Cranial Electrotherapy Stimulation for Major Depressive Disorder

PHCoE
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Q: What is cranial electrotherapy stimulation?

A: Cranial electrotherapy stimulation (CES), also known as "transcranial electrostimulation," "electrosleep therapy," and "electronarcosis," is a Food and Drug Administration (FDA)-approved, non-invasive treatment for insomnia, anxiety, and depression. CES involves the transcranial application of electrical magnetic fields to the scalp at levels that do not induce seizure (Rosa & Lisanby, 2012). CES includes a range of techniques, but all methods use low-level alternating electrical signals applied to the scalp or earlobes. In the United States, CES devices require a prescription from a licensed health care practitioner, though the treatment itself is self-administered using hand-held, electrical devices and there is significant variation in frequency and duration of treatment (Kavirajan et al., 2014).

Q: What is the potential mechanism of action underlying CES?

A: While the mechanism of action of CES is unclear, CES devices provide a weak alternating electrical current which is thought to modulate cortical excitability. CES is hypothesized to enhance naturally occurring neurological activity (Zaghi, Acar, Hultgren, Boggio, & Fregni, 2010). Research has shown that weak cranial currents applied during sleep can affect memory; weak electric fields can affect neural function; and changes in neurotransmitters and hormones can be observed, including increased levels of monoamines in the brain (Rosa & Lisanby, 2012; Kavirajan et al., 2014).

Q: Is CES recommended as a treatment for Major Depressive Disorder (MDD) in the Military Health System (MHS)?

A: No. The *2022 VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder* does not include CES as a treatment for MDD.

The MHS relies on the VA/DoD clinical practice guidelines (CPGs) to inform best clinical practices. The CPGs are developed under the purview of clinical experts and are derived through a transparent and systematic approach that includes, but is not limited to, systematic reviews of the literature on a given topic and development of recommendations using a graded system that takes into account the overall quality of the evidence and the magnitude of the net benefit of the recommendation. Recommendations for or against a treatment may be characterized as strong or weak based on a variety of factors (e.g., confidence in the quality of the evidence, weight of treatment benefits versus risks, feasibility). The CPGs also state if there is insufficient evidence to develop a recommendation. A further description of this process and CPGs on specific topics can be found on the VA clinical practice guidelines website.

Q: Do other authoritative reviews recommend CES as a treatment for MDD?

A: No. Other authoritative reviews have not substantiated the use of CES for MDD.

Other recognized organizations conduct systematic reviews and evidence syntheses on psychological health topics using grading systems similar to the VA/DoD CPGs. Notable among these is Cochrane, an international network that conducts high-quality reviews of healthcare interventions.

- Cochrane: A 2014 systematic review (Kavirajan et al., 2014) found no high-quality clinical trials of CES in people with acute depression. This review excluded trials of CES in chronic or refractory depression.

Q: What conclusions can be drawn about the use of CES as a treatment for MDD in the MHS?

A: FDA approval of CES for the treatment of MDD was obtained in 1979, before the requirement for submission of clinical trial data on safety and efficacy. Since then, new CES devices have been cleared for market without submission of this data due to an FDA provision permitting new devices be granted marketing approval if deemed "substantially equivalent" to an existing, approved device (Hines et al., 2010). Much of the existing research done on CES for depression suffers from methodological shortcomings, including failure to use standardized diagnostic criteria to diagnose depression, lack of a sham comparator condition, and inadequate blinding due to the sham CES not producing a local tingling sensation (Kavirajan et al., 2014). The current state of the CES evidence base is not mature enough to recommend CES as an evidence-based treatment for patients with MDD in the MHS. For additional guidance on selecting a treatment for MDD, please visit the PHCoE Clinician Resources section of the intranet and navigate to clinical support tools.

References

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