

# Efficacy of cranial electric stimulation for the treatment of insomnia: A randomized pilot study.

Lande RG, Gragnani C. Efficacy of cranial electric stimulation for the treatment of insomnia: A randomized pilot study. *Complementary Therapies in Medicine*, 21, 8-13, 2013.

## OBJECTIVE

The purpose of this pilot study was to examine the efficacy of Alpha-Stim CES for the treatment of insomnia.

### Design

This was an IRB approved 5 day pilot study that used a randomized, sham controlled, double-blind design. The treatment and sham groups participated in 60 minute treatments of Alpha-Stim CES using either active or sham devices for 5 consecutive days. 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  $\mu$ A, 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 total sleep time (from sleep log) for the active group compared to the sham treatment group at the endpoint of study.

### Secondary Outcome Measures

The secondary outcome measure was the change from baseline in the last post-treatment scores on the time to sleep onset and number of awakenings from sleep logs for active CES subjects compared to the sham treatment at the endpoint of study.

### Key Inclusion Criteria

Male and female active duty Service Members receiving mental health care at the Psychiatry Continuity Service at Walter Reed National Military Medical Center, Bethesda, Maryland with a score  $\geq 21$  on the psychiatric impairment rating scale (PIRS).

### Protocol Summary

Subjects were randomly assigned to a active or sham CES group by the investigator who randomly selected a device from the box containing 10 active CES devices and 10 sham CES devices. Each subject received a 60 minute active or sham CES treatment daily for 5 days. Subjects completed a sleep log daily for the 5 days. After the 5 days, subjects completed a sleep log at 2 follow-up points, 3 days and 10 days.

### Outcome Measures

The total sleep time was measured from subjects' reports in their daily sleep log.

### Subjects

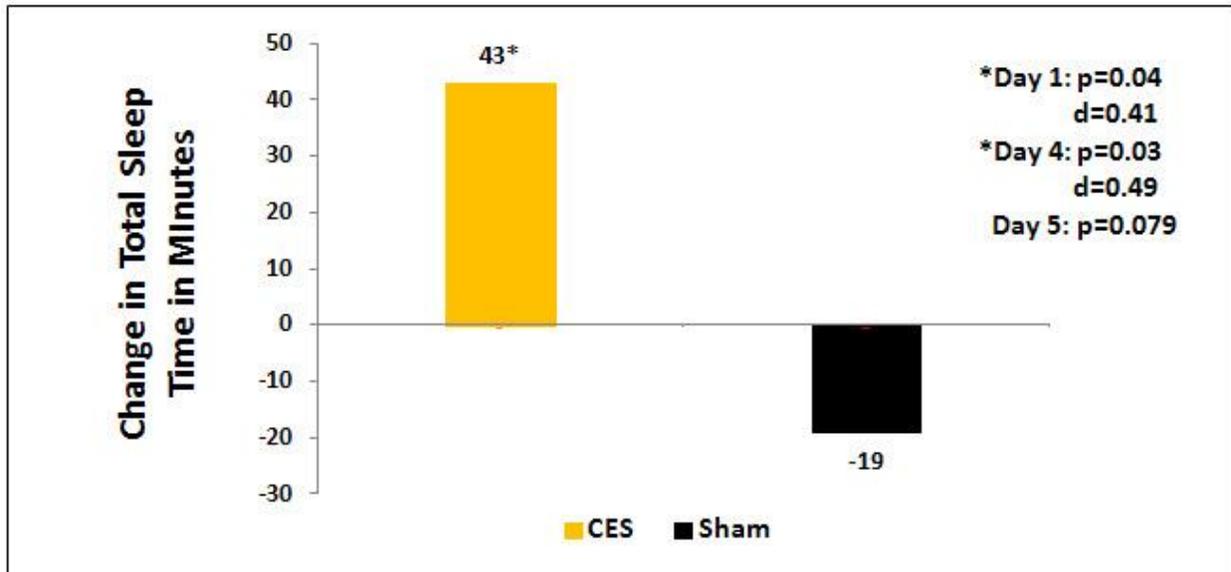
Fifty-seven (57) subjects enrolled and completed the study; 46 males and 11 females. There were 28 in the active CES group and 29 in the sham CES group. Over three-quarters of the subjects completed the full 5 CES treatments (N=44, 77%).

### Data Analysis

Data were analyzed using descriptive statistics, chi-square, 2 way analysis of variance and independent sample t-tests.

### Total Sleep Time

The total time slept approached significance ( $p=0.079$ ) on day 5 in favor of the active CES group. The active CES group average 43 extra minutes total sleep time when compared to the sham CES group. In the sham group subjects reported an average of 19 minutes less sleep time. Men in the active CES group who completed 5 sessions of CES reported a significant improvement in total time slept at 2 points in the study, after the initial ( $p=0.04$ ,  $d=0.41$ ) and after the fourth ( $p=0.03$ ,  $d=0.49$ ) treatments as compared to men in the sham group.



### CONCLUSION

This is a study of 57 active duty Service Members receiving mental health care at Walter Reed National Medical Center with a score  $\geq 21$  on the psychiatric impairment rating scale (PIRS). Subjects participated in 60 minutes of either sham or active treatments of Alpha-Stim CES. While the researchers noted the major limitation to the study was the low number of Alpha-Stim CES treatments, the active group still reported +43 more minutes of sleep a night compared to -19 minutes with the sham group.

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