Efficacy of Cranial Electrotherapy Stimulation for Anxiety, PTSD, Insomnia and Depression: US Military Service Members and Veterans Self Reports

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Abstract

Cranial electrotherapy stimulation (CES) is prescribed for US Service Members and veterans for the treatment of anxiety, PTSD, insomnia and depression. The purpose of this study was to examine US Service Members' and veterans' perceptions of the effectiveness and safety of CES treatment. Service Members and Veterans (N=1,514) who had obtained a CES device through the US Department of Defense or US Veterans Affairs Medical Center from 2006-2011 were invited to participate in the web based survey via email. One hundred fifty-two participants returned questionnaires. Data were analyzed using descriptive statistics. Participants reported clinical improvement of ≥ 25%) from using CES for anxiety (66.7%), PTSD (62.5%), insomnia (65.3%) and depression (53.9%). The majority of these participants reported ≥ 50% clinical improvement. Almost all (99.0%) respondents perceived CES to be safe. Those individuals who were not taking any prescription medication rated CES more effective than the CES and prescription medication group. CES provides US Service Members and veterans with a safe, non-invasive, non-drug, easy to use treatment for anxiety, PTSD, insomnia and depression that can be used in the clinical setting or self-directed at home.

Background Information

Cranial electrotherapy stimulation (CES) is a non-invasive US FDA-cleared prescriptive medical treatment for anxiety, insomnia and depression. About the size of a smart phone, a CES device uses electrodes typically placed on both ear lobes to send a low level (< 1 milliampere), pulsed electrical current transcranially through the brain.[1] An EEG analysis of 30 subjects who received one 20 minute CES treatment showed significant increases in alpha activity (increased relaxation) and decreases in delta activity (increased alertness) and theta activity (increased ability to focus attention).[2] These changes induce a calm, relaxed, yet alert state.

CES Safety and Efficacy

Based on a survey of Alpha-Stim CES users from 2007-2011, there were an estimated 8,248,920 Alpha-Stim® CES treatments.[3] Reported side effects were all mild and self-limiting; consisting of headache, dizziness and skin irritation at the electrode site. From all sources (EPI survey and the scientific literature) side effects were ≤ 1% with no serious side effects reported during the 31 years that CES has been on the market.[4]

Double-blind sham controlled randomized clinical trials using valid and reliable measurement scales have shown that CES significantly decreases anxiety,[5-8] insomnia[9-10] and depression.[11-12] Open clinical studies have confirmed that CES decreases symptoms associated with PTSD.[13] Cohen's *d* effect sizes for anxiety ranged from *d* = -0.60 (medium) to *d* = -1.53 (very high).[5,7-8,12] Reported Cohen's *d* effect size for depression is *d* = -0.41[12] (small) while effect sizes for insomnia are *d*=0.30[9] (small) and *d*=0.54[10] (medium).

Author's Credentials

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Methods

The Questionnaire. Participants either voluntarily chose to respond or not to respond to the questionnaire. One hundred fifty-two (N=152) responses to the questionnaire were received, yielding a response rate of 10%. The questionnaire contained 27 questions that covered the following areas: demographic information, prescription medication use, current exercise activity, and questions asking respondents to rate the effectiveness of CES technology for treating anxiety, PTSD, insomnia and depression. Seven (7) questionnaires did not include any effectiveness and safety data. Thus, the valid sample size was N=145 for the analysis of these questions.

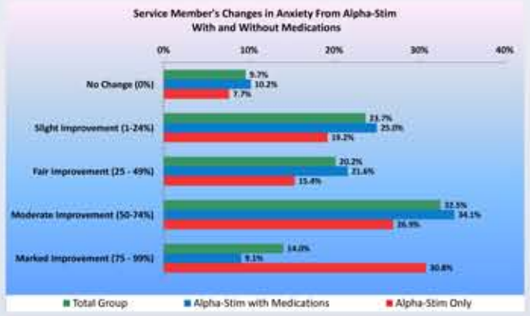
SAMPLE QUESTION

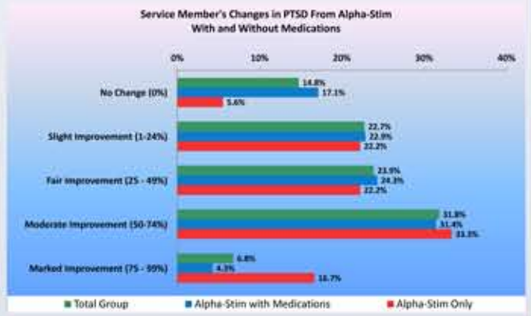
If you are using CES for ANXIETY, since starting CES rate your improvement as:

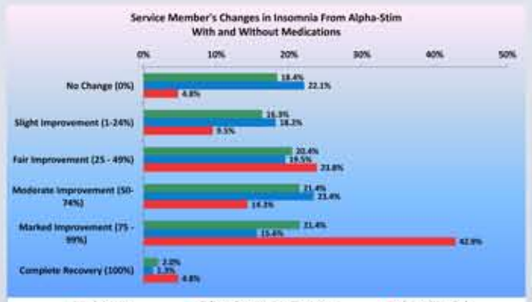
a. Worse (negative change) b. No change (0%) c. Slight improvement (1 to 24%) d. Fair improvement (25 to 49%)
e. Moderate improvement (50 to 74%) f. Marked improvement (75 to 99%) g. Complete recovery (100%)

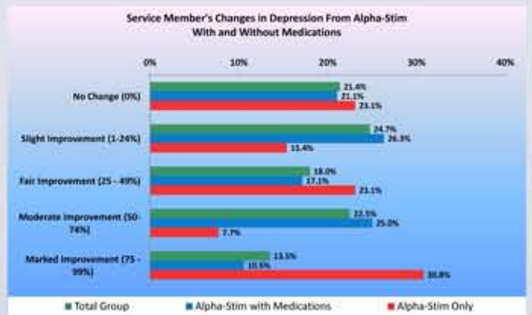
Results

Data were analyzed using descriptive statistics. In addition to analysis of improvement related questions on anxiety, PTSD, insomnia and depression, questions were also interpreted in light of respondents taking or not taking prescription medication while using CES.

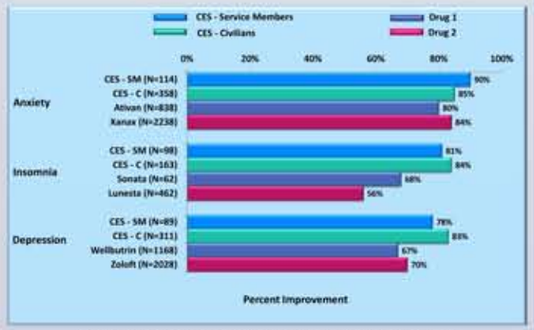








Service Members and Veterans who had improvement of substantial clinical importance (≥ 50%).



Comparison of respondents perceived responses to drug therapy with Service Members (SM) and civilians (C) perceived responses to CES

Materials

The CES Device. The Alpha-Stim CES device with ear clips electrodes (0.5 Hz, 100 – 600 µA, 50% duty cycle), was used in this study. Two electrodes that clip onto the ear lobes are used to send a mild electrical current (< 1 millampere) through the brain. Treatment duration typically lasted 20 minutes to at least 1 hour 1 time a day for a minimum of 3 weeks.

Conclusion

Respondents perceived CES as an effective and safe treatment for anxiety, PTSD, insomnia and depression. These findings are consistent with the findings of previous research studies on CES. In this study, it appears that medication may be a confounding variable that influences the effectiveness of CES. The need to control for medications (type and dose) in future CES studies is a valuable outcome of this study. CES can be used to provide patients with a safe, non-invasive, non-pharmacologic treatment for anxiety, PTSD, insomnia and depression that can be used in the clinic or self-directed at home.

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