



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Living Systematic Review on Plant-Based 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 *Living Systematic Review on Plant-Based 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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

5600 Fishers Lane

Mail Stop 06E53A

Rockville, MD 20857

Shipping Address (FedEx, UPS, etc.):

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5600 Fishers Lane

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FOR FURTHER INFORMATION CONTACT:

Jenae Bennis, Telephone: 301-427-1496 or Email: epc@ahrq.hhs.gov.

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 a *Living Systematic Review on Plant-Based Treatment for Chronic Pain*. AHRQ is conducting this systematic review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

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 *Plant-Based Treatment for Chronic Pain*, including those that describe adverse events. The entire research protocol is available online at:

<https://effectivehealthcare.ahrq.gov/products/plant-based-chronic-pain-treatment/protocol>

This is to notify the public that the EPC Program would find the following information on Plant-Based 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, 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 is very beneficial to the 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.

Key Questions (KQs)

1. In adults with chronic pain, what are the benefits of cannabinoids?
2. In adults with chronic pain, what are the harms of cannabinoids?
3. In adults with chronic pain, what are the benefits of kratom or other plant-based substances for treatment of chronic pain?
4. In adults with chronic pain, what are the harms of kratom or other plant-based substances for treatment of chronic pain?

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

PICOTS Element	Inclusion Criteria	Exclusion Criteria
Population	All KQs: Adults (including pregnant or breastfeeding women) 18 years and older with chronic pain (>12 weeks or pain persisting past the time for normal tissue healing). See categorization of specifically included pain populations below.	All KQs: Children and adolescents <18 years old; adults with acute or subacute pain; patients at end of life or in palliative care (e.g. with late stage cancer-related pain)

PICOTS Element	Inclusion Criteria	Exclusion Criteria
Interventions	KQs 1 and 2: Cannabinoids (including synthetics) using different delivery mechanisms such as oral, buccal, inhalational, topical, or other administration routes KQs 3 and 4 : Kratom or other plant-based substances; co-use of kratom or other plant-based substances and opioids All KQs: Co-use of other drugs for pain	All KQs: Non-plant-based interventions, capsaicin, herbal supplements
Comparators	All KQs: Any comparator, or usual care	All KQs: No comparison
Outcomes	All KQs: Primary efficacy outcomes (i.e., pain, function, disability, pain interference); harms and adverse effects (e.g., dizziness, nausea, sedation, development of cannabis use disorder); secondary outcomes (i.e., psychological distress including depression and anxiety, quality of life, opioid use, sleep quality, sleep disturbance, health care utilization)	All KQs: Other outcomes
Time of follow-up	All KQs: short term (1 to <6 months), intermediate term (6 to <12 months), long term (≥ 1 year)	All KQs: studies with <1-month of treatment or followup after treatment
Setting	All KQs: Any nonhospital setting or setting of self-directed care	All KQs: Hospital care, hospice care, emergency department care
Study design	All KQs: RCTs; observational studies with a concurrent control group for harms, and to fill gaps in the evidence for benefits	All KQs: Other study designs

Abbreviations: RCT = randomized controlled trial

Dated: November 27, 2020.

Marquita Cullom,

Associate Director.

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