A clinical trial of cranial electrotherapy stimulation for anxiety and comorbid depression

Barclay TH, Barclay RD. A clinical trial of cranial electrotherapy stimulation for anxiety and comorbid depression. *Journal of Affective Disorders*, 164:171-177, 2014. Presented at the American Psychological Association National Conference, Honolulu, HI, July 2013.

OBJECTIVE

The purpose of this study was to examine the efficacy of Alpha-Stim CES for the treatment of anxiety and comorbid depression.

Design

This was a 5 week study that used a randomized, sham controlled, double-blind design in which subjects in the treatment and sham groups participated in a daily one hour treatment of CES using active or sham Alpha-Stim CES devices. The sham device was identical to the active CES device, except it did not conduct an electrical current. The active CES device was set to 100 µA, a subsensory level. The subjects, investigators, physicians and staff were all masked as to the identity of the device.

Primary Effectiveness Endpoint

The primary effectiveness endpoint was the change from baseline in the last post-treatment scores on the Hamilton Anxiety Rating Scale (HAM-A) compared to the sham treatment at the endpoint of the 5 week study.

Secondary Outcome Measures

The secondary outcome measure was the change from baseline in the last post-treatment scores on the Hamilton Depression Rating Scale (HAM-D17) compared to the sham treatment at the endpoint of the 5 week study.

Key Inclusion Criteria

Diagnosis of an anxiety disorder was verified by a licensed clinical psychologist in an interview using the DSM-IV criteria with a score > 15 on the HAM-A.

Protocol Summary

Baseline measures were done prior to the first CES treatment. Subjects had 5 weeks of daily CES treatment for 60 minutes with either an active or sham device. Outcome measures were done at the end of 1, 3 and 5 weeks.

Outcome Measures

The Hamilton Anxiety Rating Scale and the Hamilton Depression Rating Scale 17 were used to quantify the severity of anxiety and depressive symptoms and to identify the response to Alpha-Stim CES.

Pre-Specified Criteria for Success

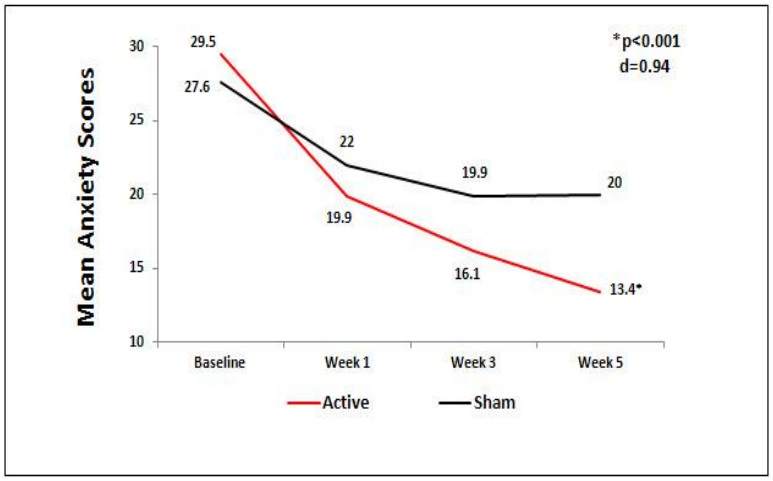
Pre-specified criteria for success was set at ≥50% improvement for anxiety and ≥50% improvement for depression. Dworkin 2008, established that ≥50% improvement is substantial clinical importance.

Subjects

Of the 115 subjects who enrolled in the study, 108 subjects completed the study. There were 57 subjects in the active CES group and 51 subjects in the sham CES group.

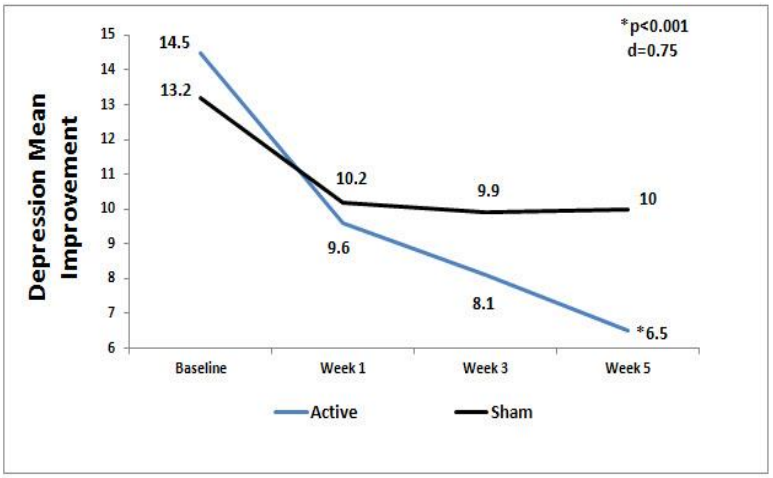
Anxiety

There was a significant difference between the active and sham groups for anxiety from baseline to endpoint of study ($p<0.001$, $d=0.94$). The mean decrease in HAM-A scores among the active group was 16.14. This was more than 2 times the mean decrease (7.58) of the sham group (See Figure 1). Eighty-three percent (83%) of the active CES group had a decrease of ≥ 50% decrease in anxiety scores on the HAM-A from baseline to endpoint of study.



Depression

There was a significant difference between the active and sham groups for depression from baseline to endpoint of study ($p<0.001$, $d=0.78$). The mean decrease in HAM-D17 scores among the active group was 8.04. This was more than 2.3 times the mean decrease of (3.26) of the sham group (See Figure 2). Eighty-two percent (82%) of the active CES group had a ≥ 50% decrease in depression scores on the HAM-D17 from the baseline to the endpoint of study.



CONCLUSION

This is a strong study of 115 patients that used a randomized, sham controlled, double-blind design and was adequately powered. Individuals had to meet the DSM-IV criteria for an anxiety disorder to be in the study. A pre-qualified measurement of success was set at ≥ 50% decrease in anxiety. Eighty-three percent (83%) of the patients achieved this substantial mark. Alpha-Stim CES was shown to be an effective treatment option for anxiety and comorbid depression.

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