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 [KQ 1, 2, 3] and among subgroups [KQ 4]), we will include head-to-head RCTs and nRCTs; prospective, controlled cohort studies (N ≥ 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 ≥ 100).

Exclusion
All other designs not listed.

Publication Language
Inclusion
All KQs: English.
Exclusion
Languages other than English.

Sharon B. Arnold,
Deputy Director.

ADDRESS:
Email submissions: SEADS@epcsrc.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@epcsrc.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.

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-list/. The systematic review will answer the following questions. This information is available online at: https://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=2478.
The Key Questions

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

1. 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?

1. 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?

1. 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

1. 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

1. Psychological interventions: Brief ecletic 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.

[FR Doc. 2017–13394 Filed 6–26–17; 8:45 am]
BILLING CODE 4160–90–P

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
clearance of the information to be
collected; (d) Minimize the burden of
the collection of information on those
who are to respond, including through

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

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
categorize 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