



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Supplemental Evidence and Data Request on Evaluation of Mental Health Applications

**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 *Evaluation of Mental Health Applications*, 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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](mailto: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 Benns, Telephone: 301-427-1496 or Email: [epc@ahrq.hhs.gov](mailto: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 *Evaluation of Mental Health Applications*. AHRQ is conducting this technical brief 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 *Evaluation of Mental Health Applications*, specifically the following:

- Characteristics and minimal standards in terms of appropriateness and effectiveness of available behavioral health applications including adverse events.
- Behavioral health applications assessment frameworks for evaluation/scoring tools
- The entire research protocol is available online at:

<https://effectivehealthcare.ahrq.gov/products/mental-health-apps/protocol>

This is to notify the public that the EPC Program would find the following information on *Evaluation of Mental Health Applications* 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 technical brief will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.*

### **Guiding Key Questions (KQs)**

1. What characteristics and minimal standards of available behavioral health mobile applications need to be analyzed in existing tools to assess the appropriateness (to various stakeholders) and effectiveness of available apps to include, but not limited to:
  - Accessibility including ease of use, health literacy, 508 compliance, digital equity, cost
  - App background including funding source, purpose
  - Security features and privacy policy such as data ownership/usage
  - Clinical foundation and linkage to current evidence-base
  - Usability, including interoperability across platforms, stability
  - Therapeutic goals, linkage to the provider, crisis warning notification/alert system
2. Identify or develop an assessment framework for evaluation/scoring tools (e.g., websites) and apply the framework to help consumers, family members and peer supports, providers and health systems select behavioral health mobile applications. The framework will take into account current FDA status on the use and classification of risks of apps in healthcare.

Dated: May 21, 2021.

**Marquita Cullom,**

*Associate Director.*

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