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Pharmacologic and Nonpharmacologic Treatments for Posttraumatic Stress Disorder: Groundwork for a Publicly Available Repository of Randomized Controlled Trials

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Key Messages

Purpose

The purpose of this project is to identify and abstract data from randomized controlled trials (RCTs) of posttraumatic stress disorder (PTSD) interventions to support the development of a publicly accessible data repository by the Veterans Affairs' National Center for Posttraumatic Stress Disorder.

Key Messages

- Three hundred eighteen RCTs of PTSD interventions published between 1988 and 2018 were included - 55% evaluated psychotherapeutic interventions, 30% studied pharmacologic interventions and 15% looked at complementary and integrative or nonpharmacologic biological treatments.
- Sixty-one percent of RCTs were conducted in the U.S., 78% enrolled < 100 participants, 57% enrolled participants from community populations (versus military/veteran), and 51% enrolled participants with mixed types of traumas rather than a specific trauma type.
- Less than half of the studies reported on the loss of PTSD diagnosis or clinically meaningful response/remission of symptoms. Reporting was incomplete for many data elements, e.g., history and number of traumatic brain injuries and the number of trauma types.
- This work will be useful in developing a publicly accessible repository of studies of PTSD treatments as well as providing information on gaps in the evidence to inform future research.

This report is based on research conducted by the XXXXX Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. XXX-20XX-XXXXX). The findings and conclusions in this document are those of the authors, who are responsible for its contents; the findings and conclusions do not necessarily represent the views of AHRQ. Therefore, no statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

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

The information in this report is intended to help health care decisionmakers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care 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.

Persons using assistive technology may not be able to fully access information in this report. For assistance contact [insert program email address].

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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 health care in the United States. The U.S. Department of Veterans Affairs requested this report from the EPC Program at AHRQ. AHRQ assigned this report to the following EPC: (INSERT EPC NAME FOR FINAL REPORT) Evidence-based Practice Center (Contract Number: INSERT CONTRACT NUMBER FOR FINAL REPORT). The reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies and strategies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses, when appropriate, prior to developing their reports and assessments.

A Technical Brief is a rapid report, typically on an emerging medical technology, strategy or intervention. It provides an overview of key issues related to the intervention—for example, current indications, relevant patient populations and subgroups of interest, outcomes measured, and contextual factors that may affect decisions regarding the intervention.

This Technical Brief was adapted to support development of a publicly available repository by the Veterans Affairs' National Center for Posttraumatic Stress Disorder by systematic abstraction of data from randomized controlled trials of posttraumatic stress disorder interventions.

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

For comments on this Technical Brief, please send 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 research methodology (e.g., inclusion criteria and elements for abstraction) at the outset of this report, the EPC consulted several technical and content experts. Broad expertise and perspectives were sought. Divergent and conflicting opinions are common and perceived as healthy scientific discourse that results in a thoughtful, relevant Technical Brief. Therefore, in the end, decisions on methodologic approaches for searching for and determining eligibility of studies for inclusion, and the elements of each included study that were abstracted in this work 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 Task Order Officer (TOO) and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

The list of Technical Experts who reviewed the report will be added for the final version.

Peer Reviewers

Prior to publication of the final evidence report, the EPC 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 non-financial conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential non-financial conflicts of interest identified.

The list of Peer Reviewers who reviewed the report will be added for the final version.

Structured Abstract

Background. Posttraumatic stress disorder (PTSD) reduces quality of life and functioning. People with PTSD have symptoms such as intrusive thoughts, nightmares, flashbacks, avoidance of trauma-related stimuli, negative beliefs about oneself and/or others, and hypervigilance. The symptoms may be due to direct or indirect exposure to trauma, such as witnessing actual or threatened death, injury, or violence including sexual violence, and threats of harm. While recent clinical practice guidelines and reviews exist, providing a single, updatable source of PTSD treatment trials would be useful for clinicians, researchers, and policymakers.

Purpose. To provide detailed information on PTSD treatment research, we systematically abstracted data from randomized controlled trials (RCTs) of PTSD interventions. The Veterans Affairs' National Center for Posttraumatic Stress Disorder (NCPTSD) intends to use the data to develop a publicly available data repository.

Data Sources. We searched the Published International Literature on Traumatic Stress (PILOTS), Ovid® MEDLINE®, Cochrane CENTRAL, PsycINFO®, Embase®, CINAHL®, and Scopus® for eligible RCTs and reviewed reference lists of selected systematic reviews and clinical practice guidelines.

Methods. In consultation with the NCPTSD, we established inclusion criteria for RCTs and specific data elements to be abstracted. We dually reviewed citations from the literature search, and then the full-text of potentially includable articles for eligibility, resolving any disagreements using consensus. One team member abstracted data from included RCTs into evidence tables, and a second reviewer checked abstracted data for accuracy and completeness. The primary publication for each RCT was abstracted; data and citations from any secondary publications appear in the same record.

Findings. We identified 318 RCTs of PTSD interventions for abstraction (106 pharmacologic studies and 212 nonpharmacologic studies) published from 1988 to 2018, with a peak in 2014. Psychotherapeutic interventions were the most commonly studied (55%), while 30% evaluated pharmacologic interventions. Most studies were conducted in the U.S. (61%), and enrolled fewer than 100 participants (78%). More participants were enrolled from a community population (57%) than from a military, veteran or other population, and the majority of studies were conducted in the outpatient setting (67%). Studies most often enrolled participants with a mix of trauma types (51%), followed by studies of participants with combat-related trauma (20%).

Although there was wide variation, the most commonly used PTSD diagnostic instruments were the Clinician-Administered PTSD Scale (CAPS) and the Structured Clinical Interview for DSM (SCID). Less than half of the studies reported loss of PTSD diagnosis and clinically meaningful response/remission of symptoms. Several other data elements were infrequently reported, including the number of participants with a history of traumatic brain injuries and the number of trauma types.

Conclusions. The data abstracted for 318 RCTs of treatments for PTSD can be used to create a publicly accessible data repository. By identifying important gaps in the research, such a data repository can inform future study design and conduct.

Contents

Executive Summary

What is this project and why are we doing it? The purpose of this project is to identify and abstract data from randomized controlled trials of treatments for posttraumatic stress disorder (PTSD). The Veterans Affairs' National Center for Posttraumatic Stress Disorder (NCPTSD) intends to use the data to develop a publicly available data repository of randomized controlled trials of PTSD treatments.

People who have experienced direct or indirect exposure to trauma, such as witnessing actual or threatened death, injury, or violence, including sexual violence and threats of harm, may develop PTSD. People with PTSD can present with a diverse and uneven collection of symptoms such as intrusive thoughts, nightmares, flashbacks, avoidance of trauma-related stimuli, negative beliefs about oneself and/or others, and hypervigilance. Untreated, these symptoms can last for years and reduce quality of life and functioning. While there are treatments that have been found to improve symptoms, there is not one single treatment known to be most effective, and selecting a treatment for a given patient can be fraught with uncertainty.

The NCPTSD data repository will serve multiple stakeholders and purposes—

- Support clinicians, policymakers, researchers, and patients and their families in selecting treatments, and understanding the benefits and harms of different treatments
- Offer a place to search for evidence on specific interventions, including the participant characteristics and settings in which they have been studied (or identify which treatments have not been studied)
- Identify evidence gaps to determine research priorities, and serve as a data source for researchers to understand these gaps more fully as they design new research

How did we look for studies and what did we do with studies we found? We consulted with the Agency for Healthcare Research and Quality (AHRQ), sponsoring partner at the Veterans Affairs' NCPTSD, and members of a multidisciplinary Technical Expert Panel to guide our work on this project. We searched multiple databases for eligible studies: Published International Literature on Traumatic Stress (PILOTS), Ovid® MEDLINE®, Cochrane CENTRAL, PsycINFO®, Embase®, CINAHL®, and Scopus®. In addition, we reviewed reference lists of selected systematic reviews and clinical practice guidelines. With input from the NCPTSD and from AHRQ, the EPC team established criteria to determine eligibility for inclusion and exclusion of studies. We abstracted data on population, study characteristics, and outcomes reported in the included studies into evidence tables. The evidence tables for this report are more detailed than the typical systematic review evidence tables in order to achieve the end goal of displaying information on PTSD treatments in a searchable and interactive repository that will be formatted for public availability. We devoted considerable time and attention to developing and documenting standard conventions for recording study data. This documentation supports consistent and comprehensive reporting of study data in the current project and potential future projects.

What did we find? After reviewing 7,843 article abstracts and 1,101 full-text publications, we identified 318 randomized controlled trials that met inclusion criteria. Studies were published from 1988 to 2018, with increased volume in the past 10 years, particularly for nonpharmacologic intervention studies. Psychotherapeutic interventions were the most commonly studied (55% of studies), while 30% evaluated pharmacologic interventions. The vast majority of studies were conducted in the U.S. (61%), and enrolled fewer than 100 participants (78%). More participants were enrolled from a community population (57%) than from a

military, veteran or other population for both pharmacologic and nonpharmacologic intervention studies. Similarly, the majority of studies were conducted in the outpatient setting (66%). These studies most often enrolled participants with a mix of trauma types (51%), followed by participants with combat-related trauma (19%).

Although there was wide variation, the most commonly used PTSD diagnostic instruments used were the Clinician-Administered PTSD Scale (CAPS) and the Structured Clinical Interview for DSM (SCID). Less than half of the studies reported key outcomes of loss of PTSD diagnosis and clinically meaningful response/remission of symptoms. Only 13% of pharmacologic studies reported diagnosis change. In addition, there are several other data elements that are infrequently reported in publications of both types of studies. For instance, history and mean number of trauma types is reported in only a small number of nonpharmacologic (9%) and pharmacologic (11%) studies. In addition, very few of the pharmacologic studies reported number of trauma types.

What comes next? Future work to help support and expand the eventual NCPTSD repository may include adding either studies or outcomes and analyses that were not eligible to be included here. Conversion of the abstracted data into an interactive and searchable repository will be completed by the sponsoring partners at the NCPTSD during a later phase of this project.

Introduction

Background

Posttraumatic stress disorder (PTSD) is characterized by group of symptoms such as intrusive thoughts, nightmares, flashbacks, avoidance of trauma-related stimuli, negative beliefs about self and/or others, and hypervigilance due to direct or indirect exposure to trauma such as witnessing actual or threatened death, injury, or violence including sexual violence/abuse and threats of harm.[2] PTSD has significant negative impacts on quality of life and functioning.[3] The national civilian 12-month and lifetime prevalence of PTSD are 4.7% and 6.1%, respectively,[4] compared to the lifetime prevalence of 6.9 percent in veterans.[5] Slightly higher lifetime prevalence estimates are common among wartime veterans.[6-8] In a RAND Corporation survey conducted in 2008, point-prevalence of PTSD among service members deployed in Operation Enduring Freedom or Operation Iraqi Freedom was 13.8 percent.[9]

In addition to being quite prevalent, PTSD is associated with a host of other health concerns. In multivariable models adjusting for age, race/ethnicity, sex, education, income, marital status, urbanicity, geographic region, and additional psychiatric disorders, PTSD was highly associated with comorbid anxiety, mood, and personality disorders in both civilians and veterans.[4,5] PTSD is also associated with cardiovascular disease, arthritis, asthma, chronic pain, diabetes, bone and joint conditions, and gastrointestinal disorders,[4] leading to high utilization of health services.

The prevalence of PTSD and its impact on health and health care utilization has prompted extensive research on effective ways to treat it. In 2017, the Department of Veterans Affairs (VA) and the Department of Defense (DoD) released an updated clinical practice guideline (CPG) on treatment of PTSD.[10] This CPG was based on literature available through March 2016, and it addressed pharmacologic and nonpharmacologic (including complementary and integrative health) interventions for PTSD.[10] The CPG recommended individual, manualized trauma-focused psychotherapy with exposure and/or cognitive restructuring, such as prolonged exposure (PE), cognitive processing therapy (CPT), eye movement desensitization and reprocessing (EMDR), specific cognitive behavioral therapies (CBT) for PTSD, brief eclectic psychotherapy (BEP), narrative exposure therapy (NET), and written narrative exposure. If trauma-focused psychotherapy is not readily available or not preferred, the CPG recommended individual non-trauma-focused psychotherapy or pharmacotherapy. Currently, only the selective serotonin reuptake inhibitors (SSRIs) sertraline and paroxetine are approved by the U.S. Food and Drug Administration (FDA) for treatment of PTSD. However, the CPG recommended the SSRI fluoxetine and the serotonin-norepinephrine reuptake inhibitor (SNRI) venlafaxine as well.

The systematic review used to develop the CPG included many randomized controlled trials (RCTs); more recent RCTs have examined new populations, combinations of interventions, or different treatment durations or modalities.[10-13] Additional recent RCTs investigated new or emerging interventions such as pharmacotherapies effective for depression or other mental health disorders associated with PTSD, repetitive transcranial magnetic stimulation, and ketamine.[14,15]

Whereas recent CPGs and reviews exist, providing a single, updatable source of PTSD treatment studies would be useful for clinicians, researchers, and policymakers. Therefore, the purpose of this project is to systematically identify and abstract data from RCTs of PTSD interventions to support development of a new data repository of PTSD treatment research. These data, when available as a publicly accessible data repository, as is planned by the National Center for PTSD (NCPTSD) through their Web site, could serve multiple stakeholders and purposes. For example, such a data repository could (1) provide policymakers with an up-to-date

accounting of evidence to facilitate quick and accurate responses to urgent government or media inquiries; (2) serve as a data source for future systematic reviews or meta-analyses; (3) identify research gaps to determine future research priorities on intervention harms or effectiveness; (4) provide the public with a place to search for evidence on interventions they or their loved ones are considering; (5) augment and inform the use of existing tools to assist in patient decision-making such as "AboutFace" videos on PTSD treatments,[16] PTSD apps,[17] or online decision aids available on the NCPTSD Web site;[18] and (6) serve as a resource for clinicians who are seeking information on effectiveness of interventions for PTSD in patients with particular demographics or exposures.

To effectively serve a variety of stakeholders and purposes, a data repository of PTSD treatment research would need to take into account the nuance and complexity of the available research data on PTSD treatments. There are several challenges to reviewing and compiling the existing PTSD RCT literature in adequate detail to serve the aforementioned clinical, research, and policy purposes. For example, many PTSD trials evaluate complex (multicomponent) interventions (e.g., participants receiving multiple types of psychotherapy components comprising one intervention arm, or receiving both medication and psychotherapy).[19] Another example of the complexity of PTSD RCTs relates to how PTSD is diagnosed in the studies. There are numerous methods of diagnosing PTSD that are not always consistent or validated. Only some are designed to diagnose PTSD (primarily structured clinical interviews such as the Clinician-Administered PTSD Scale [CAPS][20]), while self-report questionnaires often use cutoffs as a proxy for diagnosis.[21] To address these and other challenges in the data reported in PTSD RCTs, development of a repository needs to be detailed enough to include relevant, unique data from each study, yet also be cohesive enough to compare data across studies. This project, guided by the sponsoring partner, the NCPTSD, is designed to take the first steps in developing this type of large-scale data repository. Because of the modified format of this technical brief project that primarily involved abstracting data from a very large number of studies rather than serving as the basis for scoping a future systematic review, the total number of included studies for this project was limited to a maximum of 400.

Guiding Questions

The Guiding Questions for this Technical Brief are:

1. What pharmacologic interventions have been studied for the treatment of PTSD (since 1980)?
2. What nonpharmacologic interventions have been studied for the treatment of PTSD (since 1980)?

PICOTS

- The PICOTS framework was used to define the scope of the review. The population, intervention, comparator, outcomes, timing, setting, and study design (PICOTS) for this review are outlined below. The publication dates of studies reviewed for this project are January 1, 1980 (the year PTSD first appeared in the Diagnostic and Statistical Manual of Mental Disorders [DSM][2]) to July 15, 2018.

- Populations—Adults (≥18 years old) with PTSD (*DSM-III, DSM-III-R, DSM-IV, DSM-IV-TR, DSM-5, ICD-9, ICD-10).*

- Interventions—Pharmacologic treatments (defined as any drug used to treat PTSD, whether approved by FDA for any use in the United States or not, including DEA Schedule I drugs), nonpharmacologic treatments including complementary and integrative approaches, and combination of pharmacologic and nonpharmacologic treatments.

- Comparators—No restrictions on the type of comparator were applied. Direct (head-to-head) comparisons of interventions (Table 1) were included. We categorized waitlist/minimal attention, usual care, placebo, or other minimally active intervention (e.g., education or attention control) as "Control" interventions.

- Outcomes—PTSD outcomes including outcomes related to overall PTSD symptoms (e.g., change in total PTSD symptom severity score, diagnostic change, meaningful/reliable/clinically significant change); functional outcomes (e.g., social, family, vocational, education); return to school/work; comorbid psychiatric symptoms; quality of life; and adverse effects and other harms (e.g., sleep disturbance, agitation, mortality, and other serious adverse events, including harm to self or others); number who completed treatment; percent of total sessions attended; number who completed measurement; and treatment of missing data.

- Timing—No restriction by length of intervention or length of followup.

- Settings—No restriction by location of either the provider or patient (e.g., military base, Veterans Affairs clinic, community clinic, intervention delivered via telehealth, inpatient, outpatient, residential).

- Study Design—RCTs.

Methods

This technical brief follows applicable methods guidance from the Agency for Healthcare Research & Quality (AHRQ) Methods Guide for Effectiveness and Comparative Effectiveness Reviews.[22] The full protocol for this project contains a detailed description of the methods and is available at the AHRQ Effective Health Care Web site (http://effectivehealthcare.ahrq.gov/index.cfm).

Criteria for Inclusion/Exclusion of Studies

The criteria for inclusion and exclusion of studies (Table 1) are based on the Guiding Questions and are consistent with the PICOTS.

Table 1. Inclusion and exclusion criteria

Category	Inclusion Criteria	Exclusion Criteria
Population	Adults (≥18 years old) with a PTSD diagnosis (DSM-III, DSM-III-R, DSM-IV, DSM-IV-TR, DSM-5, ICD-9, or ICD-10) 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 Sample population <80% of participants diagnosed with PTSD
Interventions	Pharmacologic treatments—studies with any pharmacologic component, whether singly, in combination with other treatment categories, or compared with another intervention category Nonpharmacologic treatments—interventions without any pharmacologic component; including complementary and integrative approaches, nonpharmacologic biological treatments, and psychotherapeutic treatments	Interventions designed to simultaneously treat PTSD and comorbid conditions if they cannot be standalone PTSD interventions (e.g., 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/minimal attention, usual care, placebo, or other minimally-active treatment (e.g. education or attention control) were categorized as "Controls"	None
Outcomes	Any overall PTSD outcome	Studies reporting only individual symptoms or symptom clusters without overall PTSD outcome
Timing	Any study duration and length of followup	None
Settings	All	None
Study Design	Randomized controlled trials	Studies that do not have a randomized controlled trial design. Selected systematic reviews will be considered as reference sources for studies to be reviewed for possible inclusion; however, data will be abstracted from individual studies, rather than from systematic reviews.

Category	Inclusion Criteria	Exclusion Criteria
Publication Language and Dates	English language articles 1980 to present	Non-English language articles Unpublished data Publication date prior to 1980

DSM = Diagnostic and Statistical Manual of Mental Disorders; PTSD = Posttraumatic stress disorder

Literature Search Strategy

Multiple databases were searched: Published International Literature on Traumatic Stress (PILOTS), Ovid®, MEDLINE®, PsycINFO®, Cochrane CENTRAL, Embase®, CINAHL®, and Scopus® through July 15, 2018. Search strategies for PILOTS and MEDLINE are provided in Appendix A. The search strategies were developed and conducted by the Evidence-based Practice Center (EPC) librarian and peer reviewed by the Veterans Affairs' National Center for PTSD (NCPTSD) librarian. A gray literature (unpublished, or published in sources other than the medical literature) search was not conducted. Due to the nature of the project, an AHRQ portal for submission of Supplemental Evidence And Data for Systematic review (SEADS) was not requested.

The NCPTSD identified 20 studies[23-42] ("exemplars") that were expected to be screened for inclusion in the technical brief and that highlighted challenging decision points in reviewing the literature on PTSD treatment RCTs. In addition, studies included in the Veterans Affairs/Department of Defense (VA/DoD) clinical practice guideline[10] and in the recent AHRQ review of PTSD[43] were identified for review.

PICOTS and criteria in Table 1 were used to determine eligibility for inclusion and exclusion of citations (title/abstract review) as well as for full-text inclusion. Tables 2 and 3 illustrate the range of interventions that might be included. Due to the breadth of interventions for posttraumatic stress disorder (PTSD) this list is not comprehensive and some interventions may not be included here. For studies deemed potentially includable at the title/abstract review stage, the full-text was pulled. Each full-text article was independently reviewed for eligibility, and disagreements were resolved by consensus of the team. Articles that may be suggested by peer reviewers or that arise from the public posting of the draft report will be reviewed for the final report.

Table 2. Pharmacologic intervention examples[a]

Pharmacologic Treatments
• Antiadrenergic drugs (e.g., clonidine, guanfacine, propranolol) • Antidepressants (e.g., SSRIs, SNRIs, TCAs, MAOIs, other) • Antipsychotics (1st and 2nd generation) • Benzodiazepines • Cannabinoids (e.g., cannabidiol, dronabinol, tetrahydrocannabinol) • Mood stabilizers (e.g., anticonvulsants, lithium) • Psychostimulants (e.g., MDMA, amphetamine, methylphenidate, modafanil) • Sedatives (e.g., diphenhydramine, eszopiclone) • Steroids (e.g., dehydroepiandrosterone, hydrocortisone) • Miscellaneous (e.g., D-cycloserine, ketamine, mifepristone, others)

[a]Adapted from the Department of Veterans Affairs and the Department of Defense Clinical Practice Guideline for the Management of Posttraumatic Stress Disorder and Acute Stress Disorder. Version 3.0; 2017.[10]

Table 3. Nonpharmacologic intervention categories with examples[a]

Nonpharmacologic Biological Treatments	Complementary and Integrative Treatments	Psychotherapeutic Treatments
• Biofeedback (including neurofeedback) • Convulsive therapy • Electric shock therapy • Electroconvulsive therapy (ECT) • Hyperbaric oxygen therapy (HBOT) • Repetitive transcranial magnetic stimulation (TMS) • 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 • Mantram • Meditation (including mindfulness) • Movement therapy • Music therapy • Natural products (e.g., gingko biloba, herbs) • Phytotherapy • Progressive muscle relaxation • Psychodrama • Recreational therapies (e.g., drama, fishing, sailing) • Tai Chi • Tai Ji • Yoga	• Behavioral activation • Brief eclectic psychotherapy • Cognitive behavioral therapy (CBT) • Cognitive processing therapy (CPT) • Couples therapy • Eye movement desensitization and reprocessing therapy (EMDR) • Interpersonal therapy (IPT) • Present-centered therapy • Prolonged exposure therapy • Psychoanalysis • Stress inoculation therapy • Supportive counseling • Traditional psychotherapy • Written exposure therapy

[a]Adapted from the Department of Veterans Affairs and the Department of Defense Clinical Practice Guideline for the Management of Posttraumatic Stress Disorder and Acute Stress Disorder. Version 3.0; 2017.[10]

Technical Expert Panel

The Evidence-based Practice Center (EPC) convened a multidisciplinary Technical Expert Panel (TEP) whose members represented a range of clinical and research perspectives on PTSD treatments, including pharmacologic and nonpharmacologic interventions and combination therapies. Three conference calls were held in April and May 2018. The technical experts were invited to review the draft protocol and provide feedback. The following are examples of questions posed to the group.

1. Please review the PICOTS (Population, Interventions, Comparators, Outcomes, Setting) and inclusion/exclusion criteria in the attached protocol. Do you have any questions or feedback about these?
2. Given that the scope of the project is limited to 400 studies, we may not be able to include all of the available randomized controlled trials (RCTs). Which types of evidence are more/less important to include at this stage (e.g. based on timing of study, clinical population or group, outcomes reported, time point of outcome assessment, or sample size).
3. Can you comment on new or "emerging" interventions that we should include and also on interventions that are no longer relevant that we should not include?
4. Are there any particularly complex or confusing issues we should be aware of or can plan for during the data abstraction process?
5. What are your ideas about future uses for this type of database?

Based on the open-ended questions that we posed to the TEP members, we received input that ultimately helped to shape the final scope, eligibility criteria, and components of data

abstraction for this project. For example, we did not institute a sample size threshold for inclusion given feedback that many psychotherapeutic treatment trials, older trials, and trials investigating emerging interventions have small samples. Similarly, we did not exclude older studies from the data set.

In response to TEP feedback, we augmented the data abstraction template to include sexual orientation, ethnicity (separately from race), previous posttraumatic stress disorder (PTSD) treatment, inclusion/exclusion of suicidal participants, psychotherapist level of training, type of index trauma, duration since trauma (or illness), and mean number of trauma types and events experienced, and definition of PTSD diagnosis (e.g., DSM-IV, DSM-5, ICD-10). These elements will help to portray study characteristics that will allow interested stakeholders to identify studies relevant to their areas of interest.

Although abstraction of symptom cluster outcomes may be helpful, we could not accommodate this due to time and resource constraints. However, as a compromise and to prepare for possible future stages of this project, we indicated which studies reported item- and symptom-level outcomes. While individual participant-level data, additional data elements (e.g., symptom-level data and treatment fidelity for psychotherapy interventions), other study designs (e.g., nonrandomized trials, unpublished trials), and quality or risk-of-bias assessment for included studies may also be desirable we could not incorporate or address in this current work plan, and these are potential additions for any future expansion of this project.

Data Abstraction and Data Management

We constructed two evidence tables identifying the study characteristics and results of interest for all included studies. The evidence tables were developed using Microsoft Excel® and include components from the statement of work and additional elements based on discussions with the NCPTSD representatives and the Technical Expert Panel (Appendix A). The NCPTSD partner reviewed and approved updates and changes to the evidence tables at weekly meetings with AHRQ task order officers and the EPC investigators. Future plans for converting the abstracted data into a searchable and interactive repository will be handled by the NCPTSD.

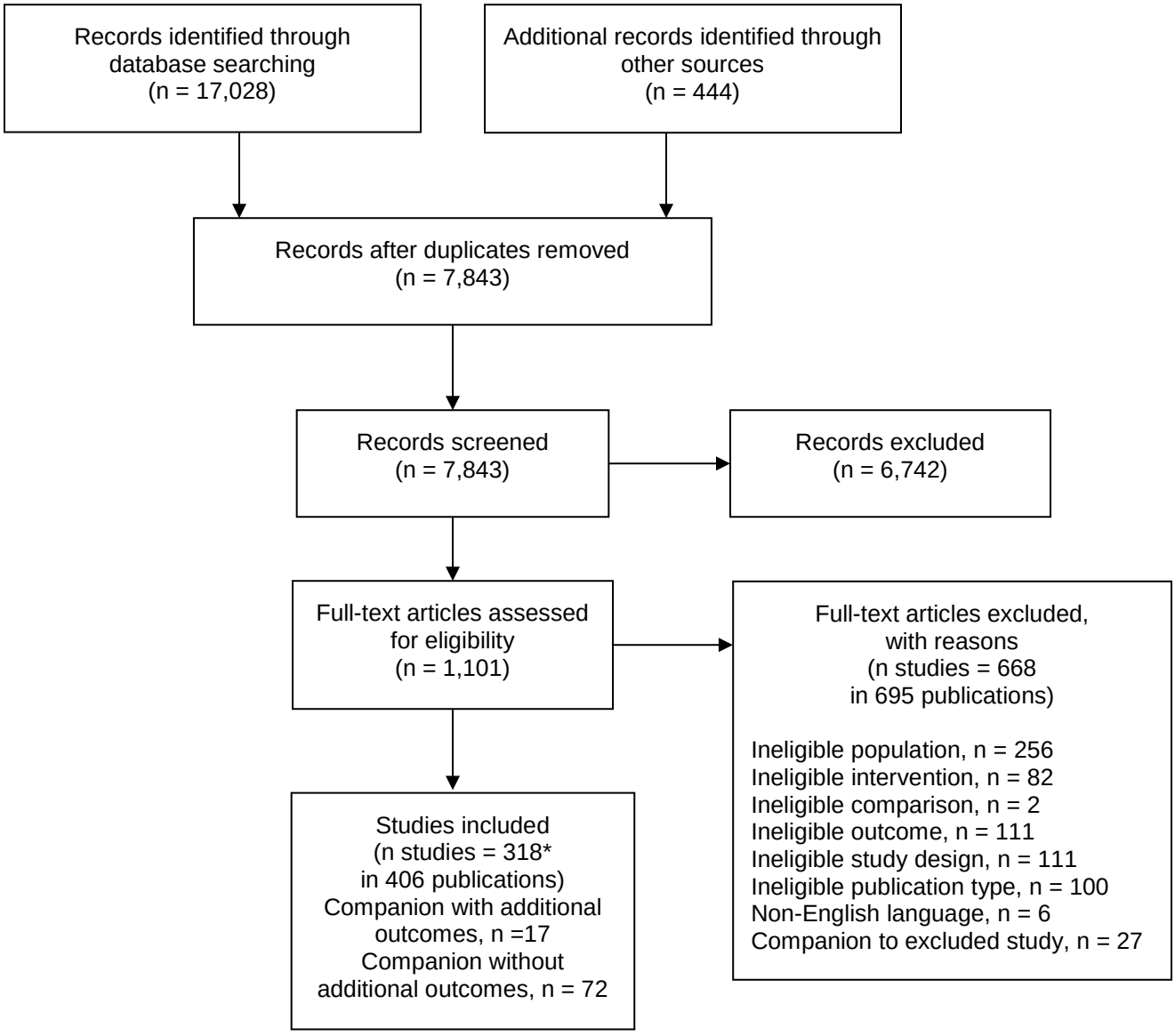
After studies were deemed to meet inclusion criteria, team members abstracted the study design, year, setting, country, sample size, eligibility criteria, study characteristics, population characteristics, intervention characteristics, results relevant to the Guiding Questions, and sources of funding, following instructions in the project data abstraction guide (Appendix B). A senior team member verified data abstracted from included studies (Appendix C) for accuracy and completeness. A record of studies excluded at the full-text level with reasons for exclusion was maintained (Appendix D). Risk of bias (quality assessment) was not conducted.

Findings

Results of Literature Searches

The search and selection of articles are summarized in the literature flow diagram (Figure 1). Database searches and examination of other sources resulted in 7,843 potentially relevant articles. After review of abstracts and titles, 1,101 articles were selected for full-text review, and 318 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 1. Literature flow diagram



*Badura-Brack, 2015[1] includes 2 studies

Included Studies

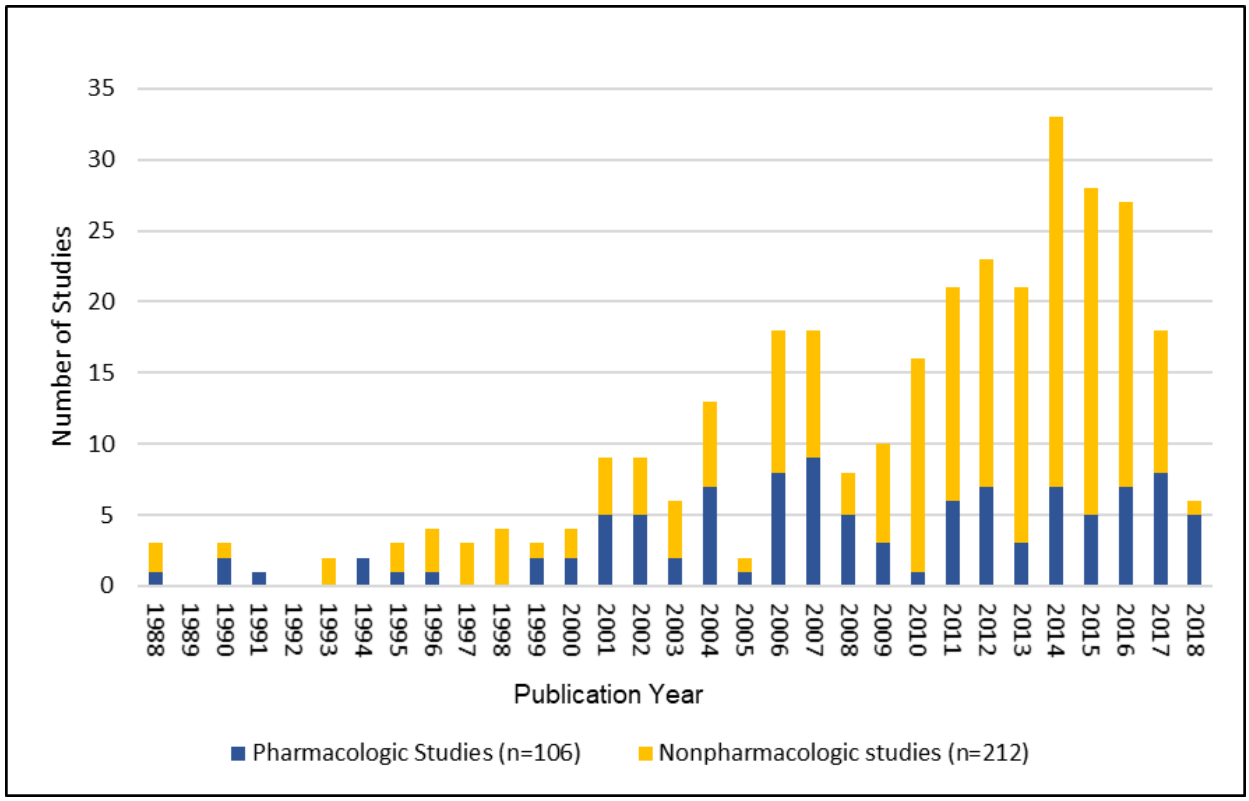
We identified 318 randomized controlled trials (RCTs) of interventions for posttraumatic stress disorder (PTSD) as includable and designated for data abstraction. The included studies list appears in Appendix C. Appendix D lists studies excluded upon full-text review and documents the reasons for exclusion.

The evidence tables (Appendixes E and F) for this report present detailed information on study and population characteristics and study outcomes for 106 studies of pharmacologic interventions[26,28,35,41,42,44-144] (Appendix E) and 214 studies of nonpharmacologic interventions, which included nonpharmacologic biological treatments, complementary and integrative treatments, and psychotherapeutic treatments[1,23,24,27,29,31-33,36,37,39,145-344] (Appendix F). Studies with any pharmacologic treatment component, whether singly (e.g., pharmacologic vs. placebo), in combination with treatment in another category (e.g., psychotherapy plus pharmacologic treatment vs. psychotherapy plus placebo), or directly compared with another intervention category (e.g., pharmacologic treatment vs. psychotherapeutic treatment), were all included in the pharmacologic evidence table. This classification stems from the observation that most studies with a pharmacologic component examined the potential additional benefits of the pharmacologic component or arm (e.g., as a standalone arm or as an augmentation or add-on to another intervention). Studies without any pharmacologic arm were categorized into the nonpharmacologic table. The National Center for Posttraumatic Stress Disorder (NCPTSD) identified 20 studies as exemplars to be considered in designing and testing the screening criteria and evidence table template,[23-42] of which 15 studies are included in the evidence tables.[23,24,26-29,31-33,35-37,39,41,42] Of the 20 exemplars identified, five were excluded as they did not meet the final inclusion criteria, and those five do not appear in the evidence tables.[25,30,34,38,40] Appendix D provides the specific reasons for exclusion.

Characteristics of Included Studies

We evaluated the characteristics of the 318 included studies based on year of study publication, treatment type (pharmacologic, nonpharmacologic and subtype of nonpharmacologic), study sample size, study population demographics, proportion of military participants, PTSD diagnostic instrument, study setting variables, and study reporting of trauma type and number. The publication dates of the included studies range from 1988 to July of 2018 (Figure 2). The number of studies published per year increased in the 2000's, reaching a peak of 33 in 2014. This increase was seen particularly with nonpharmacologic intervention studies – 26 nonpharmacologic studies were published in 2014, compared with seven pharmacologic studies.

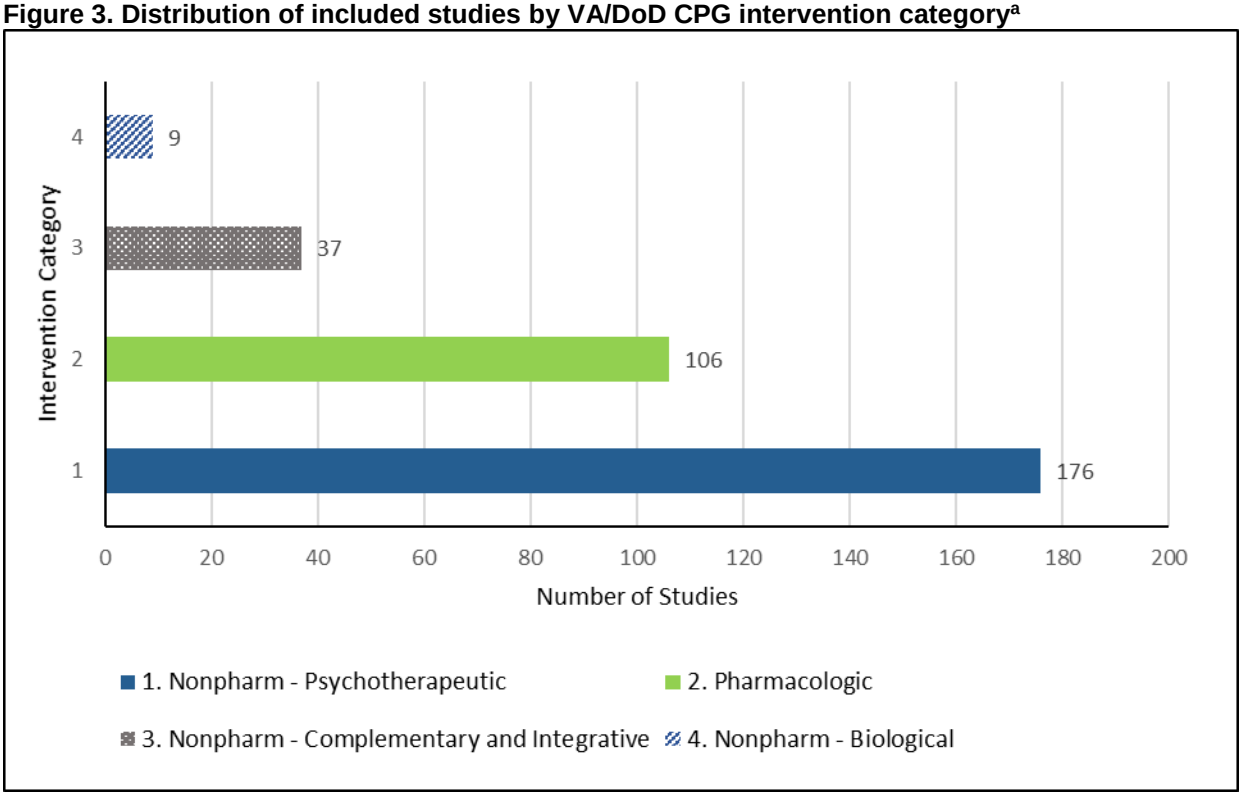
Figure 2. Distribution of included publications by year (N=318)



Studies were distributed broadly across the two treatment types, nonpharmacologic and pharmacologic. Studies investigating combination pharmacologic and nonpharmacologic therapies typically applied the same psychotherapy to both experimental and control (placebo) arms. Most included studies used only nonpharmacologic interventions (212/318, or approximately 67%); while 106/318 (33%) used one or more pharmacologic components.

In addition to the two overarching categories (pharmacologic and nonpharmacologic), each represented by a separate evidence table in this technical brief, each intervention arm was classified by intervention categories that align with the 2017 Veterans Affairs/Department of Defense clinical practice guideline,[10] as recommended by the Technical Expert Panel and NCPTSD. These categories include pharmacologic treatments and three nonpharmacologic treatment categories, which are nonpharmacologic biological treatments, complementary and integrative treatments, and psychotherapeutic treatments (Figure 3). Psychotherapeutic intervention was the most frequently studied treatment, employed in about 55% of the total number of trials identified, followed by pharmacologic intervention in approximately 33% of studies. Multicomponent treatment consisting of different intervention categories was labeled as "mixed" with specific intervention categories listed in the evidence tables (Appendix E and F).

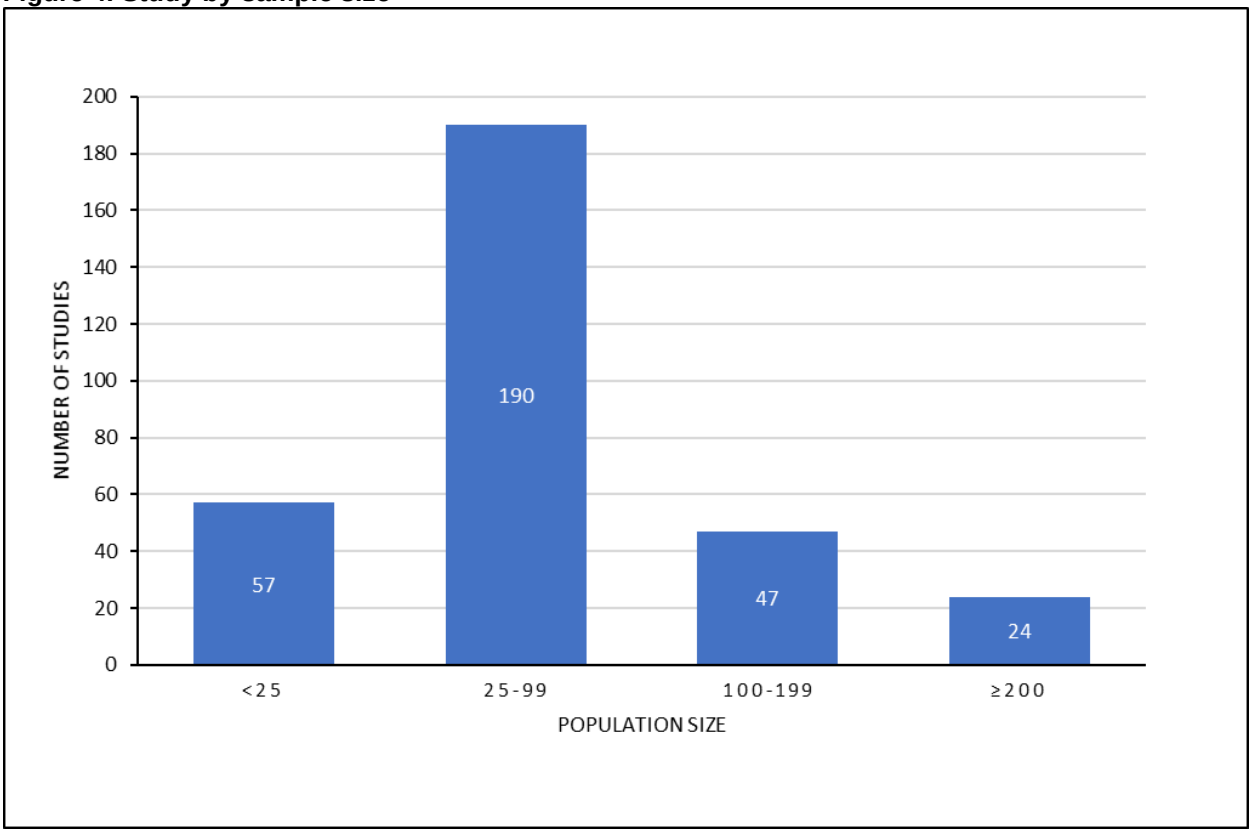
Figure 3. Distribution of included studies by VA/DoD CPG intervention category[a]



[a]Studies may fall into more than one category if they include components from multiple categories
CPG = clinical practice guideline; DoD = Department of Defense; VA = Department of Veterans Affairs; Nonpharm = Nonpharmacologic interventions

Figure 4 shows the overall distribution of sample sizes for the included studies, with the majority (78%) enrolling less than 100 participants.

Figure 4. Study by sample size



Figures 5 through 7 characterize studies by setting, including country, population type, and clinical setting where the intervention was delivered. The vast majority of included studies were conducted in the U.S. (60%), and more participants were enrolled from a community population (57%) than a military, veteran or other population for both pharmacologic and nonpharmacologic RCTs. Similarly, the majority of studies were conducted in the outpatient setting (66%).

Figure 5. Distribution of included studies by country

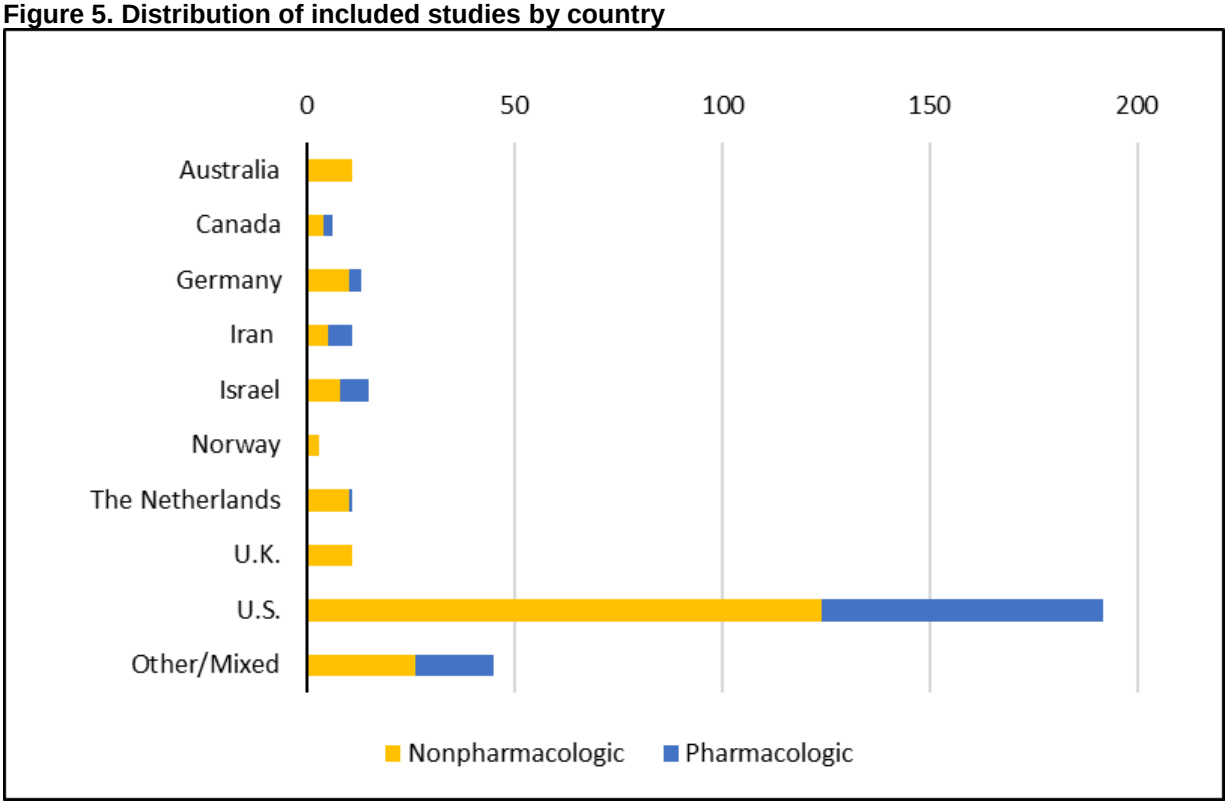


Figure 6. Distribution by population type

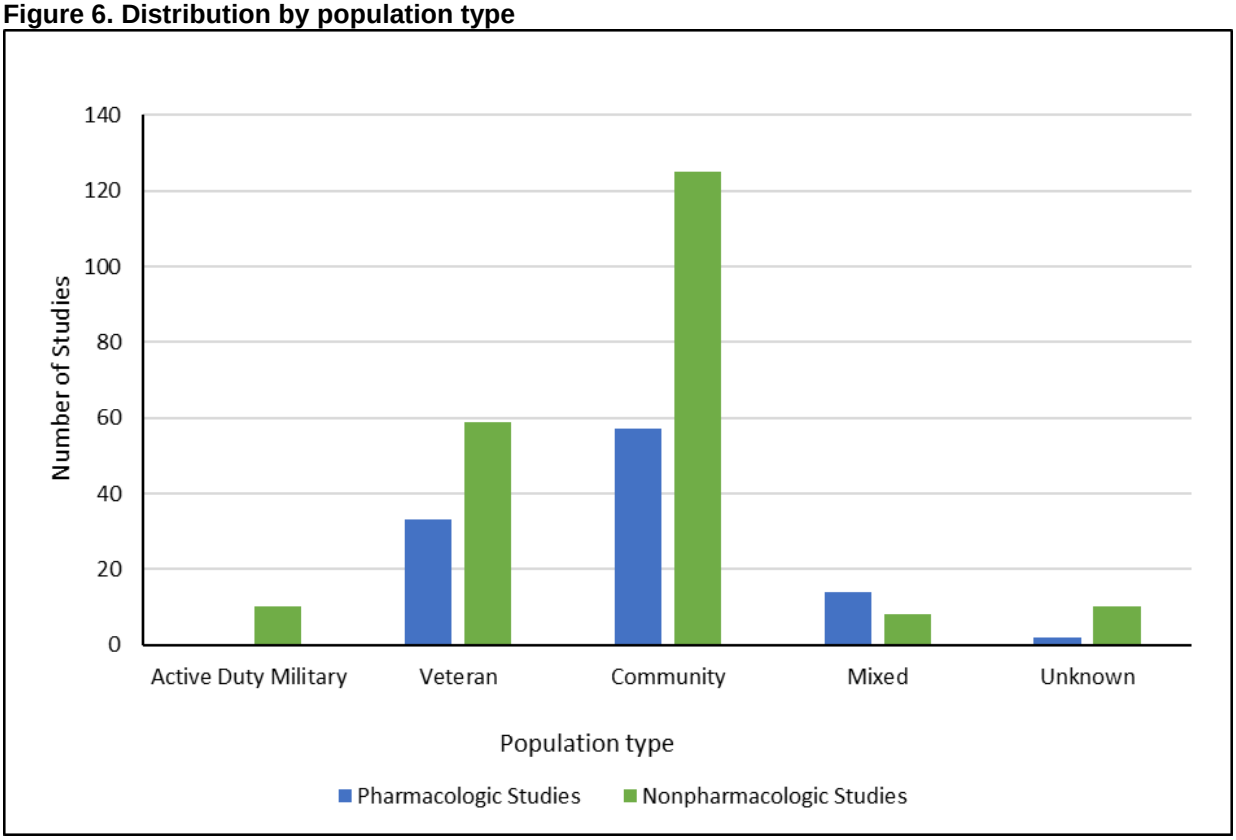
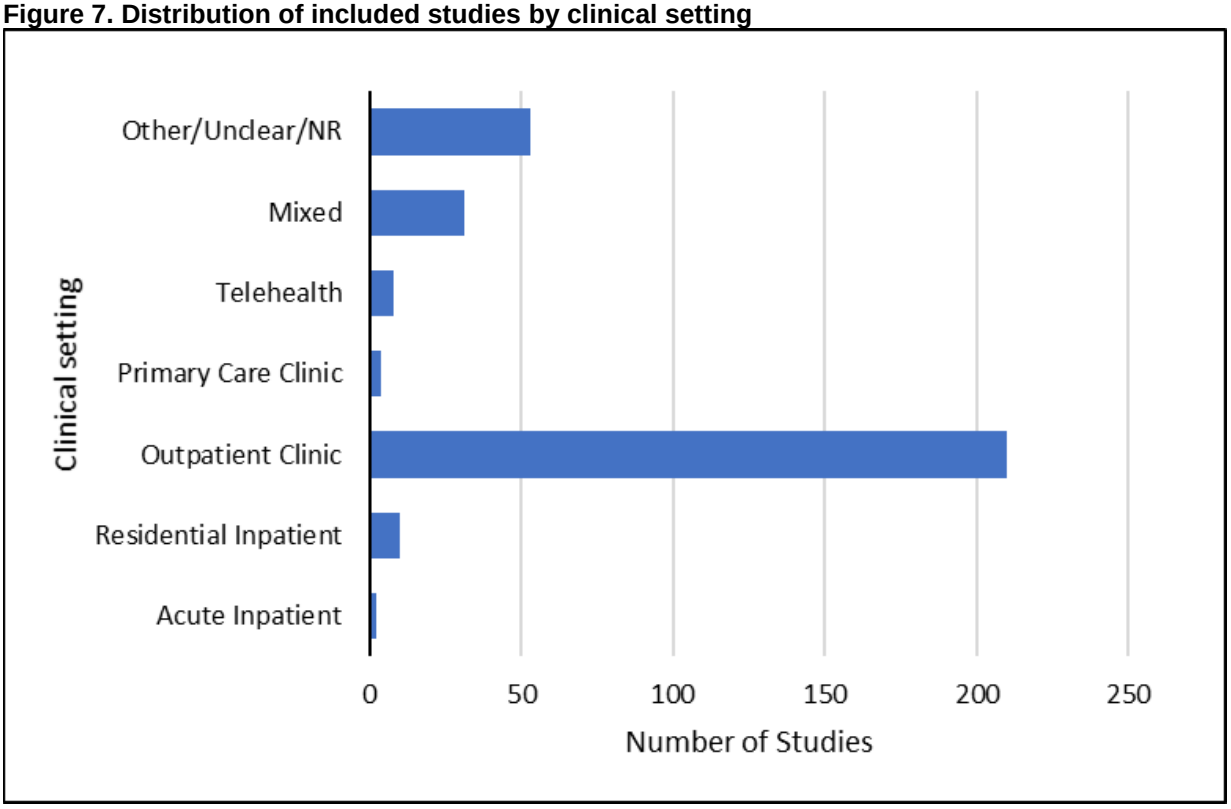


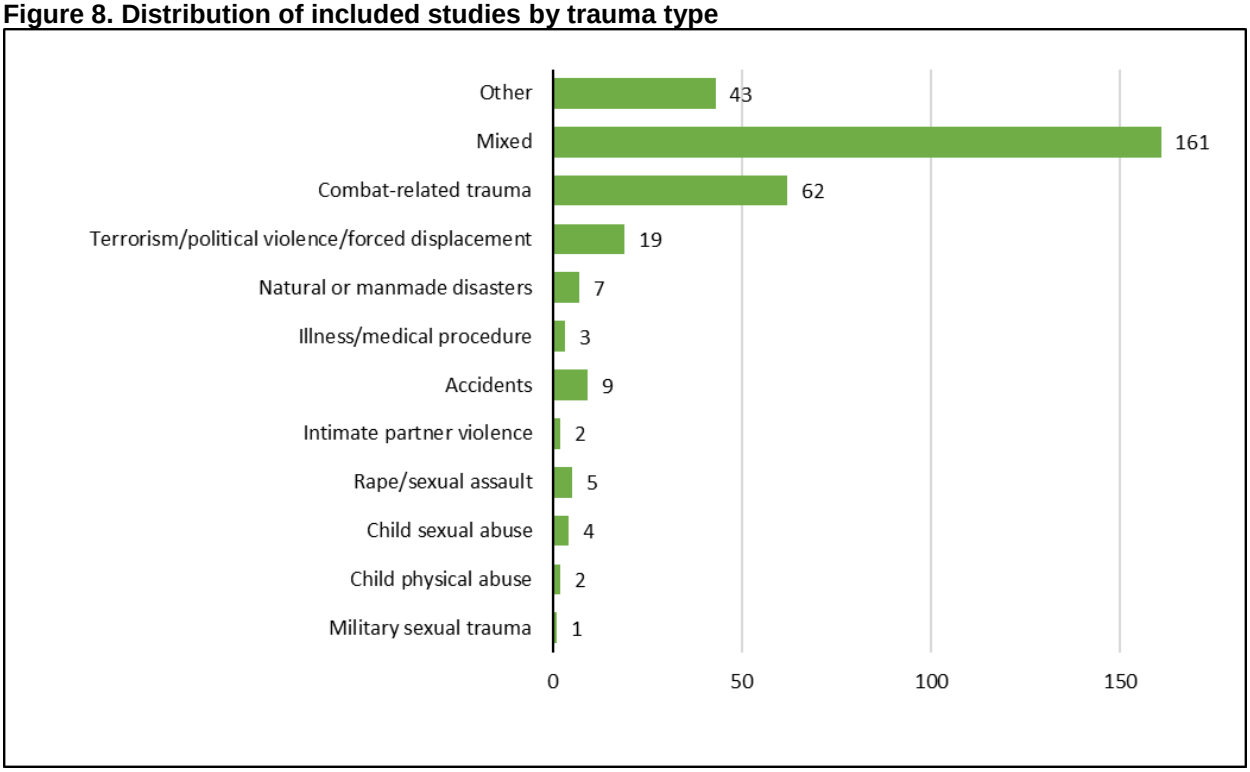
Figure 7. Distribution of included studies by clinical setting



NR = not reported

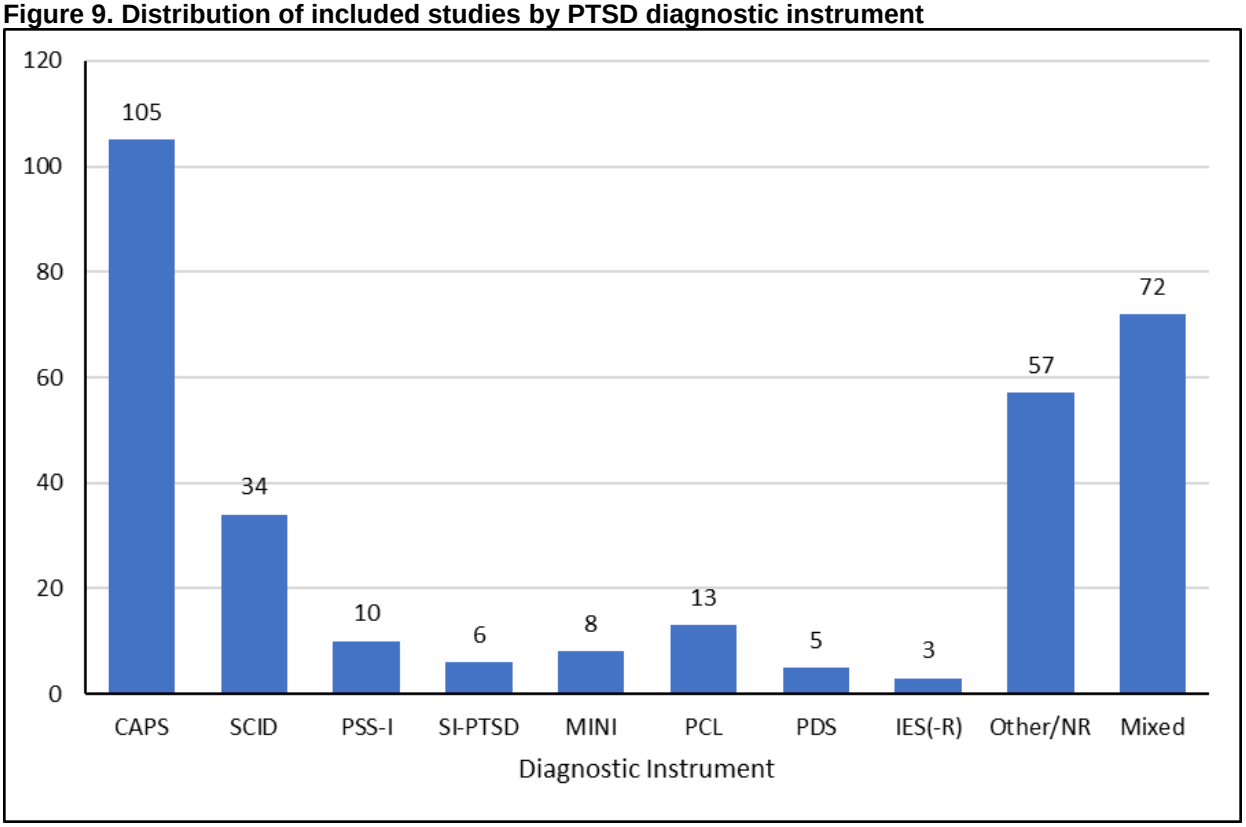
Some studies targeted specific types of trauma, while others included multiple types. The distribution of included studies by trauma type are shown in Figure 8, with "mixed" trauma types being most prevalent among these study populations (51%), followed by combat-related trauma (19%).

Figure 8. Distribution of included studies by trauma type



Numerous instruments, whether administered by clinicians or self-reported by patients, were used to diagnose PTSD and assess participants' eligibility for study entry. Figure 9 shows the ten most commonly used PTSD diagnostic instruments found in the 318 RCTs, with the Clinician-Administered PTSD Scale (CAPS) and the Structured Clinical Interview for DSM (SCID) being the two most commonly used tools. In some instances, the instrument used to diagnose PTSD differs 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).

Figure 9. Distribution of included studies by PTSD diagnostic instrument



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.

NOTE: Other category includes all other diagnostic instruments such as the Composite International Diagnostic Interview (CIDI) and the Primary Care PTSD Screen (PC-PTSD), and diagnosis according to medical classifications such as the Diagnostic and Statistical Manual of Mental Disorders (DSM) and the International Statistical Classification of Diseases and Related Health Problems (ICD). Diagnostic instruments reported less than two times were excluded from this graph to conserve space.

Table 4 shows the number of studies that included a subthreshold PTSD population and the number of studies that reported loss of PTSD diagnosis or clinically meaningful response as an outcome. Overall, less than half of the included studies reported these outcomes, particularly the loss of PTSD diagnosis in the pharmacologic RCTs (13% reporting this outcome). Overall, few studies included participants with subthreshold PTSD (no pharmacologic RCTs and only 7% of the nonpharmacologic RCTs). However, studies including more than 20% of participants with subthreshold PTSD were excluded, and therefore these data should be interpreted in the context of being from a pool of RCTs with 80% to 100% of participants having a full rather than subthreshold PTSD diagnosis.

Table 4. Number of studies reporting data element of interest

Data Element	Pharmacologic Studies Reporting Data Element, % (n/N)	Nonpharmacologic Studies Reporting Data Element, % (n/N)
Included Subthreshold PTSD	0	7% (14/212)
Loss of PTSD Diagnosis	14 (13%)	39% (83/212)
Clinically Meaningful Response/Remission for PTSD	48 (45%)	43% (91/212)

Finally, we found that studies did not consistently report all data elements that were intended to be abstracted for this project. Table 5 displays the prevalence of missing data across both pharmacologic and nonpharmacologic studies. These particular data elements were selected, with guidance from the Technical Expert Panel and the NCPTSD, for their relevance to current research and clinical practice. As seen in Table 5, there are several data elements that are more likely to be missing from both types of studies. For instance, history and number of traumatic brain injuries among participants is reported in only a small number of nonpharmacologic (8%) and pharmacologic (11%) studies. In addition, almost none of the pharmacologic studies reported the mean number of trauma types experienced per participant.

Table 5. Lack of reporting by evidence category[a]

Evidence Table Category	Data Element	Pharmacologic Studies Missing Data Element, % (n/N)	Nonpharmacologic Studies Missing Data Element, % (n/N)
Study Characteristics	Nonpharmacologic treatment provider education level	NA	34% (60/176)
Study Characteristics	Allowed PTSD and other psychotherapy co-intervention?	76% (81/106)	52% (110/212)
Study Characteristics	PTSD diagnostic instrument threshold	14% (15/106)	43% (91/212)
Population Characteristics	Duration of PTSD symptoms	57% (60/106)	64% (135/212)
Population Characteristics	Comorbid traumatic brain injury	89% (94/106)	92% (194/212)
Population Characteristics	Comorbid substance use disorder	22% (23/106)	44% (94/212)
Population Characteristics	Mean number trauma types per participant	99% (105/106)	92% (194/212)

Evidence Table Category	Data Element	Pharmacologic Studies Missing Data Element, % (n/N)	Nonpharmacologic Studies Missing Data Element, % (n/N)
Population Characteristics	Mean number of traumatic events per participant	92% (98/106)	83% (177/212)
Intervention Characteristics	Definition of treatment completion	72% (76/106)	64% (136/212)
Intervention Characteristics	Pharmacologic intervention treatment adherence or completion	79% (84/106)	NA
PTSD Outcomes	Within-group effect size	76% (81/106)	40% (85/212)
PTSD Outcomes	Score difference from baseline between groups	83% (88/106)	70% (149/212)

[a]We calculated within group score difference from baseline when possible, resulting in fewer gaps in the evidence tables even when these data were not reported in publications.

Summary and Implications

This data abstraction project was undertaken with guidance from the National Center for PTSD (NCPTSD) and Technical Expert Panel (TEP) to create evidence tables that can be used for a data repository of randomized controlled trials (RCTs) evaluating treatments for posttraumatic stress disorder (PTSD). This repository will eventually serve a variety of clinical, research, and policy purposes. To accomplish this goal, we developed detailed evidence tables informed by discussions with the NCPTSD and TEP. These discussions emphasized how to scope the current project, which data elements and studies to abstract, how to maintain data accuracy and relevance in large evidence tables, and potential next steps for the planned data repository.

The 318 included studies identified for this report were published from 1988 through 2018. 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, which showed a high prevalence of PTSD among deployed service members.[9] 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 evidence tables (Appendixes E and F) for this report are extensive and more detailed than the typical systematic review evidence tables, reflecting the objective of displaying detailed data elements in a data repository that will eventually 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.

Variations in study designs and approaches to reporting presented many challenges to the data abstractors. For example, some studies reported difference in change from baseline between groups, while some reported only within-group change from baseline or endpoint difference between groups. For other studies, determining which outcomes were primary PTSD outcomes and which were secondary was difficult, particularly in studies that report many outcomes. In some instances, the RCT may have analyzed a primary outcome other than PTSD, for example, 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, and 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; 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.

Next Steps

The completion of this project signifies the end of one phase for development of the data repository. The Veterans Affairs' National Center for Posttraumatic Stress Disorder (NCPTSD) will create the anticipated searchable and interactive repository as part of future stages of this project, using the current work as a foundation. Future additions to the repository could include symptom clusters, item-level data, subgroup analyses (e.g., to provide data on what works for whom), participant populations with >20% subthreshold posttraumatic stress disorder (PTSD), broader PTSD diagnostic criteria applied for inclusion, interventions with a dual diagnoses focus (e.g., treating comorbid PTSD and substance use disorders), interventions designed to prevent PTSD, non-randomized trials or other types of observational studies, and quality or risk of bias assessment. We base these suggestions on our interaction with the evidence base, the Technical Expert Panel (TEP), 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 goals for the final data repository and to refine and improve our methods as the evidence tables were being developed. Additionally, we consulted with both the sponsors and with the TEP early in the project to determine the appropriate level of granularity of data for abstraction, ensuring that comprehensiveness of data abstraction balanced with feasibility of data presentation and interpretation. Many of the recommendations by the TEP and NCPTSD emphasized the potential uses for such a repository, highlighting how adding variables, outcomes, subpopulations, risk of bias assessment, and other studies in the future could be useful to researchers, policymakers, clinicians, and patients. These comments provide a guide for future work in developing the evidence content of the repository; our experience with the studies suggests that the evidence base is available to support these next steps.

References

Abbreviations and Acronyms

AHRQ	Agency for Healthcare Research & Quality
BEP	brief eclectic psychotherapy
CAPS	Clinician-Administered PTSD Scale
CBT	cognitive behavioral therapy
CPG	Clinical Practice Guideline
CPT	cognitive processing therapy
DoD	Department of Defense
DSM	Diagnostic and Statistical Manual of Mental Disorders
EMDR	eye movement desensitization and reprocessing
EPC	Evidence-based Practice Center
FDA	U.S. Food and Drug Administration
MST	Military Sexual Trauma
NCPTSD	National Center for Posttraumatic Stress Disorder
NESARC-III	National Epidemiologic Survey on Alcohol and Related Conditions-III
NET	narrative exposure therapy
NR	not reported
PE	prolonged exposure
PICOTS	Population, Intervention, Comparator, Outcomes, Timing, Setting, and Study design
PTSD	Posttraumatic Stress Disorder
RCT	randomized controlled trial
SEADS	Supplemental Evidence And Data for Systematic review
SNRI	serotonin-norepinephrine reuptake inhibitor
SSRI	selective serotonin reuptake inhibitor
U.S.	United States
VA	U.S. Department of Veterans Affairs

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