotional, or physical healing responses. A trance is a natural biological state of inner absorption, concentration and focused attention. Clinical Hypnosis and Hypnotherapy are not the same as hypnosis. Hypnosis is the process of triggering a trance state in an individual. It not usually geared towards therapeutic change, but just for relaxation or increasing compliance. Without a clinician using additional tools to cause change while the person is in trance, there rarely is lasting benefit to hypnosis beyond relaxation and temporary stress reduction."
3. **Meditation (https://www.va.gov/WHOLEHEALTH/professional-resources/Meditation.asp):**
    a. VA/DOD CPG: "Meditation is a mind-body technique that refers to a broad variety of practices with the general goal of training the mind through regulation of attention and/or emotion to affect functions, symptoms, and state of being."
    b. VA Whole Health: "Meditation is a defined practice or technique, often arising from a contemplative tradition, that primarily focuses on training attention regulation processes, with the intent of cultivating general mental well-being and/or specific capacities such as concentration, compassion or insight. To differentiate from hypnosis, guided imagery, psychotherapies, the focus is on training attentional processes, rather than specifically targeting a change in mental contents. Mindfulness is an intentional and non-judgmental awareness of the present moment. It is a type of meditation based on the concept of being mindful, or having increased awareness, of the present. It may include formal meditation practices such as focusing on the breath or sensations in the body, and informal practices such as washing the dishes all intended to cultivate awareness of the present moment with a quality of acceptance and kindness. Mindfulness Based Interventions are structured mindfulness classes that include instruction in a sequence of specific mindfulness practices, group discussions, exercises and theory and include:"
        i. Mantram meditation
        ii. Mindfulness-Based Eating Awareness Training (MB-EAT)
        iii. Mindfulness-Based Cognitive Therapy (MBCT)
        iv. Mindfulness-Based Relapse Prevention (MBRP)
        v. Mindfulness-Based Stress Reduction (MBSR)

1. VA/DOD CPG: "MBSR is a manualized protocol that includes didactic training and formal practice in three meditation techniques: body scan, sitting meditation, and mindful yoga."

vi. Mindfulness-Oriented Recovery Enhancement (MORE)
vii. Mindfulness Self-Compassion (MSC)
viii. VA CALM protocol (Clinician's Guide to Teaching Mindfulness)

4. **Massage therapy (https://www.va.gov/WHOLEHEALTH/professional-resources/Massage_Therapy.asp): "**Clinical massage therapy is the manipulation of the soft tissues of the human body for therapeutic purposes. Based in ancient traditions, massage therapy is a professional health care discipline in the United States."
5. **Tai chi / qi gong (https://www.va.gov/WHOLEHEALTH/professional-resources/Tai_Chi.asp): "*Tai Chi*** is a mind-body exercise combining slow-flowing intentional movements with breathing, awareness and visualization. Rooted in the Asian traditions of martial arts, Chinese medicine and philosophy, Tai Chi enhances relaxation, vitality, focus, posture, balance, strength, flexibility, and mood. ***Qigong*** is an ancient Chinese healing art, older than, and similar to tai chi, with a focus of cultivating the body's vital energy or qi. It involves the coordination of the breath, posture, awareness, visualization and focused movements. Qigong may be a stationary or moving meditation."
6. **Yoga (https://www.va.gov/WHOLEHEALTH/professional-resources/Yoga.asp): "**Yoga is a mind and body practice with origins in ancient Indian philosophy. The various styles of yoga typically combine physical postures, breathing techniques, and meditation or relaxation."
7. **Other physical activity and recreational therapies (e.g., sailing):** activities involving moving the large muscles of the body to improve stamina, strength, flexibility, and/or balance (Whole Health) or that use recreation or that use recreational modalities to improve quality of life and functioning (ATRA: https://www.atra-online.com/page/AboutRecTherapy)
8. **Animal-assisted:** any intervention in which an animal (e.g., dogs, horses) is used to achieve therapeutic benefit
9. **Natural products (e.g., gingko biloba):** Herbs and supplements intended to have therapeutic benefit
10. **Creative therapies (e.g., music, art, drama therapy):** interventions that use creative means and processes to promote expression, communication, and well-being (American Art Therapy Association)
11. **Relaxation:** techniques intended to reduce stress and arousal and produce the body's relaxation response (e.g., slower breathing, lower blood pressure) that do not specifically include features of meditation described above; includes:
    a. Breathing retraining
    b. Guided imagery: "involves using a series of multi-sensory images designed to trigger specific changes in physiology, emotions, or mental state for the purpose of increasing healing response or unconscious changes. Guided Imagery often begins with a series of relaxation techniques, although this is not always so. Often guided imagery is performed as a self-help option without the involvement of a professional. However, in more complex situations, guided imagery is done in a clinical setting either 1:1 or in group."

c. Progressive muscle relaxation: systematic tightening and relaxing distinct muscle groups intended to relieve tension

d. Biofeedback (https://www.va.gov/WHOLEHEALTH/professional-resources/Biofeedback.asp): "Biofeedback is a process that uses your body's own signals like heart rate and body temperature to bring about healthy changes. **Neurofeedback** (or EEG biofeedback) is a type of biofeedback that specifically uses brain wave signals to bring about healthy changes. Clinical biofeedback involves interaction between a provider, a client, and a machine/device providing feedback from body-derived signals."

12. Spirituality: Interventions intended to provide meaning and connect patients to something greater than themselves, which may include religious beliefs and practices

13. **Other**

Note: CIH content drawn from VA Whole Health website (Complementary and Integrative Health - Whole Health [va.gov]: https://www.va.gov/WHOLEHEALTH/professional-resources/clinician-tools/cih.asp) unless otherwise noted.