<u>Evidence-based Synthesis Program</u>



The Effectiveness and Risks of Cranial Electrical Stimulation for the Treatment of Pain, Depression, Anxiety, PTSD, and Insomnia: A Systematic Review

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PREFACE

The VA Evidence-based Synthesis Program (ESP) was established in 2007 to provide timely and accurate syntheses of targeted healthcare topics of particular importance to clinicians, managers, and policymakers as they work to improve the health and healthcare of Veterans. QUERI provides funding for ESP Centers, and each Center has an active University affiliation. Center Directors are recognized leaders in the field of evidence synthesis with close ties to the AHRQ Evidence-based Practice Centers. The ESP is governed by a Steering Committee comprised of participants from VHA Policy, Program, and Operations Offices, VISN leadership, field-based investigators, and others as designated appropriate by QUERI/HSR&D.

The ESP Centers generate evidence syntheses on important clinical practice topics. These reports help:

- Develop clinical policies informed by evidence;
- Implement effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures; and
- Set the direction for future research to address gaps in clinical knowledge.

The ESP disseminates these reports throughout VA and in the published literature; some evidence syntheses have informed the clinical guidelines of large professional organizations.

The ESP Coordinating Center (ESP CC), located in Portland, Oregon, was created in 2009 to expand the capacity of QUERI/HSR&D and is charged with oversight of national ESP program operations, program development and evaluation, and dissemination efforts. The ESP CC establishes standard operating procedures for the production of evidence synthesis reports; facilitates a national topic nomination, prioritization, and selection process; manages the research portfolio of each Center; facilitates editorial review processes; ensures methodological consistency and quality of products; produces "rapid response evidence briefs" at the request of VHA senior leadership; collaborates with HSR&D Center for Information Dissemination and Education Resources (CIDER) to develop a national dissemination strategy for all ESP products; and interfaces with stakeholders to effectively engage the program.

Comments on this evidence report are welcome and can be sent to Nicole Floyd, ESP CC Program Manager, at <u>Nicole.Floyd@va.gov</u>.

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EXECUTIVE SUMMARY

ABSTRACT

Background

Cranial electrical stimulation (CES) is increasing in popularity as a treatment, yet of uncertain clinical benefit.

Purpose

To review evidence about the effectiveness and harms of CES for patients with chronic painful conditions, depression, anxiety, PTSD, and insomnia.

Data Searches

Searches of multiple databases from inception to 10/10/2017; reference-mining of included articles; recommendations from experts.

Study Selection

Randomized controlled trials of CES versus usual care or sham CES.

Data Extraction

Data extraction was performed in duplicate. The Principal Investigator performed the Strength of Evidence assessment.

Data Synthesis

28 relevant publications from 26 RCTs met eligibility criteria. Two small RCTs compared CES to usual care, neither reported a statistically significant benefit. Four old RCTs and one modern RCT provided low strength evidence of a possible benefit of CES compared to sham in patients with anxiety and depression. RCT results were conflicting for fibromyalgia, headache, other painful conditions, depression and insomnia. There is low strength evidence that CES does not cause serious side effects. All RCTs were judged to be at high risk of bias because of the possibility of unblinding of therapy.

Limitations

All RCTs were judged to be at high risk of bias; there were too few RCTs of the same patient population and intervention to support statistical pooling.

Conclusions

The evidence is insufficient to support conclusions that CES has clinically important effects on headache, fibromyalgia, neuromuscular pain, depression, PTSD, or insomnia. There is low-strength evidence for a possible beneficial effect of modest size in patients who have anxiety with depression. CES is probably safe, in that no serious side effects have been reported in RCTs, although reporting bias is present.

