

Settings**Inclusion**

All KQs: Outpatients.

Exclusion

Inpatients.

Country Setting**Inclusion**

All KQs: Any geographic area.

Exclusion

None.

Study Designs**Inclusion**

- I. For all KQs (*i.e.*, benefits and harms overall [KQs 1, 2, 3] and among subgroups [KQ 4]), we will include head-to-head RCTs and nRCTs; prospective, controlled cohort studies ($N \geq 100$); double-blinded, placebo-controlled trials for network meta-analysis; and SRs for identification of additional references only.
- II. For studies of harms (*i.e.*, overall [KQ 3] and among subgroups [KQ 4]), we will also include any other observational study (*e.g.*, cohort, case-control, large case series, post marketing surveillance) ($N \geq 100$).

Exclusion

All other designs not listed.

Publication Language**Inclusion**

All KQs: English.

Exclusion

Languages other than English.

Sharon B. Arnold,

Deputy Director.

[FR Doc. 2017-13395 Filed 6-26-17; 8:45 am]

BILLING CODE 4160-90-P

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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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 July 27, 2017.

ADDRESSES:

Email submissions: SEADS@epc-src.org.

Print submissions:

Mailing Address: Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, P.O. Box 69539, Portland, OR 97239.

Shipping Address (FedEx, UPS, etc.): Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, 3710 SW U.S. Veterans Hospital Road, Mail Code: R&D 71, Portland, OR 97239.

FOR FURTHER INFORMATION CONTACT:

Ryan McKenna, Telephone: 503-220-8262 ext. 51723 or Email: SEADS@epc-src.org.

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 Web site 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 email 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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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day-17-0729]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through

the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to *omb@cdc.gov*. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Customer Surveys Generic Clearance for the National Center for Health Statistics (0920-0729, Expiration 05/31/2017)—Reinstatement—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, shall collect statistics on “the extent and nature of illness and disability of the population of the United States.” This is a reinstatement request for a generic approval from OMB to conduct customer surveys over the next three years at an overall burden rate of 4000 hours.

As part of a comprehensive program, the National Center for Health Statistics (NCHS) plans to continue to assess its customers’ satisfaction with the content, quality and relevance of the information it produces. NCHS will conduct voluntary customer surveys to assess

strengths in agency products and services and to evaluate how well it addresses the emerging needs of its data users. Results of these surveys will be used in future planning initiatives.

The data will be collected using a combination of methodologies appropriate to each survey. These may include: Evaluation forms, mail surveys, focus groups, automated and electronic technology (e.g., email, Web-based surveys), and telephone surveys. Systematic surveys of several groups will be folded into the program. Among these are Federal customers and policy makers, state and local officials who rely on NCHS data, the broader educational, research, and public health community, and other data users. Respondents may include data users who register for and/or attend NCHS sponsored conferences; persons who access the NCHS Web site and the detailed data available through it; consultants; and others. Respondent data items may include (in broad categories) information regarding respondent’s gender, age, occupation, affiliation, location, etc., to be used to characterize responses only. Other questions will attempt to obtain information that will characterize the respondents’ familiarity with and use of NCHS data, their assessment of data content and usefulness, general satisfaction with available services and products, and suggestions for improvement of surveys, services and products.

In order to capture anticipated additional feedback opportunities, this reinstatement request allows for the potential increase in both respondents and time per response for a total estimated annual burden total of 4,000 hours. There is no cost to respondents other than their time to participate in the survey. The resulting information will be for NCHS internal use.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (hours)
Questionnaire for conference registrants/ attendees.	Public/private researchers, Consultants, and others.	6,000	1	15/60
Focus groups	Public/private researchers, Consultants, and others.	500	1	1
Web-based	Public/private researchers, Consultants, and others.	6,000	1	15/60
Other customer surveys	Public/private researchers, Consultants, and others.	2,000	1	15/60