Comparative Effectiveness Review
Number 235

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

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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.

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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.

The reports and assessments provide organizations with comprehensive, evidence-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).

AHRQ expects that the EPC evidence reports and technology assessments, when appropriate, will be helpful to health plans, providers, purchasers, government programs, and the healthcare system as a whole. Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the website (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an email list to learn about new program products and opportunities for input.

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, the 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 posttraumatic stress disorder (PTSD) treatment randomized controlled trials (RCTs) to update the PTSD Trials Standardized Data Repository (PTSD-Repository) with data on PTSD and mental health, including suicide-related outcomes and substance use.

Data sources. We searched PTSDpubs, Ovid® MEDLINE®, Cochrane CENTRAL, PsycINFO®, Embase®, CINAHL®, and Scopus® for eligible RCTs published from 1980 to May 22, 2020.

Review methods. In consultation with the National Center for PTSD (NCPTSD), we updated the PTSD-Repository by expanding inclusion criteria to RCTs targeting comorbid PTSD/substance use disorder (SUD) and adding data elements. 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 studies in the PTSD-Repository. We undertook an exploratory assessment of an expanded ROB system developed with guidance from a Technical Expert Panel and NCPTSD, which was pilot tested on a small subset of studies.

Results. We identified 47 new RCTs of interventions for PTSD and 21 RCTs for comorbid PTSD/SUD, resulting in 389 included studies published from 1988 to 2020. Psychotherapy interventions were the most common (63%), followed by pharmacologic interventions (25%). Most studies were conducted in the United States (62%) and had sample sizes ranging from 25 to 99 participants (60%). Approximately half of studies enrolled community participants (55%), and most were conducted in the outpatient setting (72%). Studies typically enrolled participants with a mix of trauma types (53%). Most RCTs (60%) were rated as having a medium ROB, and only 6 percent were rated as having a low ROB. Our pilot testing of an expanded ROB assessment tool emphasized more detailed assessment of elements, including: (1) methods for managing missing data, including both dropout from treatment and missing measurements (i.e., loss to followup); (2) differential assessment of subjective and objective outcomes; and (3) consideration of a five-category overall rating system.

Conclusions. The PTSD-Repository is a comprehensive database of data from PTSD trials. The PTSD-Repository allows clinical, research, education, and policy stakeholders to understand current research on treatment effectiveness and harms, and enable informed decisions about future research, mental health policy, and clinical care priorities. This report updates the studies and variables included in the PTSD-Repository to include recently published trials, interventions targeting comorbid PTSD/SUD, variables related to comorbidities such as suicide and SUDs, and ROB assessment.

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Evidence Summary

Main Points

- This update adds newly published studies on posttraumatic stress disorder (PTSD, 47 randomized controlled trials [RCTs]), studies targeting comorbid PTSD and substance use disorders (SUDs, 21 RCTs), and variables related to comorbidities such as SUDs and suicidal ideation/behavior, to the PTSD-Repository, a database of RCTs of interventions to treat PTSD.
- We abstracted data from 389 RCTs, which included psychotherapeutic interventions (63%), pharmacologic interventions (25%), and complementary and integrative or nonpharmacologic biological treatments (12%).
- Reporting was incomplete for many data elements in published studies: less than half of studies reported on the loss of PTSD diagnosis (i.e., no longer meeting criteria for PTSD) or clinically meaningful response/remission of symptoms.
- Risk of bias (ROB) was assessed for all included studies; most were rated as having a medium ROB (57%), and only 6 percent were rated as having a low ROB.
- An exploration of an expanded ROB system was developed and pilot tested.

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 functioning. The purpose of this project was to update and expand the PTSD Trials Standardized Data Repository (PTSD-Repository), a publicly accessible clinical trials database maintained by the National Center for PTSD (NCPTSD). 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. It will also 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. The PTSD-Repository included data published between 1980 and May 22, 2020 from 318 RCTs of interventions targeting treatment of PTSD. This update expands on our previous work (Agency for Healthcare Research and Quality [AHRQ] Technical Brief No. 32)[1,2] by adding RCTs published since that work was completed, broadening some inclusion criteria (e.g., studies of comorbid PTSD/SUD) and elements of data abstracted (e.g., inclusion/exclusion criteria related to suicide and psychotic disorders), and conducting ROB assessments for all studies included in the repository (both those found in this update and those included previously). We also explored expanding specific elements of the ROB criteria that may affect studies of PTSD more particularly, pilot testing on a small set of RCTs.

Methods

We followed methods outlined in the AHRQ Evidence-based Practice Center (EPC) Program Methods Guidance (https://effectivehealthcare.ahrq.gov/topics/cer-methods-guide/overview) where applicable.[3] For this update, we searched PTSDpubs (formerly PILOTS), Ovid®

MEDLINE®, Cochrane CENTRAL, PsycINFO®, Embase®, CINAHL®, and Scopus® for eligible RCTs published from June 2018 to May 22, 2020. We also reviewed studies excluded in Technical Brief No. 32[1] (a prior version of this report) for interventions targeting comorbid PTSD and SUD that would meet the expanded inclusion criterion. 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 into evidence tables developed for Technical Brief No. 32,[1] and a second reviewer checked for accuracy and completeness. An investigator assessed ROB for previously included studies and newly added studies following the methods used in a prior review of PTSD intervention studies, Comparative Effectiveness Review No. 207,[4] and a second reviewer checked for accuracy. At the request of the sponsor, NCPTSD, and with guidance from NCPTSD and a Technical Expert Panel with expertise in ROB assessment methods, we explored development of additional, or refinement of existing, ROB elements relevant to the PTSD-Repository. The revised criteria were tested on a small subset of studies.

Results

In this update, we added 47 RCTs targeting PTSD and 21 targeting comorbid PTSD/SUD for a total of 389 RCTs included in the PTSD-Repository. The updated report now includes 115 pharmacologic studies (trials with at least one medication arm) and 274 nonpharmacologic studies (trials with no medication arms – all other types of studies including psychotherapy, nonpharmacologic biologic, and complementary and integrative health interventions were classified as nonpharmacologic). The trials were published from 1988 to 2020, with the majority published within the last 10 years. Psychotherapeutic interventions were the most commonly studied (63%), followed by pharmacologic interventions (25%). The majority of studies were conducted in the United States (62%), and most had sample sizes in the range of 25 to 99 participants (60%), with a relatively small number of studies enrolling more than 200 participants (9%). More studies enrolled participants from a community population (55%) than from a military, veteran, or other population, and the majority of studies were conducted in the outpatient setting (72%). Studies typically enrolled participants with a mix of trauma types (53%), followed by studies of participants with combat-related trauma (18%). Sixty percent of all studies included in the PTSD-Repository were rated as having a medium ROB, and only 6 percent were rated as having a low ROB. Our exploration and pilot testing of an expanded ROB assessment system emphasized more detailed assessment of elements relevant to PTSD studies including: (1) assessment of methods for managing missing data, including both drop out from treatment and missing measurements (i.e., loss to followup), (2) differential assessment of subjective and objective outcomes, and (3) consideration of a 5-category overall rating system.

Limitations

Many data elements were not reported or were reported in an inconsistent manner across the available body of literature. For example, less than half of the included studies reported loss of PTSD diagnosis or clinically meaningful response/remission of symptoms. Several other 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. As part of this PTSD-Repository update, we abstracted additional details about many of these important variables (e.g., suicide-related inclusion/exclusion criteria as well as

outcomes), and also documented when these data were not reported in primary studies so that users of the PTSD-Repository are aware of the source of missing data.

Implications and Conclusions

The PTSD-Repository is a comprehensive database of detailed data compiled from trials of PTSD interventions in adults. The PTSD-Repository will allow clinical, research, education, and policy stakeholders to understand current research on treatment effectiveness and harms, and enable these stakeholders to more quickly and accurately make informed decisions about future research, mental health policy, and clinical care priorities.

This report updates the studies and variables included in the PTSD-Repository to include recently published trials of interventions for PTSD (47 RCTs), interventions targeting comorbid PTSD/SUD (21 RCTs), variables related to comorbidities such as suicidal ideation/behavior and SUDs, and risk of bias assessment. Data abstraction and ROB assessment for all 389 included RCTs are being used by NCPTSD to update the Web-based, interactive PTSD-Repository, a publicly available trials database available at https://www.ptsd.va.gov/ptsdrepository/index.asp.

The PTSD-Repository may be expanded in the future by including new studies or additional outcomes and by using an expanded ROB system. Conversion of the abstracted data into an interactive and searchable Web-based dissemination of the PTSD-Repository was recently completed by the NCPTSD and includes key data summaries of the trials included in the PTSD-Repository.

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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 6.1 percent in US civilians and 6.9 percent in U.S. military veterans.[2,3] Individuals with PTSD are often more likely to experience other mental health comorbidities compared to those without, particularly substance use. For example, studies estimate that around one quarter to one half of individuals who have experienced PTSD in their lifetime also met criteria for a substance use disorder.[3,4]

Since PTSD was first included by the Diagnostic and Statistical Manual of Mental Disorders, third edition (DSM-III) in 1980, there have been approximately 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 in theory would number in the thousands. Given the large and varied body of evidence, to make the review 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.[5] 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.[6,7] 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.

This review seeks to build upon the data repository developed in Technical Brief No. 32,[8,9] called the PTSD Trials Standardized Data Repository, or "PTSD-Repository" (https://www.ptsd.va.gov/ptsdrepository/index.asp). 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[10] or the online PTSD Treatment Decision Aid.[11]

This update builds on the previously established PTSD-Repository by including additional studies and variables or data elements. Specifically, this report updates the database to include RCTs of PTSD interventions published from June 2018 through May 22, 2020 (studies published since the PTSD-Repository was initially developed), expands inclusion criteria to interventions targeting comorbid PTSD and substance use disorders (SUDs), adds new data elements such as inclusion and exclusion criteria and baseline characteristics related to suicide and psychosis, and adds risk of bias (ROB) assessment for all studies included in the PTSD-Repository (both prior studies and those added in this update) consistent with the prior review on this topic, Agency for Healthcare Research and Quality Comparative Effectiveness Review No. 207. Additionally, this update explores an expanded ROB system using expert consultation and pilot testing. This expansion of the ROB process included abstraction of additional bias-related elements, a more detailed consideration of these elements for some of the ROB criteria, and additional categories for overall ROB ratings. The expanded ROB criteria were then pilot tested with ten studies included in the PTSD-Repository. This expanded ROB process was conducted to address sponsor concerns about the limitations of existing ROB assessment methods.

Key Questions

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

Key Question 2. What nonpharmacologic interventions have been studied for the treatment of PTSD alone or with comorbid SUD?

The Key Questions are based on updating the same body of literature included in Technical Brief No. 32[8] and expanded to include interventions targeting comorbid PTSD/SUD. For all Key Questions, the following PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings, Study Design) criteria apply:

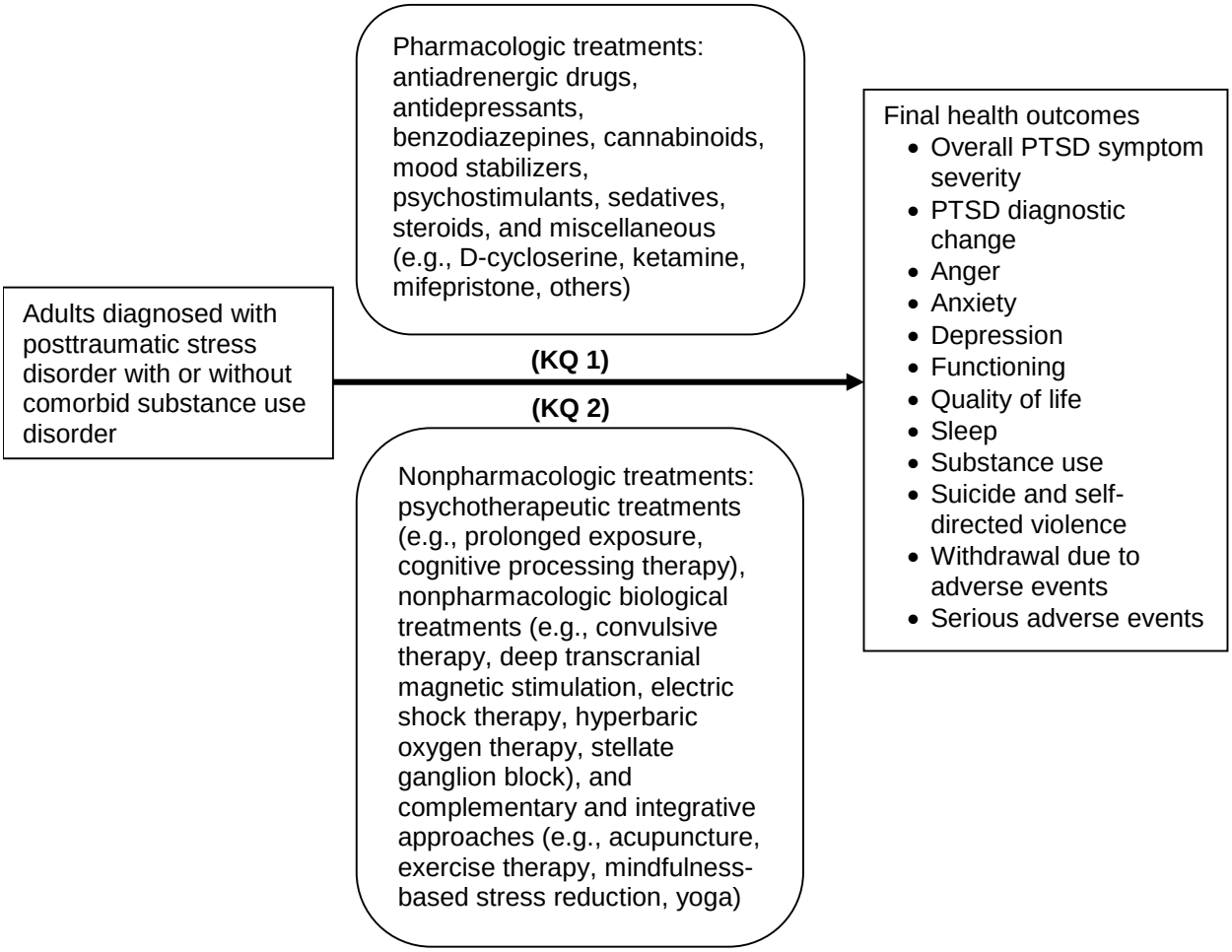
- **Population(s):**
  - Adults (≥18 years old) diagnosed with PTSD by a clinician or through a patient-reported assessment tool
- **Interventions:**
  - Pharmacologic and nonpharmacologic interventions, including complementary and integrative approaches, for PTSD or comorbid PTSD/SUD
- **Comparators:**
  - Any comparator, including another intervention, waitlist/minimal attention, usual care, or placebo
- **Outcomes:**
  - Overall PTSD outcome, PTSD diagnostic change
  - Other outcomes – Anxiety, anger, depression, functioning, quality of life, sleep, substance use, suicide- and self-directed violence-related outcomes including suicidal ideation/behavior, 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:**
  - Randomized controlled trials

Analytic Framework

Figure 1 depicts the Key Questions within the context of the PICOTS inclusion and exclusion criteria presented in Table 1. The figure illustrates how pharmacologic and nonpharmacologic treatments – which includes psychotherapeutic treatments, nonpharmacologic biological treatments, and complementary and integrative approaches – may be associated with health and functional outcomes including 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 pharmacologic and nonpharmacologic treatments for posttraumatic stress disorder



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,[12] where applicable, to creating a systematic data repository. Methods followed Technical Brief No. 32[8] and were determined *a priori* after discussion with National Center for Posttraumatic Stress Disorder (NCPTSD) and AHRQ. A protocol was published on the AHRQ website (https://effectivehealthcare.ahrq.gov/products/ptsd-repository-expanded/protocol). Notably, because this project focused both on updating the evidence base with new posttraumatic stress disorder (PTSD) trials as well as updating and pilot testing risk of bias (ROB) 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 and suicide prevention research. The ROB TEP had ROB methods expertise and provided guidance related to the updated ROB methods that were pilot tested.

Criteria for Inclusion/Exclusion of Studies in the Review

Detailed inclusion and exclusion criteria for all Key Questions are listed in Table 1 and are consistent with the PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Setting/Study Design) criteria identified above. These inclusion and exclusion criteria are the same as those applied during the initial development of the PTSD-Repository. This update expanded the criteria to include interventions targeting comorbid PTSD/substance use disorder (SUD). Interventions targeting PTSD and a comorbid condition other than SUD were included as long as the intervention could be used as a treatment for PTSD alone (i.e., without the presence of the comorbid condition). For example, interventions for PTSD and insomnia were included because sleep difficulties are often part of a standalone PTSD diagnosis, and therefore these interventions could be used to treat 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. In this update and expansion of the preliminary evidence tables that serve as the basis for the PTSD-Repository, inclusion and exclusion criteria reflect the updates to the preliminary phase of development through the inclusion of newly published studies of PTSD interventions, studies targeting comorbid PTSD and SUDs, and variables related to comorbidities such as suicidal ideation/behavior and SUDs.

Table 1. PICOTS: Inclusion and exclusion criteria

PICOTS	Include	Exclude
Populations	Adults (≥18 years old) with PTSD diagnosed by a clinician or through the administration of a validated clinician-administered or patient-reported assessment tool	Children (<18 years old) Diagnosis of acute stress disorder Studies that do not specify criteria used to diagnose PTSD Studies in which more than 20% of participants did not meet full PTSD criteria
Interventions	Pharmacologic interventions for PTSD or **comorbid PTSD/SUD** with any pharmacologic component, whether singly, in combination with other treatment categories, or compared with another intervention category Nonpharmacologic interventions for PTSD or **comorbid PTSD/SUD**, including complementary and integrative approaches, nonpharmacologic biological treatments, and psychotherapeutic treatments	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
Comparators	No limitations applied. Direct head-to-head comparison of PTSD interventions were included. Interventions such as waitlist, usual care, placebo, or other minimally-active treatment (e.g., education or attention control) are categorized as "Controls"	None
Outcomes	Any overall PTSD symptom severity outcome; PTSD diagnostic change. Other outcomes including anxiety, anger, depression, functioning, quality of life, sleep, substance use, suicide- and self-directed violence-related outcomes including suicidal ideation/behavior, withdrawal due to adverse events, serious adverse events	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 sources for studies to be reviewed for possible inclusion (data will be abstracted from individual studies rather than from systematic reviews)

Note: Bold text indicates PICOTS expansion in this update.
PICOTS = Populations, Interventions, Comparators, Outcomes, Timing, Setting/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 May 22, 2020, containing 3 months of overlap with the last database search for Technical Brief No. 32.[8] Additionally, the databases originally searched for Technical Brief No. 32 were searched again for previously excluded studies related to interventions targeting comorbid PTSD and SUD..

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 for PTSDpubs and MEDLINE 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 described under Key Questions and criteria in 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 list of included studies (Appendix B) was reviewed by NCPTSD and the Content TEP for completeness. A record of studies excluded at the full-text level with reasons for exclusion is in Appendix C.

Data Abstraction

After studies were screened and deemed to meet inclusion criteria, study design, year, setting, country, sample size, eligibility criteria, source(s) of funding, study characteristics, population characteristics, intervention characteristics, and study results were abstracted (see Appendix D for a complete list of data elements abstracted). Data were abstracted into detailed evidence tables in Microsoft® Excel developed for Technical Brief No. 32[8] and revised for this update project 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. A senior investigator verified all abstracted data for accuracy and completeness.

Data were abstracted into a detailed evidence table. 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.

Assessment of Methodological Risk of Bias of Individual Studies

Risk of bias was assessed for all randomized controlled trials (RCTs) included in the PTSD repository. This included RCTs identified in our prior report (Technical Brief No. 32),[8] new studies found in updated searches for this report, and new studies found as a result of expanding the inclusion criteria for this report (see above). We followed the approach used in a prior report on PTSD intervention studies (Comparative Effectiveness Review [CER] No. 207, Psychological and Pharmacologic Treatments for Adults with Posttraumatic Stress Disorder[5]) in accordance with the AHRQ Methods Guide for Effectiveness and Comparative Effectiveness Review.[13] This process included rating 12 ROB elements according to standardized procedures. An overall

rating (low, medium, and high ROB) was assigned based on satisfaction of ROB domains (selection, performance, detection, attrition, and reporting bias; see Appendix D for a description of ROB assessment elements). For this project, ROB was rated on an overall study basis, not according to individual outcomes. When ROB elements were different for multiple outcomes within a single study, the primary PTSD outcome was prioritized for ROB ratings. Studies included in AHRQ CER No. 207 were not re-evaluated; individual ROB items and overall ratings from the previous CER are reported in the current report. The process of using the same ROB assessment across the review projects ensured that ROB assessment of included studies was comparable regardless of the study team conducting the original review. Including and incorporating ROB assessment from prior reviews is supported by AHRQ methods guidance.[14] All risk of bias assessment and dual review were conducted by senior investigators.

At the request of the sponsor (NCPTSD), and with input from a separate panel of experts in clinical trial design and risk of bias assessment (the ROB TEP) and sponsor, we explored an expanded ROB assessment approach relevant to studies in the PTSD-Repository, to address the sponsor's concerns about possible limitations in existing ROB approaches. The ROB TEP had focused expertise in systematic review methods, particularly ROB assessment methods and applying ROB criteria to behavioral and mental health clinical trials. After discussion with NCPTSD and the ROB TEP, we explored an expanded framework examining alternative ways of assessing ROB. The specific criteria we expanded and evaluated were varying types of attrition (i.e., treatment dropout versus loss to followup for individual measurements), methods for addressing missing data, the interaction between subjective outcomes and blinding of participants and assessors, and consideration of more than three levels of final ROB ratings. The expanded ROB system was pilot tested on 10 trials included in the PTSD-Repository.

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

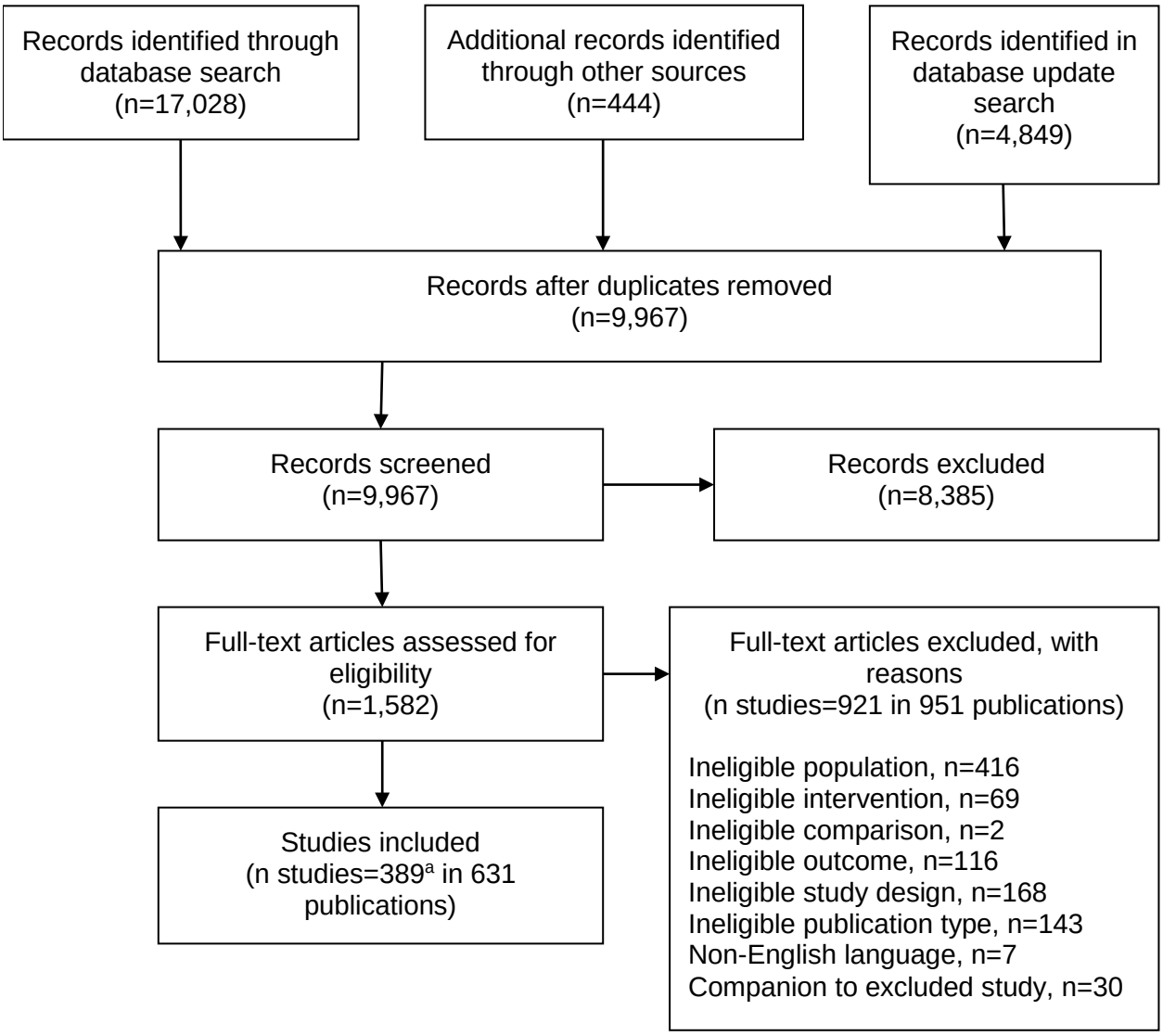
Experts in the field of PTSD conditions were invited to provide external peer review of this review and evidence tables. Comments and editorial review were also sought from the AHRQ Task Order Officer, an associate editor, and partners at NCPTSD. The draft report was posted on the AHRQ website for 4 weeks to elicit public comment. In response to comments, we revised the text. A report with the disposition of comments made by individual reviewers/commenters was submitted to AHRQ and will be posted after the publication of the final evidence report on the AHRQ website.

Results

Results of Literature Search

The results of the literature search and selection of articles are summarized in the literature flow diagram (Figure 2). This flow diagram documents the search and selection of articles from Technical Brief No. 32 and from this update to provide a comprehensive overview of all repository studies. Combining all database searches and other sources yielded 9,967 unique records. After review of abstracts and titles, 1,582 articles were selected for full-text review, and 389 studies were determined to meet inclusion criteria and were designated for data abstraction. Reasons for exclusion of studies were ineligible population, intervention, outcomes, study design, publication type, and foreign language articles.

Figure 2. Literature flow diagram



[a]The total number of studies and publications reflect excluding 5 previously included studies (in 6 publications) and adding 8 studies (in 9 publications) that met inclusion criteria for the previous work. In this updated report, 68 studies (in 184 publications) met the expanded inclusion criteria or were published since the original work.

Characteristics of Included Studies

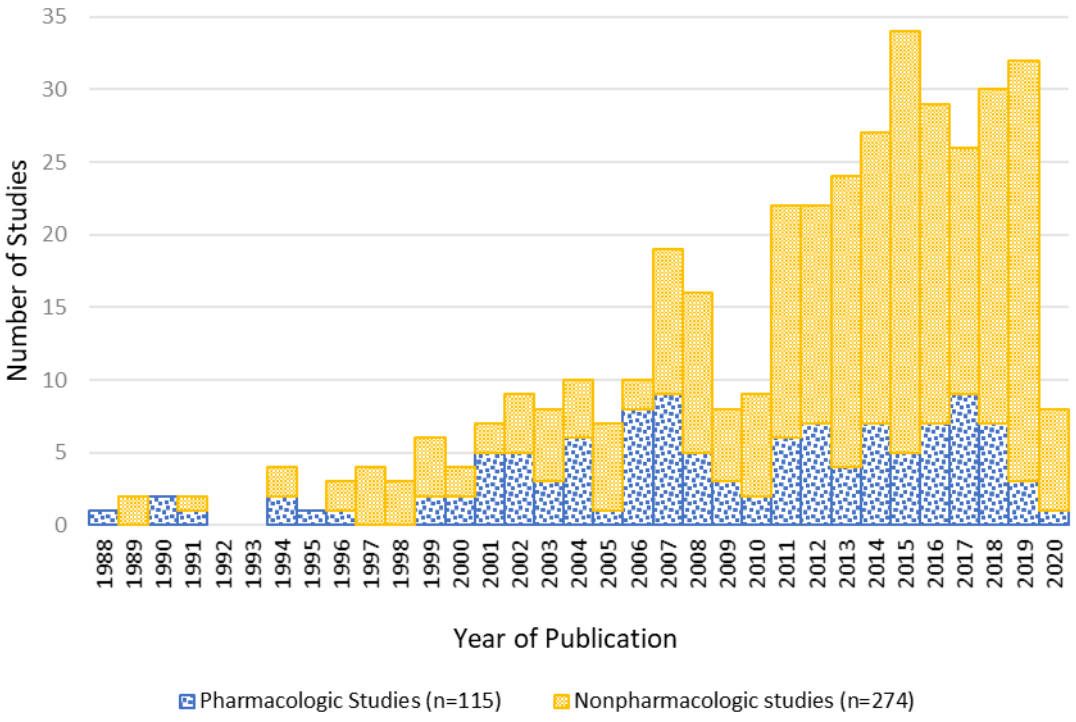
In addition to 318 randomized controlled trials (RCTs) included in Technical Brief No. 32,[8] we added 47 RCTs[15-61] of interventions for posttraumatic stress disorder (PTSD) and 21 RCTs for comorbid PTSD and substance use disorder (SUD)[62-82] as includable and designated for data abstraction in this update. In this update, we identified eight RCTs that met inclusion criteria but were not included in Technical Brief No. 32.[83-90] These studies were included after confirmation with the National Center for Posttraumatic Stress Disorder (NCPTSD) that treatments for insomnia due to PTSD could improve overall PTSD symptom severity and therefore met inclusion criteria because they could be standalone treatments for PTSD. These studies were erroneously excluded during the preliminary phase of PTSD-Repository development, and have now been included and data have been abstracted in this update. We also identified five RCTs

that were previously included, but were reexamined and determined to not meet all inclusion criteria; therefore, these five studies are now excluded from the PTSD-Repository.[91-95] A list of included studies is in Appendix B and a list of studies excluded upon full-text review with reasons for exclusion appears in Appendix C.

The data abstraction evidence table (Appendix E) for this report presents detailed information on study and population characteristics and study outcomes for the 389 included studies. Studies were categorized according to Key Question: pharmacologic or nonpharmacologic interventions. Most included studies used only nonpharmacologic interventions (274/389, 70%); while 115/389 studies (30%) included one or more pharmacologic components. Only a small proportion of studies included participants with subthreshold PTSD (27/274 or 10% of nonpharmacologic RCTs and 1/115 or just under 1% of pharmacologic RCTs); studies including more than 20 percent of participants with subthreshold PTSD were excluded. Therefore, these data should be interpreted in the context of being from a pool of RCTs with 80 to 100 percent of participants having a full PTSD diagnosis.

The publication dates of the included studies ranged from 1988 to 2020 (Figure 3). The number of studies published per year increased in the 2000s, reaching a peak of 34 in 2015. This increase was seen particularly with nonpharmacologic intervention studies—29 nonpharmacologic studies were published in 2015, compared with 5 pharmacologic studies.

Figure 3. Distribution of included publications by year



In addition to classification by Key Question (pharmacologic and nonpharmacologic), we also classified individual treatment arms within each study. Study arms were classified by intervention categories in Table 2, which aligns with the 2017 Department of Veterans Affairs/Department of Defense clinical practice guideline,[96] as recommended by the Content TEP and NCPTSD. These categories included pharmacologic treatments and three nonpharmacologic treatment subtypes, which are nonpharmacologic biological treatments, complementary and integrative treatments, and psychotherapeutic treatments (Figure 4). Psychotherapeutic intervention was the most frequently studied treatment, employed in 63 percent of the total number of included studies, followed by pharmacologic intervention in 25 percent of studies. Multicomponent treatment consisting of different intervention categories within a single arm of the study were labeled as "mixed" interventions.

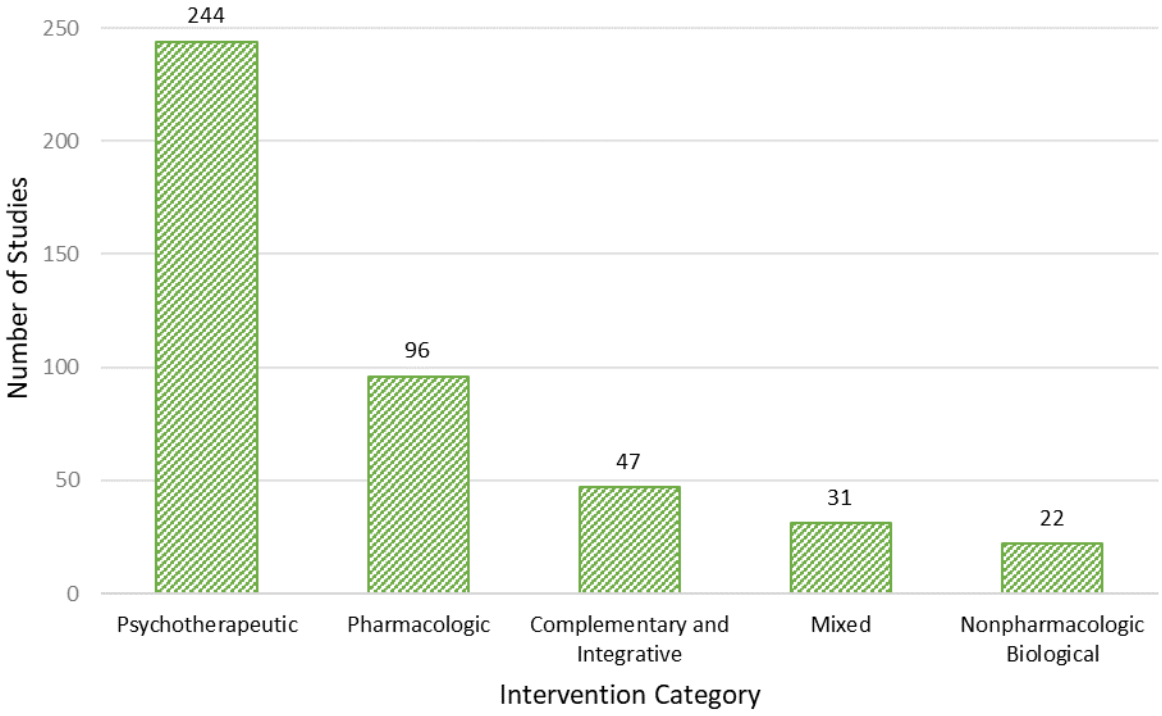
Table 2. Intervention categories with examples

Pharmacologic Treatments	Nonpharmacologic Biological Treatments	Complementary and Integrative Treatments	Psychotherapeutic Treatments	Control
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)	Biofeedback (including neurofeedback) Convulsive therapy Electric shock therapy Electroconvulsive therapy (ECT) Hyperbaric oxygen therapy (HBOT) Repetitive transcranial magnetic stimulation (rTMS) Shock therapy Stellate ganglion block (SGB) Vagal nerve stimulation (VNS)	Acupuncture Animal-Assisted Therapy Art Therapy Dietary Supplements Drama Therapy Exercise Therapy (e.g., dance) Homeopathy Hypnosis Mantram Repetition Program (MRP) Meditation (including mindfulness) Mindfulness-Based Stress Reduction (MBSR) Movement Therapy Music Therapy Natural products (e.g., gingko biloba, herbs)	Accelerated Resolution Therapy Acceptance and Commitment Therapy (ACT) Anger Management Therapy Attention Control Behavioral Activation and Therapeutic Exposure Brief Eclectic Psychotherapy (BEP) Brief Psychodynamic Therapy Cognitive Behavioral Therapy (CBT) Cognitive Behavioral Therapy for Insomnia (CBT for Insomnia) Cognitive Behavioral Therapy for Sleep (CBT for Sleep) Cognitive Processing Therapy (CPT) Cognitive Restructuring (CR) Couples Therapy Dialectic Behavior Therapy (DBT) Emotional Freedom Techniques Exposure Therapy Eye Movement Desensitization and Reprocessing (EMDR) Graded Exposure Therapy Interpersonal Psychotherapy (IPT) Mindfulness-Based Exposure Therapy Narrative Exposure Therapy (NET) Present-Centered Therapy (PCT) Prolonged Exposure (PE) Psychoanalysis Seeking Safety	Placebo Psychoeducation Sham Treatment as Usual (TAU) Waitlist (WL)

Pharmacologic Treatments	Nonpharmacologic Biological Treatments	Complementary and Integrative Treatments	Psychotherapeutic Treatments	Control
		Phytotherapy Progressive Muscle Relaxation Psychodrama Recreational Therapies (e.g., drama, fishing, sailing) Tai Chi Tai Ji Yoga	Skills Training in Affect and Interpersonal Regulation (STAIR) Stress Inoculation Training (SIT) Supportive Counseling Trauma Management Therapy Written Emotional Disclosure Written Exposure Therapy Written Narrative Exposure	

MAOI = monoamine oxidase inhibitor; MDMA = 3,4-methylenedioxy-methamphetamine; SNRI = serotonin and norepinephrine reuptake inhibitor; SSRI = selective serotonin reuptake inhibitor; TCA = tricyclic antidepressant; Table 2 intervention lists and categories adapted from the 2017 Department of Veterans Affairs/Department of Defense clinical practice guideline[96]

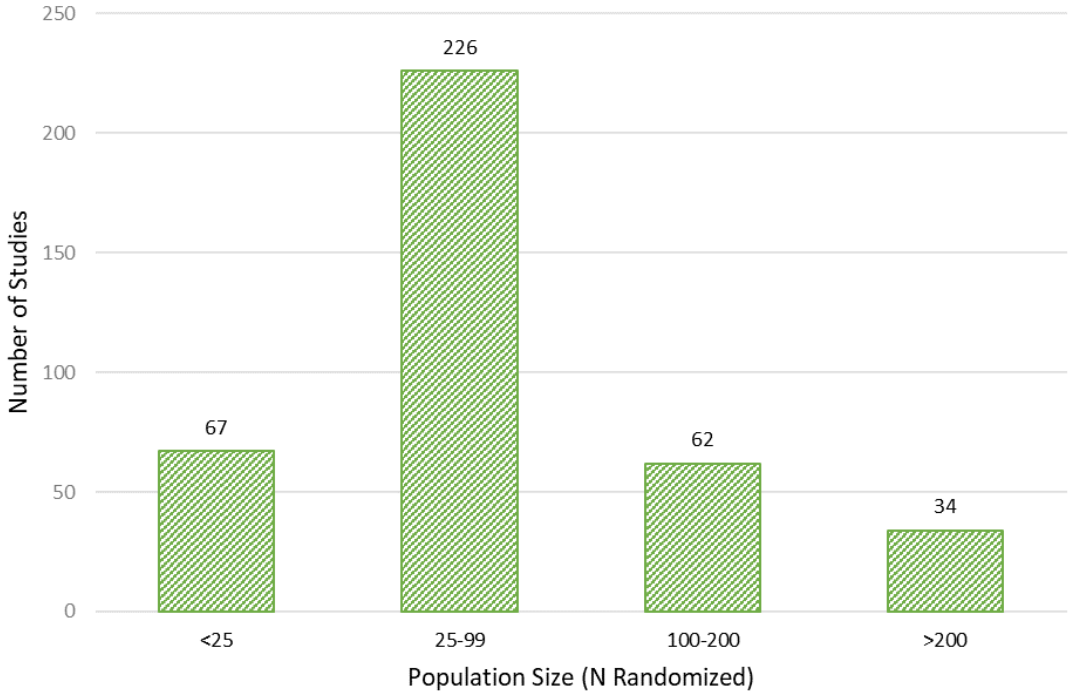
Figure 4. Distribution of treatment arms by VA/DoD CPG intervention category[a]



[a] Studies may have more than one treatment arm
CPG = clinical practice guideline; DoD = Department of Defense; VA = Department of Veterans Affairs; "Mixed": refers to multicomponent studies which include two or more intervention categories in the tested intervention (e.g., sertraline plus prolonged exposure, or yoga plus cognitive processing therapy would be called "mixed" interventions).

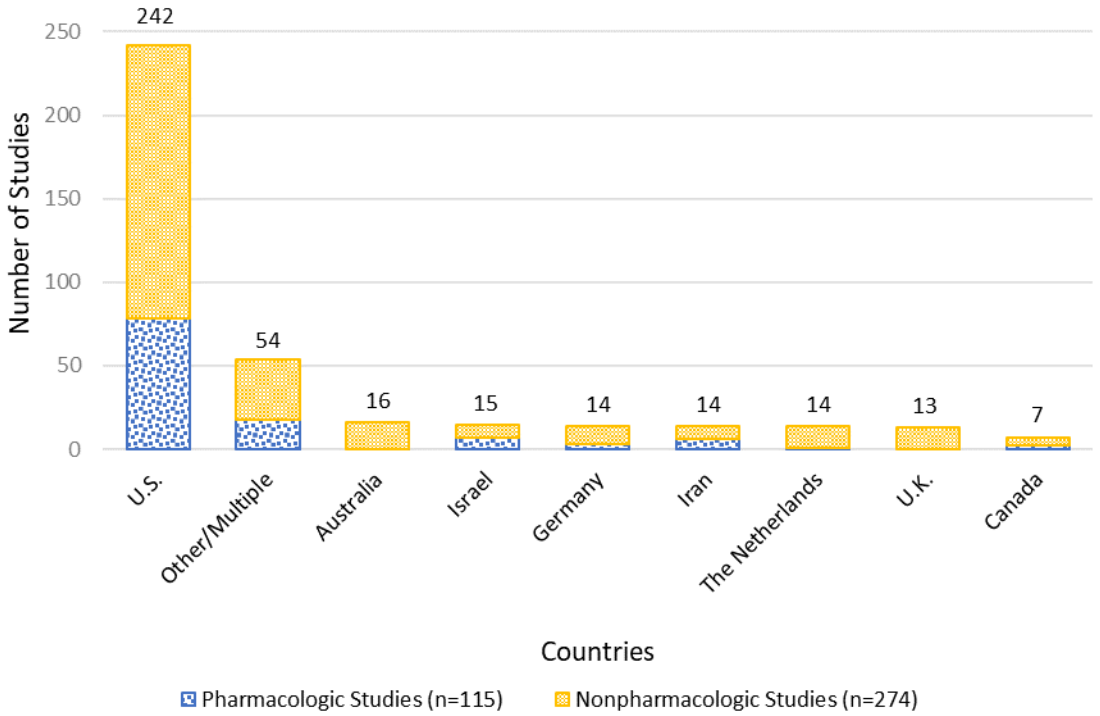
Figure 5 shows the distribution of included studies by sample sizes. The majority of studies (60%) had sample sizes in the range of 25 to 99 participants and a relatively small number of studies enrolled fewer than 25 participants (18%).

Figure 5. Studies by sample size



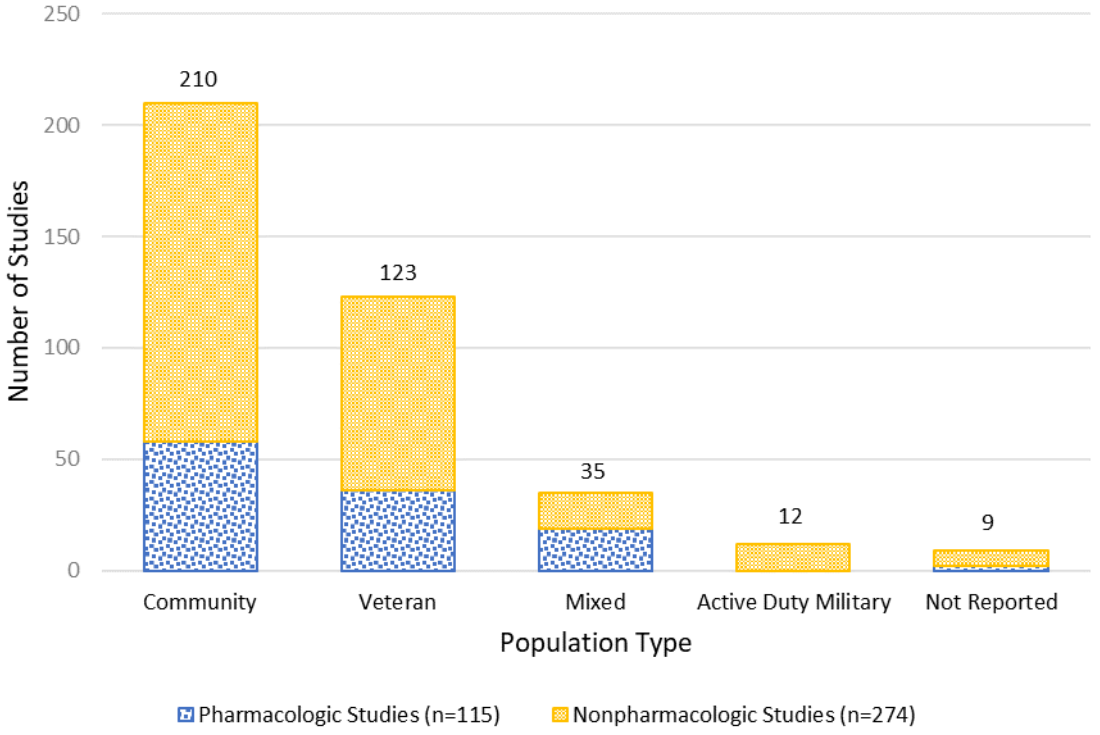
Figures 6 through 8 characterize studies by setting, including country, population type, and clinical setting where the intervention was delivered. The majority of included studies were conducted in the United States (62%), and more participants were enrolled from a community population (55%) than a military, veteran, or other population for both pharmacologic and nonpharmacologic RCTs. The majority of studies were conducted in the outpatient setting (72%).

Figure 6. Distribution of included studies by country



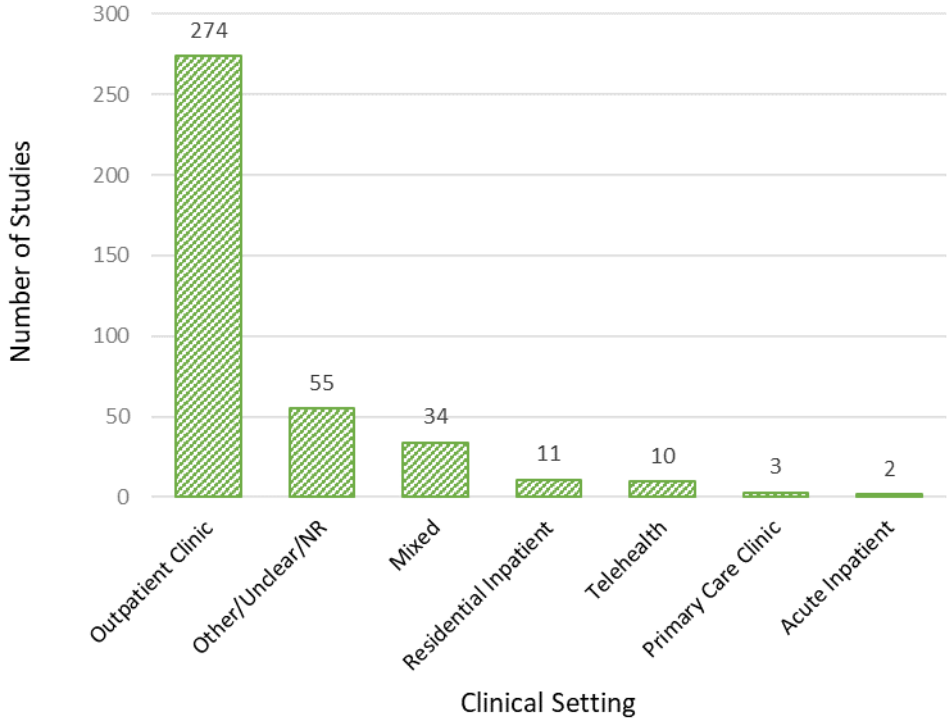
Multiple = study conducted in multiple countries. Note: countries with fewer than two studies were excluded from this graph to conserve space, the corresponding studies are counted in "Other/Multiple".

Figure 7. Distribution of included studies by population type



Mixed = Any combination of Active Duty Military, Veteran, and Community based samples. Note: Community samples may or may not include Active Duty Military or Veteran participants as many studies did not clarify these variables when describing community samples.

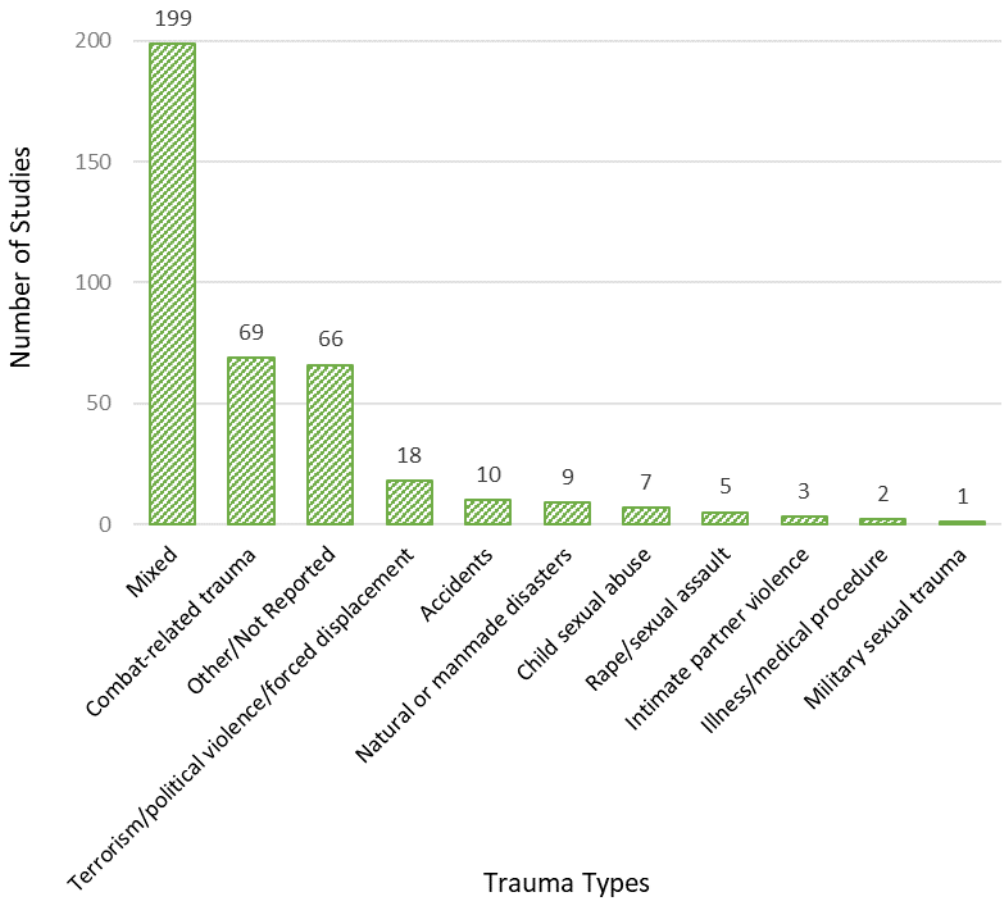
Figure 8. Distribution of included studies by clinical setting



Mixed = Any combination of two or more setting categories (e.g., a study in which one intervention was delivered in an outpatient clinic and one intervention was delivered by telehealth would be categorized as "Mixed"); NR = not reported. Note: Outpatient clinics include a wide range of clinics (e.g., VA clinics, community mental health clinics, University counseling centers). Due to the wide range of terms used to describe these clinics across included studies, they were grouped into the more general, though very diverse, category of "outpatient clinic" for this figure.

Some studies targeted specific types of trauma (e.g., required participants to have experienced combat-related trauma or sexual assault), though in most cases other additional trauma types were allowed. Most studies did not target specific types of trauma and included participants with a mix of trauma types. The distribution of included studies by trauma type are shown in Figure 9, with "mixed" trauma types being most prevalent among these study populations (53%), followed by combat-related trauma (18%).

Figure 9. Distribution of included studies by trauma type



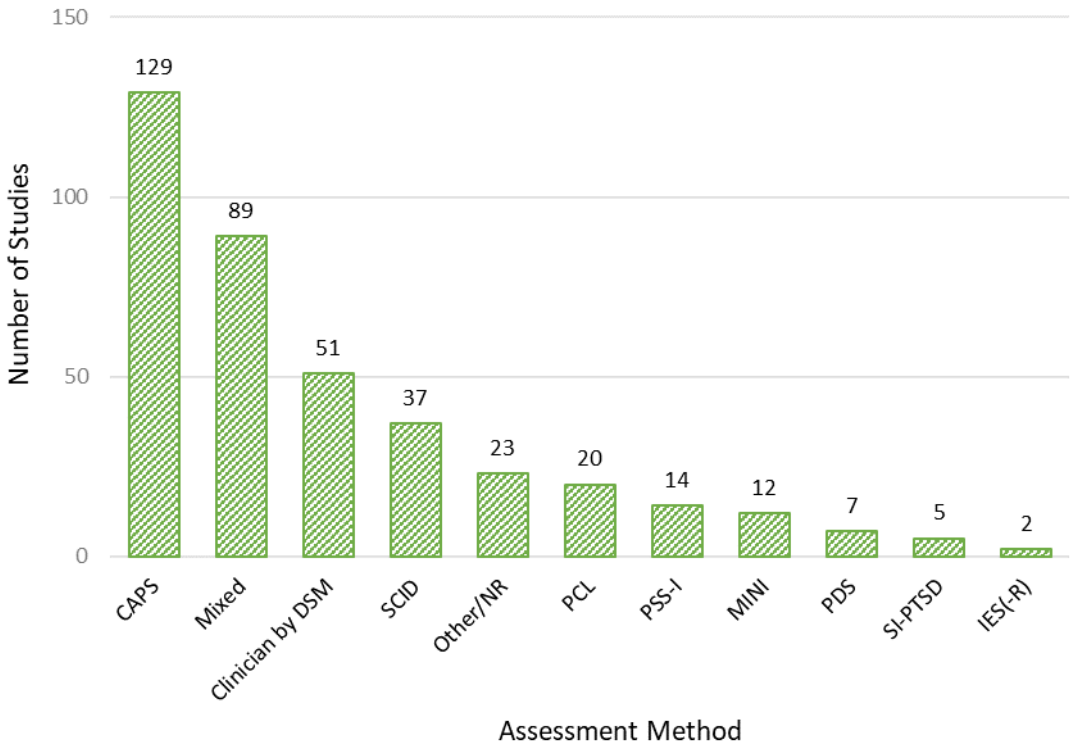
Mixed = multiple trauma types were targeted/included (e.g., a study which included participants with either child sexual abuse or rape/sexual assault would be classified as "Mixed")

Numerous instruments, whether administered by clinicians or self-reported by patients, were used to diagnose PTSD and assess participants' eligibility for study entry. Figure 10 shows the most commonly used PTSD assessment methods found in the 389 RCTs, with the Clinician-Administered PTSD Scale (CAPS), the Structured Clinical Interview for DSM (SCID), and clinician-assessed Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria being the most commonly used assessment methods. In some instances, the instrument used to diagnose PTSD differed from the instrument used to assess the PTSD outcome throughout the treatment and/or at followup (e.g., CAPS may have been used to determine PTSD diagnosis and eligibility, but only the PTSD checklist [PCL] was used to track symptom severity changes longitudinally in some studies).

It is important to note, however, that this Figure 10 only displays the primary outcome measure abstracted into the PTSD-Repository. Determining which outcomes were primary PTSD outcomes and which were secondary was often challenging in the included studies, particularly in those that reported many outcomes. In some instances, studies analyzed a primary outcome other than PTSD (e.g., depression, anxiety, or sleep outcomes). However, provided that a study analyzed and reported an overall PTSD outcome, the study was included in the evidence tables. If more than one PTSD assessment was included, we used a standardized approach to classify the

PTSD outcomes as primary or secondary, prioritizing clinician administered, validated measures as primary outcomes. Therefore, Figure 10 should be interpreted with caution because the procedures prioritized certain measures, which are therefore more commonly represented in the figure even if the study also included other measures.

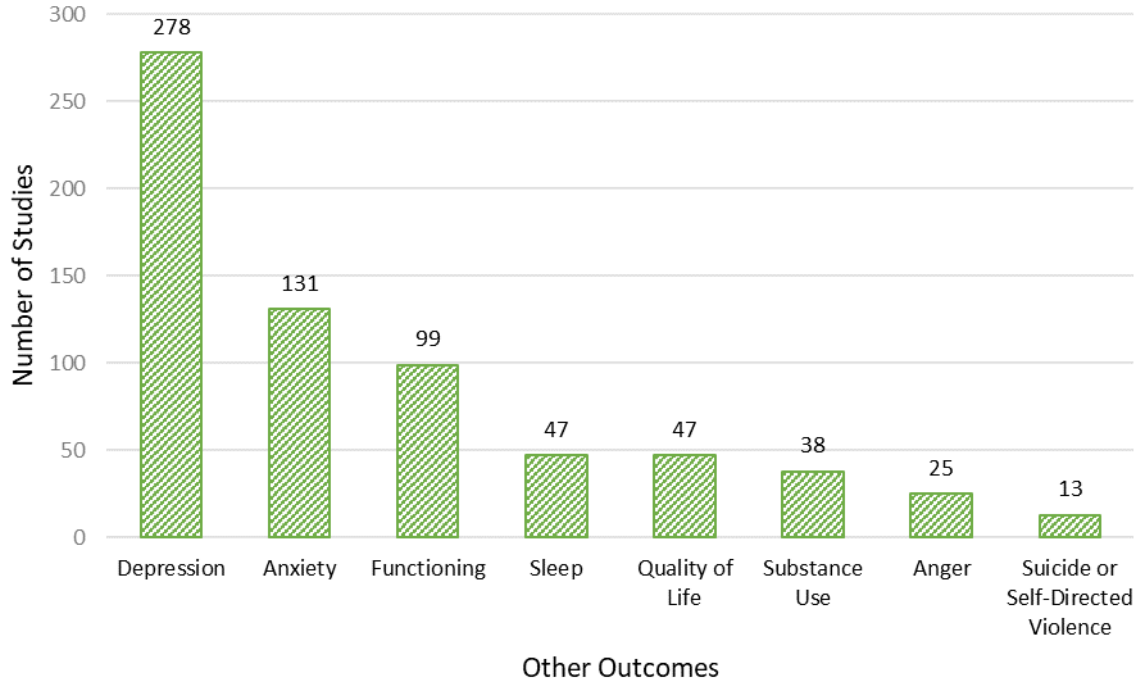
Figure 10. Distribution of included studies by PTSD assessment method



CAPS = Clinician-Administered PTSD Scale; IES(-R) = Impact of Event Scale (-Revised); MINI = Mini-International Neuropsychiatric Interview; NR = not reported; PCL = PTSD Checklist; PDS = Posttraumatic Diagnostic Scale; PSS-I = PTSD Symptom Scale - Interview; PTSD = posttraumatic stress disorder; SI-PTSD = Structured Interview for PTSD; SCID = Structured Clinical Interview for DSM; clinician by DSM = diagnosis according to medical classifications of the Diagnostic and Statistical Manual of Mental Disorders (DSM).
NOTE: Other category includes all other assessment instruments such as the Composite International Diagnostic Interview (CIDI) and the Primary Care PTSD Screen (PC-PTSD), and diagnosis according to medical classifications such the International Statistical Classification of Diseases and Related Health Problems (ICD); Mixed = study used multiple assessment instruments in combination. Assessment instruments reported less than two times were excluded from this graph to conserve space.

Most studies (71%) reported depression outcomes as well as change in PTSD symptoms. Other outcomes often associated with PTSD were less frequently reported across the trials. Figure 11 summarizes rates of reporting for these outcomes including depression, anxiety, functioning, quality of life, sleep, substance use, anger, and suicide-related outcomes.

Figure 11. Other outcomes reported in included studies



Studies did not consistently report all data elements that were intended to be abstracted for this PTSD-Repository. Table 3 displays the prevalence of unreported data elements across pharmacologic and nonpharmacologic studies. These particular data elements were selected, with guidance from the Content TEP and NCPTSD, for their relevance to current research and clinical practice. As seen in Table 3, data are generally unreported equally in both pharmacologic and nonpharmacologic studies with a few exceptions. Nonpharmacologic studies were more likely to report whether psychotherapy cointervention was allowed (39% vs. 57% unreported), number of traumatic events experienced per participant (80% vs. 92% unreported), within-group effect size or p-value (42% vs. 77% unreported), and loss of PTSD diagnosis (59% vs. 83% unreported). Studies reported race and ethnicity data very inconsistently, making it difficult to abstract into preselected categories and compare in a standard manner across studies. These data are not presented in Table 3 with other lack of reporting data because many studies reported these data, though they were not able to be included in the PTSD-Repository because of different categories and metrics used across the studies. Table 3 presents the percentage of studies that *did not* report particular data elements, identifying potential research gaps; however, some elements (e.g., history of traumatic brain injury) might be more relevant for some types of trials than others (e.g., those focused on Veterans and members of the military).

Table 3. Lack of reporting by evidence category

Evidence Table Category	Data Element	Pharmacologic Studies Unreported Data Element, % (n/N)	Nonpharmacologic Studies Unreported Data Element, % (n/N)
Study Characteristics	Nonpharmacologic treatment provider education level	NA	30% (81/274)
	Allowed PTSD or other psychotherapy co-intervention?	57% (66/115)	39% (107/274)
	PTSD assessment method threshold	17% (19/115)	41% (111/274)
Population Characteristics	Duration of PTSD symptoms	56% (64/115)	65% (178/274)
	Comorbid traumatic brain injury	88% (101/115)	87% (239/274)
	Comorbid substance use disorder	17% (19/115)	42% (115/274)
	Number trauma types per participant	98% (113/115)	94% (258/274)
	Number of traumatic events per participant	92% (106/115)	80% (218/274)
Intervention Characteristics	Definition of treatment completion or adherence	71% (82/115)	54% (149/274)
	Pharmacologic intervention treatment adherence or completion	73% (84/115)	NA
PTSD Outcomes	Within-group effect size or p-value	77% (89/115)	42% (114/274)
	Score difference from baseline between groups	83% (96/115)	80% (218/274)
	Loss of PTSD diagnosis	83% (95/115)	59% (162/274)
	Clinically meaningful response/remission for PTSD	45% (52/115)	63% (172/274)

NA = not applicable; PTSD = posttraumatic stress disorder. Variables were abstracted based on how they were defined and reported in published studies.

Risk of Bias Assessment

Risk of bias (ROB) assessment was conducted for all included studies following the framework established in a prior review of PTSD interventions, CER No. 207,[5] as described above in Methods. The ROB assessment tool used for the PTSD-Repository and ROB ratings from CER No. 207 are compiled with our ROB assessment in Appendix F; a summary is presented in Table 4. Overall, 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 5). In addition, over half of the studies rated as high ROB did not conduct intent to treat analyses (57%), reported over 20% overall attrition (54%), and lacked provider and patient masking (74% and 71% respectively). Proportions of studies rated for each category were comparable between pharmacologic and nonpharmacologic studies.

Table 4. Risk of bias summary ratings for studies included in the PTSD-Repository

ROB	Pharmacologic Studies	Nonpharmacologic Studies	Total
Low ROB	5% (6/116)	6% (16/273)	6% (22/389)
Medium ROB	61% (71/116)	60% (164/273)	60% (235/389)
High ROB	33% (39/116)	34% (93/273)	34% (132/389)

ROB = risk of bias

Table 5. Studies assessed as having high risk of bias (n=139)

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%

ITT = intent-to-treat

Since the release of CONSORT (Consolidated Standards of Reporting Trials) guidelines in 2001,[97] reporting of ROB elements in RCTs has generally improved. This trend was also seen in the RCTs included in the PTSD-Repository (Table 6). When comparing studies published before versus after these guidelines were released in 2001, the two ROB elements for which reporting improved the most were adequate randomization (13% before versus 45% after) and allocation concealment (6% vs. 39%). Studies published in 2001 or later also more frequently reported intent-to-treat (ITT) analyses (66% vs. 28%). Reporting of prognostic factors that allow reviewers to determine whether groups were similar at baseline (i.e., a measure of adequate randomization) also improved in studies published in 2001 or later, with unclear reporting decreasing from 44% to 21%. Reporting of overall attrition from a study also improved: 16% of studies were unclear before 2001 versus 5% in later studies. A similar trend was seen in differential attrition (22% unclear or no reporting of differential attrition prior to 2001 compared to only 8% in later years). As a result of improved reporting of these ROB elements, fewer studies published in 2001 or later were rated as having high ROB. However, fewer older studies met all inclusion criteria for the PTSD-Repository (n=23 studies), compared with more recent studies (n=357). An example of reasons for not being included is that older studies were less likely to report the percent of participants who met full criteria for PTSD. Table 6 summarizes these findings.

Table 6. Risk of bias assessment for pre-2001 studies vs studies 2001 and later

Domain	Criterion	≤2000 (n=32) Yes	≤2000 (n=32) No	≤2000 (n=32) Unclear	≥2001 (n=357) Yes	≥2001 (n=357) No	≥2001 (n=357) Unclear
Selection Bias	Randomization Adequate?	13%	3%	84%	45%	3%	52%
	Allocation Concealment Adequate?	6%	3%	91%	39%	3%	59%
	Groups Similar at Baseline?	22%	34%	44%	57%	23%	21%
	ITT?	28%	59%	13%	66%	30%	4%
Performance Bias	Care Provider Masked?	6%	66%	28%	18%	71%	10%
	Patient Masked?	28%	66%	6%	25%	68%	7%
Detection Bias	Outcome Assessor Masked?	31%	25%	44%	60%	14%	26%
Attrition	Overall Attrition <20%?	50%	34%	16%	46%	49%	5%
	Differential Attrition <15%?	56%	22%	22%	67%	25%	8%
Overall ROB Rating		Low 0%	Medium 41%	High 59%	Low 6%	Medium 62%	High 32%

ITT = intent-to-treat; ROB = risk of bias

Exploration of an Expanded Risk of Bias System

In addition to conducting ROB assessments in accordance with AHRQ methods used in a previous systematic review of PTSD interventions, CER No. 207,[5] for all included studies in the PTSD-Repository, the NCPTSD sponsor requested exploration of an expanded ROB system to address concerns about transparency, reproducibility, and sensitivity of ROB assessment. They noted that most studies fall into the middle (i.e., medium ROB) final category, and were concerned that final ratings were potentially inconsistently applied across raters due to lack of transparency and clarity in assessment methods. A discussion of these issues was conducted with the ROB Technical Expert Panel (TEP), the Evidence-based Practice Center, and members of the sponsor organization (NCPTSD).

During this discussion, expansion of numerous ROB elements were deliberated for possible exploration in a pilot test of 10 RCTs. These included: 1) assessment of methods for accounting for missing data due to dropout from treatment versus loss to followup for individual outcome measurement, 2) how missing data were addressed statistically and how those methods may mitigate some ROB due to missing data depending on the amount and randomness of the missing data, 3) differential assessment of blinding of participants and outcome assessors for subjective and objective outcomes, and 4) consideration of a 5-category overall ROB rating system with more specific, transparent criteria applied to each category, including criteria related to how to consider interactions among the individual ROB elements.

Discussion of each ROB element proposed for possible further exploration focused on strengths and weaknesses of current versus proposed methods, in the context of the assessment tool used for ROB for this report. Additionally, the group discussed how refining the ROB assessment tool could impact clarity, transparency, replicability, and distribution of studies in final rating categories. The ROB TEP and NCPTSD sponsor discussed pros and cons to each approach (e.g., improved granularity or concerns about the potential for false sensitivity and reproducibility of additional categories).

The ROB TEP call discussion also focused on ways that ROB elements and domains interact, how these interactions should be considered in determining the final ROB rating, and how the ROB assessment tool could be revised to provide more clarity on these procedures for ROB assessors. For example, the ROB TEP discussed ways that subjective, self-reported outcomes were more prone to increased ROB from lack of participant masking than objective outcomes such as a laboratory test. Similarly, the group discussed how attrition from measurement could sometimes be somewhat mitigated by advanced statistical methods for handling such missing data (e.g., through multiple imputation rather than using last observation carried forward methods). The group discussed using a nuanced approach as part of the exploratory pilot testing of expanded ROB elements, considering the interactions of domains and specifically the items noted above to determine overall ratings.

Overall, the consultation with the ROB TEP and NCPTSD sponsor resulted in adding more granular abstraction instructions and clarification about how to abstract and assess ROB-related data elements, including how they affect the final ratings. The consultation guided the development of an expanded ROB assessment tool that was pilot tested on 10 PTSD-Repository studies selected for their complexity and diversity in study design elements, populations, and interventions. A full reporting of the ROB discussion and guidance provided by the ROB TEP and NCPTSD is included in Appendix G, including tables summarizing augmented ROB elements, rating methods considered, and the complete pilot ratings for each of the 10 studies for both raters as well as original ROB ratings. Additional ROB assessment using the expanded

ROB assessment system is planned for PTSD-Repository studies which will enable more robust comparisons of the impact of changes to ROB assessment across a broad, diverse group of RCTs.

Discussion

Summary and Implications

The data abstracted from 389 randomized controlled trials (RCTs) of treatments for posttraumatic stress disorder (PTSD) and comorbid PTSD/substance use disorder (SUD) are being used by National Center for PTSD (NCPTSD) to update the data set for 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). This report updates the studies and variables included in the PTSD-Repository to include recently published trials (47 RCTs), interventions targeting comorbid PTSD and SUDs (21 RCTs), variables related to comorbidities such as suicidal ideation/behavior and SUDs for the previously included 318 RCTs, and risk of bias assessment. A total of 389 RCTs are now included in the PTSD-Repository with detailed data abstracted and risk of bias assessment.

The PTSD-Repository (https://www.ptsd.va.gov/ptsdrepository/index.asp) 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?"

The PTSD-Repository evidence tables and Web-based, interactive database 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, 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 parsimonious 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[98] and depression[99,100] have served these and other purposes and have been used as the basis for numerous publications and grant efforts.

This work developing and updating the PTSD-Repository 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 an annual update, how to maintain data accuracy and relevance in large evidence tables, how to refine risk of bias assessment methods, and potential next steps for the PTSD-Repository. The TEPs and NCPTSD recommended annual updates in order to keep the PTSD-Repository updated with the most current trial data, but also to ensure that there was 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.

The 389 included studies identified for this report were published from 1988 through May 22, 2020 (the search date started in 1980, though no studies met inclusion criteria until 1988). Some changes in the field of PTSD research over time are reflected in the PTSD-Repository. For example, earlier studies rely on older diagnostic criteria and assessment tools. Newer studies are more likely to report and use more advanced and robust study designs and statistical methods. Research on PTSD interventions greatly increased during the last decade, which is not surprising given the early research on the Operation Enduring Freedom and Operation Iraqi Freedom

conflicts published in 2008, and that these conflicts resulted in a high prevalence of PTSD among deployed service members.[101] Heightened awareness of PTSD prevalence and its negative impacts on quality of life and functioning likely spurred interest in research to develop and assess effective interventions to treat the disorder, and associated funding increases by the Department of Defense also likely increased the amount of research conducted on PTSD during this timeframe.

The PTSD-Repository evidence table (Appendix E) for this report is extensive and 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. In this update and expansion of the preliminary evidence tables that serve as the basis for the PTSD-Repository, we added newly published studies of PTSD interventions, studies targeting comorbid PTSD and SUDs, and variables related to comorbidities such as suicidal ideation/behavior and SUDs. We also conducted risk of bias assessment of all included studies consistent with a prior, largescale systematic reviews of PTSD treatments (AHRQ Comparative Effectiveness Review No. 207),[5] and developed abstraction criteria for new risk of bias data elements to address sponsor concerns about the limitations of existing risk of bias assessment, which will be pilot tested on a small group of studies.

Variations in study designs and approaches to reporting presented many challenges to the data abstraction process. For example, some studies reported difference in change from baseline between groups, while others reported only within-group change from baseline or endpoint difference between groups. Determining which outcomes were primary PTSD outcomes and which were secondary was difficult in some studies, particularly those that report many outcomes. 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 (i.e., 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). Lastly, gaps in reporting of certain data elements meant that some study abstractions may seem incomplete because, while no evidence table cells were left empty, there are many cells that say only "not reported" (NR). Recognition of these gaps may help future researchers to report study methods and results more comprehensively.

Similarly, inconsistent reporting presented challenges to the risk of bias (ROB) assessment process. As described in greater detail in Appendix F, reporting of ROB elements was inconsistent for studies published earlier. After publication of the Consolidated Standards of Reporting Trials (CONSORT) criteria establishing good practices in reporting on RCTs in 2001,[97] reporting of ROB elements generally improved. In addition to

improved reporting of ROB elements, studies were more often rated as having lower ROB for elements under the control of the researchers (e.g., aspects of study design such as randomization and allocation concealment). While ROB elements that are less able to be controlled by research teams were reported more often in more recent publications, some of these aspects of study design are difficult to change. Attrition is an example of an element that the researcher does not have full control over. Another example is that although blinding of outcome assessors is expected, blinding of participants in behavioral trials is difficult to address. ROB ratings for these elements were similar pre- and post-2001.

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. Additionally, ROB assessment was completed not only by different investigators for this project, but also included from a prior systematic review. This leads to the possibility that systematic differences between raters or by research groups might be reflected in the ratings.

Next Steps

The completion of this project signifies the end of the first annual update and expansion of the PTSD-Repository dataset. The NCPTSD created and recently released the Web-based, searchable, interactive PTSD-Repository database (https://www.ptsd.va.gov/ptsdrepository/index.asp), and the current project updates and expands the evidence table that serves as the foundation for that work. Future updates will take into account this interactive Web resource and ensure that the PTSD-Repository data tables developed by the Evidence-based Practice Center are able to be more seamlessly integrated with the Web-based PTSD-Repository databases. This work will likely involve reformatting data abstraction tables and procedures to correspond more closely with the data structures required for Web integration. It will also likely include additional adjustments to how variables are coded to further separate and clarify individual quantitative and qualitative variables to ensure standardization and accuracy across studies in spite of differences in how data is reported in the trials.

In addition to annual updates of newly published RCTs, future additions to the PTSD-Repository have been explored and recommended by the Content TEP. These future additions could include reporting and calculating standardized effect sizes to facilitate cross-study comparisons of results, 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 and quantitative synthesis of key outcome data, and expanded ROB assessment to compare ROB assessment methods. We base these suggestions on our interaction with the evidence base, the Content and ROB TEPs, and NCPTSD, the sponsoring partner with the Agency for Healthcare Research and Quality for this project. We consulted with the sponsors weekly throughout this project to ensure compatibility with NCPTSD's goals for the PTSD-Repository and to refine and improve our methods as the evidence tables were being developed, expanded, and integrated into a searchable, Web-based format. Additionally, we consulted with both the sponsors and with the Content TEP early in the project to determine the appropriate level of granularity of data for abstraction and appropriate methods to abstract complex data elements reported differently

across studies. This process ensured comprehensiveness of data abstraction balanced with feasibility of data presentation and interpretation.

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 and adding new variables. 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[10] or the online PTSD Treatment Decision Aid.[11] 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. The Content and ROB TEP comments compiled during the initial and continuation stages of this project provide a guide for future work in developing the evidence content of the PTSD-Repository. Our experience with the included studies and overall body of PTSD trial literature suggests that the evidence base is available to support these next steps.

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Abbreviations and Acronyms

Acronym or Abbreviation	Definition
AHRQ	Agency for Healthcare Research and Quality
CAPS	Clinician-Administered PTSD Scale
CER	Comparative Effectiveness Review
CIDI	Composite International Diagnostic Interview
CPG	clinical practice guideline
DoD	Department of Defense
DSM	Diagnostic and Statistical Manual of Mental Disorders
EPC	evidence-based practice center
ICD	International Statistical Classification of Diseases and Related Health Problems
IES	Impact of Event Scale
ITT	intent-to-treat
KQ	Key Question
MAOI	monoamine oxidase inhibitor
MDMA	3,4-methylenedioxy-methamphetamine
MINI	Mini-International Neuropsychiatric Interview
NA	not applicable
NCPTSD	National Center for Posttraumatic Stress Disorder
NR	not reported
PC-PTSD	Primary Care PTSD Screen
PCL	PTSD Checklist
PDS	Posttraumatic Diagnostic Scale
PICOTS	Population, Intervention, Comparator, Outcomes, Timing, Setting, and Study design
PSS-I	PTSD Symptom Scale-Interview
PTSD	posttraumatic stress disorder
ROB	risk of bias
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
SUD	substance use disorder
TEP	Technical Expert Panel
TCA	tricyclic antidepressant
VA	U.S. Department of Veterans Affairs

Appendix A. Literature Search Strategies

Database: Ovid MEDLINE®, Ovid MEDLINE® In-Process & Other Nonindexed 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)

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)

Database: PTSDpubs)

(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

Pharmacologic interventions
1 exp posttraumatic stress disorder/
2 ("post traumatic stress disorder" or "posttraumatic stress disorder" or PTSD).ti,ab.
3 exp drug therapy/
4 exp drugs/
5 ("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.
6 ("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.
7 (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.
8 (("monoamine oxidase" adj2 inhibitor*) or MAOI or isocarboxazid or phenelzine or selegiline or tranylcypromine).ti,ab.
9 (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.
10 ("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.
11 (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.

12 (amphetamine or armodafanil or atomoxetine or dexmethylphenidate or dextroamphetamine or lisdexamphetamine or MDMA or methamphetamine or methylphenidate or modafanil).ti,ab.
13 (DHEA or hydrocortisone or steroid*).ti,ab.
14 (cannabi* or marijuana or tetrahydrocannabinol or THC).ti,ab.
15 (ketamine or propranolol).ti,ab.
16 (1 or 2) and (or/3-15)
17 treatment effectiveness evaluation/
18 Treatment Outcomes/
19 followup studies/
20 (random* or control* or trial or sham or placebo* or blind* or dumm* or mask*).ti,ab.
21 16 and (or/17-20)
22 limit 21 to english language
23 limit 22 to human

Nonpharmacologic interventions
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

Database: EBM Reviews - Cochrane Central Register of Controlled Trials

1 Stress Disorders, Post-Traumatic/dt, pc, rh, th
2 ("posttraumatic stress disorder" or "post traumatic stress disorder").mp. or "ptsd".ti,ab.
3 2 and (dt or pc or rh or th).fs.
4 1 or 3
5 limit 4 to medline records

6 4 not 5

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

1. Acarturk C, Konuk E, Cetinkaya M, et al. The efficacy of Eye Movement Desensitization and Reprocessing for post-traumatic stress disorder and depression among Syrian refugees: results of a randomized controlled trial. Psychol Med. 2016 Sep;46(12):2583-93. doi: 10.1017/S0033291716001070. PMID: 27353367.
2. Acierno RE, Knapp RG, Tuerk PW, et al. A non-inferiority trial of prolonged exposure for posttraumatic stress disorder: in person versus home-based telehealth. Behav Res Ther. 2017 Feb;89:57-65. doi: 10.1016/j.brat.2016.11.009. PMID: 27894058.
3. Adenauer H, Catani C, Gola H, et al. Narrative exposure therapy for PTSD increases top-down processing of aversive stimuli -- evidence from a randomized controlled treatment trial. BMC Neuroscience. 2011 Dec 19;12:127. doi: 10.1186/1471-2202-12-127. PMID: 22182346.
4. Aderka IM, Gillihan SJ, McLean CP, et al. The relationship between posttraumatic and depressive symptoms during prolonged exposure with and without cognitive restructuring for the treatment of posttraumatic stress disorder. J Consult Clin Psychol. 2013 Jun;81(3):375-82. doi: 10.1037/a0031523. PMID: 23339538.
5. Ahmadi K, Hazrati M, Ahmadizadeh MJ, et al. REM desensitization as a new therapeutic method for post-traumatic stress disorder: a randomized controlled trial. Acta Med Indones. 2015 Apr;47(2):111-9. PMID: 26260553.
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7. Ahmadizadeh MJ, Rezaei M, Fitzgerald PB. Transcranial direct current stimulation (tDCS) for post-traumatic stress disorder (PTSD): a randomized, double-blinded, controlled trial. Brain Res Bull. 2019;153:273-8. doi: 10.1016/j.brainresbull.2019.09.011 PMID: 31560945.
8. Ahmadpanah M, Sabzeiee P, Hosseini SM, et al. Comparing the effect of prazosin and hydroxyzine on sleep quality in patients suffering from posttraumatic stress disorder. Neuropsychobiology. 2014 Jul;69(4):235-42. doi: 10.1159/000362243. PMID: 24993832.
9. Akbarian F, Bajoghli H, Haghighi M, et al. The effectiveness of cognitive behavioral therapy with respect to psychological symptoms and recovering autobiographical memory in patients suffering from post-traumatic stress disorder. Neuropsychiatr Dis Treat. 2015;11:395-404. doi: 10.2147/NDT.S79581. PMID: 25737635.
10. Akuchekian S, Amanat S. The comparison of topiramate and placebo in the treatment of posttraumatic stress disorder: a randomized, double-blind study. J Res Med Sci. 2004;9(5):240-4.
11. Aldahadha B, Al-Harthy H, Sulaiman S. The efficacy of Eye Movement Desensitization and Reprocessing in resolving the trauma caused by the road accidents in the Sultanate of Oman. Journal of Instructional Psychology. 2012;39(3/4):146-58.
12. Alghamdi M, Hunt NC, Thomas SA. The effectiveness of narrative exposure therapy with traumatised firefighters in Saudi Arabia: a randomized controlled study. Behav Res Ther. 2015 Mar;66:64-71. doi: 10.1016/j.brat.2015.01.008. PMID: 25701801.
13. Anderson ML, Najavits LM. Does seeking safety reduce PTSD symptoms in women receiving physical disability compensation? Rehabil Psychol. 2014 Aug;59(3):349-53. doi: 10.1037/a0036869. PMID: 24978844.

14. Ardani AR, Hosseini G, Bordbar MRF, et al. Effect of rivastigmine augmentation in treatment of male patients with combat-related chronic posttraumatic stress disorder: a randomized controlled trial. J Clin Psychopharmacol. 2017 Feb;37(1):54-60. doi: 10.1097/jcp.0000000000000624. PMID: 27930500.

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Appendix C. List of Excluded Studies

Table C-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

1. A randomised controlled trial of cognitive-behavioural therapy for the treatment of PTSD in the context of chronic whiplash. SportEX Medicine. 2013 Jan(55):6. Exclusion: 9.
2. Acarturk C, Konuk E, Cetinkaya M, et al. EMDR for Syrian refugees with posttraumatic stress disorder symptoms: results of a pilot randomized controlled trial. Eur J Psychotraumatol. 2015 May 18;6(1):27414. doi: 10.3402/ejpt.v6.27414. PMID: 25989952. Exclusion: 3.
3. Acierno RE, Gros DF, Ruggiero KJ, et al. Behavioral activation and therapeutic exposure for posttraumatic stress disorder: a noninferiority trial of treatment delivered in person versus home-based telehealth. Depress Anxiety. 2016 May;33(5):415-23. doi: 10.1002/da.22476. PMID: 26864655. Exclusion: 3.
4. Acosta MC, Possemato KA, Maisto SA, et al. Web-delivered CBT reduces heavy drinking in OEF-OIF veterans in primary care with symptomatic substance use and PTSD. Behav Ther. 2017 2017-03-24;48(2):262-76. doi: 10.1016/j.beth.2016.09.001. PMID: 28270335. Exclusion: 3.
5. Agopian TN, Abrams G, Kornblith E. Executive function training in veterans with PTSD and mild TBI. Brain Injury. 2017;31(6-7):830. doi: 10.1080/02699052.2017.1312145. PMID: 28678627. Exclusion: 9.
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10. Alderman CP, McCarthy LC, Condon JT, et al. Topiramate in combat-related posttraumatic stress disorder. Ann Pharmacother. 2009 Apr;43(4):635-41. doi: 10.1345/aph.1L578. PMID: 19336652. Exclusion: 8.

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12. Alkozei A, Smith R, Fridman A, et al. Neural responses to emotional stimuli in individuals with PTSD after daily morning blue light exposure. Biol Psychiatry. 2017;81(10):S400. Exclusion: 9.

13. Allan NP, López-Castro T, Hien DA, et al. Response-to-Treatment for Comorbid Post-Traumatic Stress and Substance Use Disorders: the Value of Combining Person- and Variable-Centered Approaches. Journal of Psychopathology and Behavioral Assessment. 2020 doi: 10.1007/s10862-020-09803-w. Exclusion: 8.

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41. Barilla H, Gehrman P, Phelps E, et al. Efficacy of cognitive behavioral therapy for insomnia on nightmares in veterans with PTSD. Journal of sleep research. 2018;27(104). Exclusion: 9.

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51. Bedard-Gilligan MA, Duax Jacob JM, Doane LS, et al. An investigation of depression, trauma history, and symptom severity in individuals enrolled in a treatment trial for chronic PTSD. J Clin Psychol. 2015 Jul;71(7):725-40. doi: 10.1002/jclp.22163. PMID: 25900026. Exclusion: 6.

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53. Beetz A, Schofmann I, Girgensohn R, et al. Positive Effects of a Short-Term Dog-Assisted Intervention for Soldiers With Post-traumatic Stress Disorder-A Pilot Study. Frontiers in Veterinary Science. 2019;6:170. doi: 10.3389/fvets.2019.00170. PMID: 31231664. Exclusion: 8.

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55. Beidel DC, Frueh BC, Neer SM, et al. The efficacy of Trauma Management Therapy: a controlled pilot investigation of a three-week intensive outpatient program for combat-related PTSD. J Anxiety Disord. 2017 Aug;50:23-32. doi: 10.1016/j.janxdis.2017.05.001. PMID: 28545005. Exclusion: 5.

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60. Bergen-Cico D, Possemato K, Pigeon W. Reductions in cortisol associated with primary care brief mindfulness program for veterans with PTSD. Med Care. 2014 Dec;52(12, Suppl 5):S25-S31. doi: 10.1097/MLR.0000000000000224. PMID: 25397819. Exclusion: 6.

61. Bergen-Cico D, Smith Y, Wolford K, et al. Dog Ownership and Training Reduces Post-Traumatic Stress Symptoms and Increases Self-Compassion Among Veterans: Results of a Longitudinal Control Study. J Altern Complement Med. 2018 Sep 25;25:25. doi: 10.1089/acm.2018.0179. PMID: 30256652. Exclusion: 8.

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63. Biggs QM, Fullerton CS, McCarroll JE, et al. Early intervention for post-traumatic stress disorder, depression, and quality of life in mortuary affairs soldiers postdeployment. Mil Med. 2016;181(11/12):e1553-e60. doi: 10.7205/milmed-d-15-00579. PMID: 27849489. Exclusion: 3.

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65. Bisson J. Cognitive therapy improves post-traumatic stress disorder associated with civil conflict in Northern Ireland. Evidence Based Mental Health. 2008 Feb;11(1):25. doi: 10.1136/ebmh.11.1.25. PMID: 18223060. Exclusion: 9.

66. Bisson JI. Cognitive therapy reduces symptoms in people with recent onset post-traumatic stress disorder. Evidence Based Mental Health. 2004 May;7(2):51. doi: 10.1136/ebmh.7.2.51. PMID: 15107347. Exclusion: 9.

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Appendix D. Data Abstraction and Risk of Bias Elements

Data elements added to those abstracted for Technical Brief No. 32[1] are in bold below, and were abstracted for all studies, including the 318 RCTs included in Technical Brief No. 32.

Study Characteristics

a. Author
b. Year of publication
c. Bibliographic citation
d. PubMed ID
e. PTSDpubs (formerly PILOTS) ID number, if available
f. ClinicalTrials.gov identifier
g. Funding source
h. Country/Countries of study sites
i. Site Type (VA/DoD, non-VA/DoD, Mixed, MIL, Non-MIL)
j. Clinical setting
k. Study design
l. Indicate if subscale or symptom cluster data is reported (Y/N)
m. Indicate if subgroup analyses are reported (Y/N)
n. Indicate if psychotherapy providers have graduate degree (Y/N)
o. Indicate if treatment includes group therapy (Y/N)
p. Indicate if allowed PTSD psychotherapy, other psychotherapy, and psychotropic medication co-intervention (Y/N)
q. Diagnostic instrument(s)
r. Operational definition of PTSD (i.e., score or cutoff required for inclusion)
s. Suicide- and self-directed violence-related inclusion/exclusion criteria
t. Psychotic disorder- and symptom-related inclusion/exclusion criteria

Population Characteristics

a. Number of randomized participants
b. Proportion of participants meeting study-defined criteria for PTSD at baseline
c. Mean PTSD severity at baseline
d. Duration of PTSD symptoms
e. % Active duty military
f. % Veteran
g. % Community

[1] O'Neil M, McDonagh M, Hsu F, et al. Pharmacologic and Nonpharmacologic Treatments for Posttraumatic Stress Disorder: Groundwork for a Publicly Available Repository of Randomized Controlled Trial Data. Technical Brief No. 32. (Prepared by the Pacific Northwest Evidence-based Practice Center under Contract No. 290-2015-00009-I.) AHRQ Publication No. 19-EHC018-EF. Rockville, MD: Agency for Healthcare Research and Quality; May 2019. www.effectivehealthcare.ahrq.gov/reports/final.cfm. Posted final reports are located on the Effective Health Care Program search page: https://effectivehealthcare.ahrq.gov/. PMID: 31145565.

h. Mean age
i. % Female
j. Gender and sexual orientation, if reported
k. Race % (by U.S. Census categories)
l. Ethnicity (by U.S. Census categories)
m. % Treatment-naïve
n. % with depression
o. % with substance use disorder
p. % with history of traumatic brain injury
q. Indicate if patients with suicidality were excluded (Y/N)
r. Participants' trauma type(s)
s. Mean number of trauma types and traumatic events experienced per participant
t. % with suicidal ideation/intent/plan/attempt(s) or self-directed violence
u. % with psychotic disorder
v. % with personality disorder
w. % with anxiety disorder
x. % with prior inpatient hospitalization
y. % service connected Veterans

Interventions

a. Intervention classification (pharmacologic, psychotherapy, nonpharmacologic biological, complementary and integrative, mixed, control)
b. Treatment conditions (interventions)
c. Number of participants randomized to each study arm
d. Treatment dose and/or session length
e. Frequency of treatment
f. Duration of treatment
g. Definition of treatment completion and/or adherence
h. Proportion of participants who completed and/or adhered to treatment
i. Mean number of psychotherapy sessions completed or dose of pharmacotherapy
j. Intervention type (PTSD-only, SUD-only, PTSD+SUD, PTSD+other, Control)

Outcomes

a. Primary PTSD outcome measure
b. Method for handling missing data for primary PTSD outcome measure
c. Analysis type of primary PTSD outcome measure (ITT, completer)
d. Statistical analysis method for primary PTSD outcome
e. Assessment time point(s) for primary PTSD outcome
f. Number of participants who completed the primary PTSD outcome assessment
g. Results for primary PTSD outcome (measure score and within-group effect size)
h. Between-group effect size for primary PTSD outcome
i. Proportion of participants who achieved study-defined PTSD diagnostic change
j. Proportion of participants who achieved study-defined clinically meaningful change
k. Results for other PTSD outcome measure(s) for studies that used a clinician-administered measure abstracted as primary PTSD outcome measure
l. Between-group effect sizes for all reported depression outcomes

m. Between-group effect sizes for all reported anxiety outcomes
n. Between-group effect sizes for all reported sleep outcomes
o. Between-group effect sizes for all reported anger outcomes
p. Between-group effect sizes for all reported quality of life outcomes
q. Between-group effect sizes for all reported functioning outcomes
r. Results for all reported substance use outcomes
s. Results for all suicide- or self-directed violence-related outcomes
t. Harms outcomes (withdrawals due to adverse events, serious adverse events)

Risk of Bias Assessment Elements

a. Was randomization adequate?
b. Was allocation concealment adequate?
c. Were groups similar at baseline?
d. Were outcome assessors masked?
e. Were care providers masked?
f. Were patients masked?
g. Was overall attrition 20% or higher?
h. Was differential attrition 15% or higher?
i. Did the study use intention-to-treat analysis?
j. Did the study use adequate methods for handling missing data?
k. Were outcome measures equal, valid, and reliable?
l. Did study report adequate treatment fidelity (therapist adherence) based on measurement by independent raters?

Appendix E. Data Abstraction of New Included Studies Evidence Tables

The evidence tables are shown in the associated Excel® file:

- Table E-1. Study descriptions
- Table E-2. PTSD outcomes
- Table E-3. Other outcomes
- Table E-4. New characteristics
- Table E-5. New outcomes

Appendix F. Risk of Bias Assessment and Analysis of Studies Included in the PTSD-Repository

Risk of bias (ROB) assessment was conducted for all included studies following the framework established in Comparative Effectiveness Review (CER) No. 207,[1] which is based on the Agency for Healthcare Research and Quality (AHRQ) Methods Guide for Comparative Effectiveness Reviews[2] with an added question on whether authors reported all prespecified outcomes (assessing reporting bias). The ROB assessment is detailed in the associated Excel® file (Appendix Table F-1). A summary of the ROB ratings appears in Table F-2.

Table F-2. Risk of bias summary ratings for studies included in the PTSD-Repository

	Pharmacologic Studies	Nonpharmacologic Studies	All Studies
Low ROB	5% (6/115)	6% (16/274)	6% (22/389)
Medium ROB	61% (70/115)	60% (165/274)	60% (235/389)
High ROB	34% (39/115)	34% (93/274)	34% (132/389)

ROB = risk of bias

Since the release of CONSORT guidelines in 2001,[3] reporting of ROB elements in randomized controlled trials (RCTs) has generally improved (Table F-3). When comparing studies published before versus after these guidelines were released in 2001, the greatest improvement in reporting of these ROB elements in posttraumatic stress disorder (PTSD) RCTs was observed in reporting randomization (13% were reported as having adequate randomization prior to 2001, whereas 45% were reported as having adequate randomization in 2001 or later) and allocation concealment (6% vs. 39%). Studies published in 2001 or later also reported more frequent conduct of intent-to-treat (ITT) analyses (66% vs. 28%). Reporting of prognostic factors that allow reviewers to determine whether groups were similar at baseline (i.e., a measure of adequate randomization and sample size) also improved in studies published in 2001 or later, with unclear reporting decreasing from 44% to 21%. Reporting of overall attrition also improved: 16% of studies were rated as having unclear reporting of overall attrition prior to 2001, which decreased to 5% in later studies. A similar trend was seen in differential attrition (22% of studies rated as having unclear reporting of differential attrition prior to 2001 compared to only 8% in later years). As a result of improved reporting of these ROB elements, fewer studies published in 2001 or later were rated as having high ROB. However, older studies were also less likely to report other elements like percent of participants who met full criteria for PTSD, an inclusion criterion for the PTSD-Repository. Notably, because of the recent increased rate of publication of PTSD RCTs, only 32 RCTs are included from before 2001, yielding a small comparison to the larger number of included studies published in 2001 or later (n = 357).

Table F-3. Risk of bias ratings for pre-2001 (n=32) versus post-2000 (n=357) studies

ROB Domain	ROB Element	Pre-2001 Yes	Pre-2001 No	Pre-2001 Unclear	Post-2000 Yes	Post-2000 No	Post-2000 Unclear
Selection Bias	Randomization adequate?	13%	3%	84%	45%	3%	52%
	Allocation concealment adequate?	6%	3%	91%	39%	3%	59%
	Groups similar at baseline?	22%	34%	44%	57%	23%	21%
	ITT?	28%	59%	13%	66%	30%	4%
Performance Bias	Care provider masked?	6%	66%	28%	18%	71%	10%
	Patient masked?	28%	66%	6%	25%	68%	7%
Detection Bias	Outcome assessor masked?	31%	25%	44%	60%	14%	26%
Attrition	Overall attrition <20%	50%	34%	16%	46%	49%	5%
	Differential attrition <15%?	56%	22%	22%	67%	25%	8%
Overall Rating		Low (0%)	Medium (41%)	High (59%)	Low (6%)	Medium (62%)	High (32%)

ITT = intent-to-treat; ROB = risk of bias

Studies were assessed as having high risk of bias (Table F-4) due to poor reporting of selection and detection bias elements, lack of provider and participant masking (performance bias elements), and high levels of attrition.

Table F-4. Studies assessed as having high risk of bias (n=132 randomized controlled trials)

	Selection Bias: Randomization adequate?	Selection Bias: Allocation concealment adequate?	Selection Bias: Groups similar at baseline?	ITT?	Performance Bias: Care provider masked?	Performance Bias: Patient masked?	Detection Bias: Outcome assessor masked?	Attrition: Overall attrition <20%	Attrition: Differential attrition <15%
Yes	18%	15%	33%	36%	10%	18%	29%	36%	55%
No	5%	4%	30%	57%	74%	71%	27%	54%	31%
Unclear	77%	81%	38%	8%	16%	11%	45%	10%	14%

ITT = intent to treat

Pharmacologic and nonpharmacologic studies assessed as having high ROB were rated similarly for most ROB elements and domains with a couple notable exceptions (Table F-5). Although nonpharmacologic studies rated as having high ROB are more likely to report adequate randomization, other elements within the selection bias domain had similar rates of poor reporting to pharmacologic studies, resulting in the overall domain being downgraded. While providers (28% vs. 2%) and participants (51% vs. 4%) were more likely to be masked in pharmacologic studies, masking of providers and participants was not reported in half and one quarter (respectively) of the pharmacologic studies with an overall high ROB assessment, resulting in the performance bias domain being downgraded in many cases. In the vast majority of nonpharmacologic studies, providers (97%) and participants (91%) were reported as not being masked to treatment assignment, leading to the performance bias domain being downgraded for these studies.

Table F-5. Comparison of high risk of bias studies by pharmacologic and nonpharmacologic study type

ROB Domain	ROB Element		Pharmacologic Studies (n=39)	Nonpharmacologic Studies (n=93)
Selection Bias	Randomization adequate?	Yes	5%	24%
		No	0%	6%
		Unclear	95%	70%
	Allocation concealment adequate?	Yes	18%	14%
		No	0%	5%
		Unclear	82%	81%
	Groups similar at baseline?	Yes	38%	30%
		No	21%	33%
		Unclear	41%	37%
	ITT?	Yes	46%	31%
		No	49%	60%
		Unclear	5%	9%
Performance Bias	Care provider masked?	Yes	28%	2%
		No	23%	97%
		Unclear	49%	2%
	Patient masked?	Yes	51%	4%
		No	23%	91%
		Unclear	26%	4%
Detection Bias	Outcome assessor masked?	Yes	33%	27%
		No	13%	32%
		Unclear	54%	41%
Attrition	Overall attrition <20%	Yes	31%	39%
		No	62%	51%
		Unclear	8%	11%
	Differential attrition <15%	Yes	49%	57%
		No	31%	31%
		Unclear	21%	12%

ITT = intent-to-treat; ROB = risk of bias

A comparison of ROB domains and elements across all included studies only showed subtle differences between pharmacologic and nonpharmacologic studies (Table F-6). Overall, nonpharmacologic studies were slightly more likely to report adequate randomization methods compared to pharmacologic studies (48% vs. 30%). However, there were similar rates of adequate allocation concealment in both pharmacologic and nonpharmacologic studies (35% vs. 37%), and the overall domain of selection bias was rated similarly across study types. The largest contrast between pharmacologic and nonpharmacologic studies was observed in the performance bias domain, which is expected due to difficulty in masking provider and patient to treatment

assignment: pharmacologic studies reported adequate masking of providers and participants in 50% and 70% of studies, respectively, while nonpharmacologic studies reported adequate masking of providers and participants in only 4% and 7% of studies, respectively. There were similar rates of differential attrition reported across the study types, though pharmacologic studies were slightly more likely to report greater than 20% overall attrition compared to nonpharmacologic studies (59% vs. 43%).

Table F-6. Comparison of risk of bias for pharmacologic versus nonpharmacologic studies for all included studies

ROB Domain	ROB Element		Pharmacologic Studies (n=115)	Nonpharmacologic Studies (n=274)
Selection Bias	Randomization adequate?	Yes	30%	48%
		No	0%	4%
		Unclear	70%	49%
	Allocation concealment adequate?	Yes	35%	37%
		No	1%	3%
		Unclear	64%	60%
	Groups similar at baseline?	Yes	56%	53%
		No	17%	27%
		Unclear	28%	20%
	ITT?	Yes	64%	62%
		No	30%	33%
		Unclear	5%	5%
Performance Bias	Care provider masked?	Yes	50%	4%
		No	17%	94%
		Unclear	33%	3%
	Patient masked?	Yes	70%	7%
		No	16%	90%
		Unclear	15%	4%
Detection Bias	Outcome assessor masked?	Yes	50%	61%
		No	8%	18%
		Unclear	42%	22%
Attrition	Overall attrition <20%	Yes	34%	52%
		No	59%	43%
		Unclear	7%	5%
	Differential attrition <15%	Yes	63%	68%
		No	23%	25%
		Unclear	14%	7%

ITT = intent-to-treat; ROB = risk of bias

References for Appendix F

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3. Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. Lancet. 2001 Apr 14;357(9263):1191-4. PMID: 11323066.

Appendix G. Exploration of Risk of Bias Elements and Assessment Methods

At the request of the sponsor, the National Center for PTSD (NCPTSD), we engaged in additional technical expert panel (TEP) consultation regarding the exploration and development of alternative risk of bias (ROB) assessment methods due to concerns about limitations in existing ROB methods. The purpose of the additional ROB-focused TEP consultation was to provide guidance regarding ways to augment or alter the ROB assessment tool and methods used for the PTSD-Repository trials. Additionally, the goal of this exploration was ensure transparent, consistent, and replicable ROB methods related to assessment of pharmacologic and nonpharmacologic PTSD intervention trials. On the TEP call, NCPTSD noted concerns about existing ROB methods related to transparency and reproducibility of final ratings, most studies falling into the middle (i.e., medium ROB) final category, and the possibility of engaging in an additive combinations of domains rather than a nuanced consideration of interactions across ROB domains. The discussion was focused on how increased transparency and specificity of ROB methods could improve reliability of ROB ratings.

During the consultation call, many ROB TEP members described existing ROB assessment methods and tools (the associated Excel® file, Table G-1) such as Cochrane 1.0[1] and 2.0[2] tools as well as methods described in the AHRQ methods guide.[3] ROB TEP members noted that these existing ROB tools are explicit in describing their assumptions and how to operationalize them. They also noted that existing ROB methods and tools do not attempt to capture actual bias in a study because that variable is unknown; however, they do attempt to assess the *risk* of bias (i.e., *potential* for biased results). ROB TEP members also discussed changes across the broader field of systematic review methods, including new ROB assessment tools.

NCPTSD and ROB TEP members discussed potential interactions between self-reported or subjective outcomes when participants are not masked to treatment condition. Specifically, ROB TEP members noted that self-reported or subjective outcomes (even clinician administered measures of subjective symptoms) could increase ROB when participants are aware of their treatment condition. While these interactions are not relevant for objective outcomes like blood tests, they present significant ROB for outcomes such as reports of PTSD symptoms, even when clinicians are using structured clinical interviews to assess these outcomes.

NCPTSD and ROB TEP members discussed the importance of differentiating dropout from treatment (i.e., not completing the study intervention, but completing study assessments) versus dropout from the study (i.e., loss to followup or not completing study assessments). They noted that dropout from treatment would not increase ROB as long as participants were still included in study assessments and analyses were conducted as intent-to-treat (ITT) rather than only including treatment completers.

ROB TEP members also discussed how methods of handling missing data in ITT analyses varied, and these methods were differentially associated with ROB. For example, NCPTSD and ROB TEP members discussed how last observation carried forward (LOCF) methods of handling missing data were likely to increase ROB when a study had a high rate of attrition but that for studies with low attrition from measurement, LOCF would not necessarily result in high ROB. Likewise, even moderate attrition from measurement with appropriate statistical approaches such as multiple imputation may not necessarily result in high ROB.

NCPTSD and ROB TEP members also discussed how attrition thresholds may be different for binary or dichotomous outcomes versus continuous outcomes. While they noted that some

ROB methods recommended pre-established thresholds for attrition, ROB TEP members were cautious about establishing a universal attrition threshold for all outcomes because they noted that event rate and loss to followup could impact this assessment. They also noted pragmatic concerns about using different attrition thresholds for different outcomes, especially when thresholds are arbitrary. ROB TEP members suggested operationalizing early completers or responders and recommended that abstraction include the number of participants enrolled and assessed so that this information could be documented and taken into account for ROB assessment.

Based on these discussions about different types of missing data and different methods to handle missing data, the ROB TEP recommended abstracting three data elements related to attrition: outcome attrition, treatment attrition, and method for handling missing data. The ROB TEP also recommended grouping advanced methods for handling missing data together (e.g., grouping statistical techniques such as multiple imputation and multilevel modeling strategies that include all participants with missing data by incorporating all available information in analyses, but keeping LOCF as a separate category). They recommended assuming that there was less ROB using these advanced statistical methods even when there are higher levels of attrition as long as overall attrition does not exceed 50%.

NCPTSD and ROB TEP members discussed changing overall ROB ratings and potentially including more categories for the overall ROB assessment. Many ROB TEP members acknowledged that it is common for the majority of assessed studies to be rated as medium ROB, though cautioned against increasing the number of overall rating categories as a way to address this concern. ROB TEP members noted concerns about false sensitivity and reproducibility of additional categories. When discussing how to present ROB information in the PTSD-Repository, some ROB TEP members suggested flagging high ROB studies, or providing lay language descriptions of high ROB vs. medium or low ROB studies as a way to make this information more accessible and understandable to a broad range of potential PTSD-Repository stakeholders.

Overall, ROB TEP members noted concerns about adding new ROB domains and suggested adding more granular abstraction of ROB-related data elements and clarification about how to abstract them, maintaining ROB elements and definitions that are consistent with current tools and methods in the field.[4] The consultation with the ROB TEP and NCPTSD guided the development of an updated ROB assessment tool that augments the existing tool with additional definitions of key ROB elements to aid ROB assessors in consistency of ratings. At the request of NCPTSD, this updated tool also includes a 5- rather than 3-tier overall ROB rating scale.

The updated ROB assessment tool was pilot tested on 10 PTSD-Repository studies and compared to the prior ROB assessment using the same AHRQ-based methods used in Comparative Effectiveness Review (CER) No. 207.[5] The updated ROB assessment methods are similar to the standard AHRQ methods used for ROB assessment for the PTSD-Repository. Specifically, the updates include additional definitions, wording changes to improve clarity, and additional components added to items related to (1) assessing interactions between self-reported outcomes and lack of masking (2) handling and documentation of overall attrition, differential attrition, missing data, and dropout/loss to follow-up, and (3) overall ROB rating, which changed from a 3- to a 5-tier scale in the updated, pilot tested assessment tool. The items included in this updated ROB assessment are described in the associated Excel® file (Table G-1). The table also lists original ROB ratings as well as both ratings by the investigators conducting the updated ROB assessments. In comparing the pilot test assessments and prior assessments, one study had

the same rating in both systems, four studies were rated as having a slightly worse ROB (moving only 1 category, e.g., from medium to medium-high), four studies were rated as having a slightly better ROB rating (moving only 1 category, e.g., from medium to medium-low), and one study was rated lower by two categories (changed from medium to high ROB overall rating). As is typical with any ROB assessment process, there were some initial disagreements across raters (15 items across all the items and all the studies were disagreements, or 12.5% of all ratings). These disagreements were later resolved by meeting and discussing the publications and coming to consensus on the ratings. There were 19 total item-level ratings (15.8%) that differed from original ROB ratings across all items and all studies when original ratings were compared to the updated ratings after consensus.

References for Appendix G

1. Higgins JP, Altman DG, Gøtzsche PC, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. BMJ. 2011 Oct 18;343:d5928. doi: 10.1136/bmj.d5928. PMID: 22008217.
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