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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Noninvasive Nonpharmacologic 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 on *Noninvasive Nonpharmacologic 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address:

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

ATTN: EPC SEADs Coordinator

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Rockville, MD 20857

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FOR FURTHER INFORMATION CONTACT:

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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 *Noninvasive Nonpharmacologic 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*

Nonpharmacologic Treatment for Chronic Pain, including those that describe adverse events. The entire research protocol is available online at: https://effectivehealthcare.ahrq.gov/topics/noninvasive-nonpharm-pain-update/protocol

This is to notify the public that the EPC Program would find the following information on Noninvasive Nonpharmacologic 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. 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/email-updates.

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:

1. In adults with chronic low back pain:
    a. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with sham treatment, no treatment, waitlist, attention control, or usual care?

b. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with pharmacologic therapy (e.g., NSAIDS, acetaminophen, antiseizure medications, antidepressants)?

c. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with exercise?

2. In adults with chronic neck pain:

   a. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with sham treatment, no treatment, waitlist, attention control, or usual care?

   b. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with pharmacologic therapy?

   c. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with exercise?

3. In adults with osteoarthritis-related pain:

   a. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with sham treatment, no treatment, waitlist, attention control, or usual care?

   b. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with pharmacologic therapy?

   c. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with exercise?

4. In adults with fibromyalgia:

a. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with sham treatment, no treatment, waitlist, attention control, or usual care?
b. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with pharmacologic therapy?
c. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with exercise?

5. In adults with chronic tension headache:
    a. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with sham treatment, no treatment, waitlist, attention control, or usual care?
    b. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with pharmacologic therapy?
    c. What are the benefits and harms of noninvasive nonpharmacologic therapies compared with biofeedback?
6. Do estimates of benefits and harms differ by age, sex, presence of comorbidities (e.g., emotional or mood disorders) or degree of nociplasticity/central sensitization?

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

- Population(s): Adults (including pregnant or breastfeeding women) 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):
  - Exercise
  - Psychological therapies
  - Physical modalities
  - Manual therapies
  - Mindfulness practices
  - Mind-body practices
  - Acupuncture
  - Multidisciplinary/interdisciplinary rehabilitation (including functional restoration training)
- Comparators:
  - **For all Key Questions, subquestion "a"**
    - Sham treatment

        - Waitlist
        - Usual care
        - Attention control
        - No treatment
    - **For all Key Questions, subquestion "b"**
        - Common nonopioid pharmacologic therapy used for chronic pain (NSAIDs, acetaminophen, antiseizure medications, antidepressants, muscle relaxants (including benzodiazepines) topical agents,(diclofenac, lidocaine capsaicin)
        - Medical marijuana (any formulation)
        - Opioid analgesics
    - **Key Questions 1-4, 6, subquestion "c":** Exercise
    - **Key Question 5, 6, subquestion "c"**: Biofeedback.
- Outcomes:
    - Primary efficacy outcomes (in priority order); we will focus on outcomes from validated measures
        - Function/disability/pain interference
        - Pain
    - Harms and adverse effects
    - Secondary outcomes
        - Psychological distress (including depression and anxiety)
        - Quality of life

        - Opioid use
        - Sleep quality, sleep disturbance
        - Health care utilization.
- Timing:
    - 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
    - Studies with <1 month followup after treatment will be excluded.
- Settings:
    - Any nonhospital setting or setting of self-directed care
    - Exclusions: Hospital care, hospice care, emergency department care.

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Director.

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