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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Noninvasive, Nonpharmacological Treatment for Chronic Pain

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 *Noninvasive, Nonpharmacological Treatment for Chronic Pain,* 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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

Scientific Resource Center
ATTN: Scientific Information Packet Coordinator
PO Box 69539
Portland, OR 97239

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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 *Noninvasive, Nonpharmacological Treatment for Chronic Pain*. 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 *Noninvasive, Nonpharmacological Treatment for Chronic Pain*, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: https://www.effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=2470

This is to notify the public that the EPC Program would find the following information on *Noninvasive, Nonpharmacological Treatment for Chronic Pain* helpful:

- 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. The contents of all submissions will be made available to the public upon request. 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 EPC 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

I. In adults with chronic low back pain:
    A. What are the benefits and harms of noninvasive nonpharmacological therapies compared with sham treatment, no treatment, waitlist, attention control, or usual care?
    B. What are the benefits and harms of noninvasive nonpharmacological therapies compared with pharmacological therapy (e.g., opioids, NSAIDS, acetaminophen, anti-seizure medications, antidepressants)?
    C. What are the benefits and harms of noninvasive nonpharmacological therapies compared with exercise?
II. In adults with chronic neck pain:
    A. What are the benefits and harms of noninvasive nonpharmacological therapies compared with sham treatment, no treatment, waitlist, attention control, or usual care?
    B. What are the benefits and harms of noninvasive nonpharmacological therapies compared with pharmacological therapy?
    C. What are the benefits and harms of noninvasive nonpharmacological therapies compared with exercise?

III. In adults with osteoarthritis-related pain:
    A. What are the benefits and harms of noninvasive nonpharmacological therapies compared with sham treatment, no treatment, waitlist, attention control, or usual care?
    B. What are the benefits and harms of noninvasive nonpharmacological therapies compared with pharmacological therapy?
    C. What are the benefits and harms of noninvasive nonpharmacological therapies compared with exercise?

IV. In adults with fibromyalgia:
    A. What are the benefits and harms of noninvasive nonpharmacological therapies compared with sham treatment, no treatment, waitlist, attention control, or usual care?
    B. What are the benefits and harms of noninvasive nonpharmacological therapies compared with pharmacological therapy?
    C. What are the benefits and harms of noninvasive nonpharmacological therapies compared with exercise?

V. In adults with chronic tension headache:
    A. What are the benefits and harms of noninvasive nonpharmacological therapies compared with sham treatment, no treatment, waitlist, attention control, or usual care?
    B. What are the benefits and harms of noninvasive nonpharmacological therapies compared with pharmacological therapy?
    C. What are the benefits and harms of noninvasive nonpharmacological therapies compared with biofeedback?

VI. Do estimates of benefits and harms differ by age, sex, or presence of comorbidities (e.g., emotional or mood disorders)?

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

Population(s): Adults with the following chronic pain (defined as pain lasting 12 weeks or longer or pain persisting past the time for normal tissue healing) conditions specified in the Key Questions:

Key Question 1: Nonradicular chronic low back pain
Key Question 2: Chronic neck pain without radiculopathy or myelopathy
Key Question 3: Pain related to primary or secondary osteoarthritis
Key Question 4: Fibromyalgia
Key Question 5: Primary chronic tension headache (defined as 15 or more headache days per month for at least 3 months)
Key Question 6: Patients with any of the five chronic pain conditions.

Interventions: (All Key Questions)

I. Exercise
II. Psychological therapies
III. Physical modalities
IV. Manual therapies
V. Mindfulness practices
VI. Mind-body practices
VII. Acupuncture
VIII. Functional restoration training
IX. Multidisciplinary/interdisciplinary rehabilitation.

Comparators

I. For all Key Questions, subquestion "a"
    A. Sham treatment
    B. Waitlist
    C. Usual care
    D. Attention control
    E. No treatment
II. For all Key Questions, subquestion "b"

    A. Non-opioid pharmacological therapy(nonsteroidal anti-inflammatory drugs, acetaminophen, antiseizure medications, antidepressants)
    B. Opioid analgesics
III. Key Questions 1-4, 6, subquestion "c": Exercise
IV. Key Question 5, 6, subquestion "c": Biofeedback.

Outcomes

I. Primary efficacy outcomes (in priority order); we will focus on outcomes from validated measures
    A. Function/disability/pain interference
    B. Pain
II. Harms and adverse effects
III. Secondary outcomes
    A. Psychological distress (including depression and anxiety)
    B. Quality of life
    C. Opioid use
    D. Sleep quality, sleep disturbance
    E. Health care utilization

Timing

I. Duration of followup: short term (up to 6 months), intermediate term (6-12 months) and long term (at least 1 year); we will focus on longer-term (>1 year) effects where possible
II. Studies with <1 month followup after treatment will be excluded.

Settings

I. Any nonhospital setting or setting of self-directed care

II. Exclusions: Hospital care, hospice care, emergency department care.

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