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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Psychological and Pharmacological Treatments for Adults with Posttraumatic Stress Disorder (PTSD): A Systematic Review Update.

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review of *Psychological and Pharmacological Treatments for Adults with Posttraumatic Stress Disorder (PTSD): A Systematic Review Update,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES:

E-mail submissions: SEADS@epc-src.org.

Print submissions:

Mailing Address:

Portland VA Research Foundation

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SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Psychological and Pharmacological Treatments for Adults with Posttraumatic Stress Disorder (PTSD): A Systematic Review Update*. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Psychological and Pharmacological Treatments for Adults with Posttraumatic Stress Disorder (PTSD): A Systematic Review Update*, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: https://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=2478

This is to notify the public that the EPC Program would find helpful the following information on *Psychological and Pharmacological Treatments for Adults with Posttraumatic Stress Disorder (PTSD): A Systematic Review Update*:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number*.

- *For completed studies that do not have results on ClinicalTrials.gov*, please provide a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.

- *A list of ongoing studies that your organization has sponsored for this indication*. In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute ALL Phase II and above clinical trials sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution will be very beneficial to the EPC Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: https://www.effectivehealthcare.ahrq.gov/index.cfm/join-the-email-list1/.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

The Key Questions

Key Question (KQ) 1. What is the comparative effectiveness of different psychological treatments for adults diagnosed with PTSD?

I. How does comparative effectiveness vary by patient characteristics or type of trauma experienced?

KQ 2. What is the comparative effectiveness of different pharmacological treatments for adults diagnosed with PTSD?

I. How does comparative effectiveness vary by patient characteristics or type of trauma experienced?

KQ 3. What is the comparative effectiveness of different psychological treatments and pharmacological treatments for adults diagnosed with PTSD?

I. How does comparative effectiveness vary by patient characteristics or type of trauma experienced?

KQ 4. What adverse events (AEs) are associated with treatments for adults diagnosed with PTSD?

Contextual Question (CQ)

CQ 1a. What are the components of effective psychological treatments (e.g., frequency or intensity of therapy, and/or aspects of the therapeutic modality)?

CQ 1b. For psychological interventions that are effective in trial settings, what is the degree of fidelity when implemented in clinical practice settings?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings).

Populations:

Inclusion

I. Adults 18 years or older with PTSD based on any DSM diagnostic criteria.
II. Subgroups of interest (KQs 1a, 2a, 3a) include those distinguished by patient characteristics (e.g., gender, age, race/ethnicity, comorbid mental and physical health conditions, employment types requiring trauma exposure [for example, first responders], severity of trauma experienced, different symptoms of PTSD, dissociation, and/or psychosis, PTSD symptom chronicity or severity) or type of trauma experienced (e.g., military/combat, natural disaster, war, political instability, relational [physical, emotional, or sexual abuse or exposure to domestic violence], repeat victimizations, cumulative).

Exclusion

All other

Intervention:

Inclusion

I. Psychological interventions: Brief eclectic psychotherapy, CBT including cognitive restructuring, cognitive processing therapy, exposure-based therapy, coping skills therapy (e.g., stress inoculation therapy, assertiveness training, biofeedback , relaxation training), psychodynamic therapy, EMDR, IPT, group therapy, hypnosis or hypnotherapy, and energy psychology (including EFT)
II. Pharmacological interventions: SSRIs (citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, and sertraline), SNRIs (desvenlafaxine, venlafaxine, and duloxetine), tricyclic antidepressants (imipramine, amitriptyline, and desipramine), other second-generation antidepressants (bupropion, mirtazapine, nefazodone, and trazodone), alpha blockers (prazosin), atypical antipsychotics (olanzapine, risperidone, ziprasidone, aripiprazole and quetiapine), benzodiazepines (alprazolam, diazepam, lorazepam, and clonazepam),

anticonvulsants/mood stabilizers (topiramate, tiagabine, lamotrigine, carbamazepine, and divalproex)

Exclusion

I. Complementary and alternative medicine approaches
II. Psychological or pharmacological interventions not listed as included

Comparator:

Inclusion

I. KQ 1 (1a): Psychological interventions listed above compared with one another, waiting list assignment, usual care (as defined by the study), no intervention, or sham.
II. KQ 2 (2a): Pharmacological interventions listed above compared with one another or placebo.
III. KQ 3 (3a): Psychological interventions listed above compared with pharmacological interventions listed above.
IV. KQ 4: Any intervention listed above

Exclusion

All other comparisons

Outcomes:

Inclusion

I. KQs 1–3: PTSD symptom reduction, prevention or reduction of comorbid medical or psychiatric conditions (e.g., coronary artery disease; depressive symptoms; anxiety symptoms; suicidal ideation/plans/attempts; and substance use, abuse, or dependence), remission (i.e., no longer having symptoms or loss of PTSD diagnosis), quality of life, disability or functional impairment, return to work or active duty status

II. KQ 4: Overall and specific AEs (e.g., disturbed sleep, increased agitation, sedation, weight gain, metabolic side effects, and mortality), withdrawals due to AEs

Exclusion
All other outcomes

Time frame:
Inclusion

I. Studies published from 2012 to the present will be searched to identify new studies meeting the review criteria. Findings of these newly identified studies will be synthesized with those from studies included in the prior review that continue to meet the new review criteria.
II. At least 4 weeks study duration after randomization

Exclusion
Less than 4 weeks

Settings:
Inclusion
Outpatient and inpatient primary care or specialty mental health care; community settings e.g., churches, community health centers, rape crisis centers), military settings

Exclusion
Other settings

Study design:
Inclusion

I. KQs 1–3: Randomized controlled trials (RCTs) of any sample size, systematic reviews (for references)

II. KQ 4: AE data from trials for KQs 1–3, systematic reviews and meta-analyses (for references), nonrandomized controlled trials, prospective cohort studies with an eligible comparison group and a sample size of at least 500, case-control studies with a sample size of at least 500

Exclusion
All other designs and studies using included designs that do not meet the sample size criterion

Language:
Inclusion
Studies published in English

Exclusion
Studies published in languages other than English

Sharon B. Arnold
Deputy Director
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