Alpha-Stim® Improves Sleep Quality in Placebo-Controlled Randomized Clinical Trial

Alpha-Stim® significantly outperformed sham stimulation for the treatment of insomnia in a controlled clinical trial.

Primary Outcome: Change in Pittsburgh Sleep Quality Index (PSQI) and Heart Rate Variability (HRV).

Study Design: Randomized, controlled trial included 40 participants ages 18 to 44 years of age. The active treatment was five days per week 20 minutes of Alpha-Stim administered for three weeks.

I**ntervention Details:** Alpha-Stim is a cranial electrotherapy (CES) non-invasive brain stimulation device that delivers low-amplitude electric current to the brain via stimulation of cranial nerves and temporal cortex with a patented rhythmic, low-amplitude waveform applied by earclip electrodes. Alpha-Stim is FDA cleared for the treatment of anxiety and insomnia.

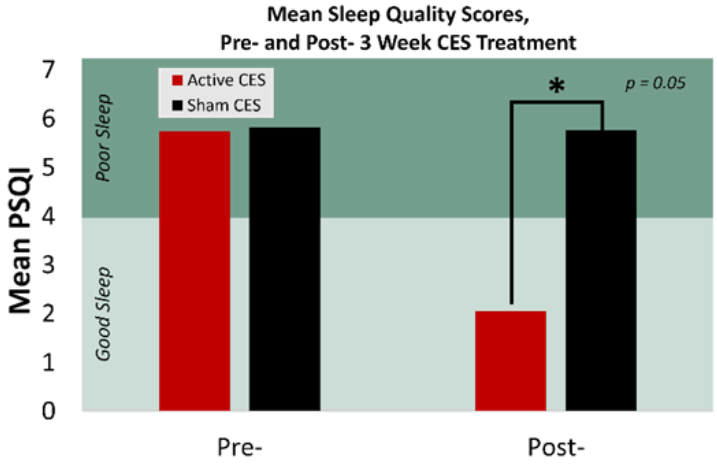
Alpha-Stim was demonstrated to be superior to placebo stimulation for the treatment of anxiety symptoms in a large, randomized, placebo-controlled clinical trial. Given the bidirectional relationship between insomnia and anxiety, Alpha-Stim may treat insomnia by targeting the anxious rumination associated with anxiety.

Alpha-Stim® for the Treatment of Insomnia

Non-pharmacological treatment of insomnia has broad clinical appeal due to the multitude of concerns about treatment with prescription medication, including drowsiness, difficulty concentrating, headaches, nausea, dry mouth, oversleeping, and nightmares. Alpha-Stim non-invasive brain stimulation is FDA-cleared for the treatment of insomnia. A recent clinical trial demonstrated improved sleep quality when compared to placebo (sham stimulation).

Improved sleep quality:
Post-treatment sleep quality (PSQI) improved by 64% in the active group compared to 1% in the sham group.

Increased sleep duration:
On average, patients in the active Alpha-Stim group showed a trend of 2 additional hours of sleep post-treatment compared to pre-treatment. Patients in the sham group showed no improvement in sleep duration.



In addition, Alpha-Stim improved markers of HRV, suggesting a successful engagement of the autonomic nervous system as a mechanism of action of Alpha-Stim for insomnia.

Conclusions

The clinically meaningful and significant improvement of both sleep quality and sleep duration in this randomized, sham-controlled study demonstrates the clinical utility of Alpha-Stim as a medication-free treatment option for the treatment of insomnia. Given the limited side-effects of Alpha-Stim due to the low-amplitude current, this study supports Alpha-Stim for the treatment of insomnia in evidence-based practice.

Khyatee, S., Sarker, A., & Aggarwal, R. (2019). Impact of Cranial Electrotherapy Stimulation Based Analysis of Heart Rate Variability in Insomnia. In: Prateek, M., Sharma, D., Tiwari, R., Sharma, R., Kumar, K., Kumar, N. (eds) Next Generation Computing Technologies on Computational Intelligence. NGCT 2018. *Communications in Computer and Information Science*, Vol 922. Springer, Singapore.

epi
ELECTROMEDICAL
Products International, Inc.

About Alpha-Stim® & EPI

Electromedical Products International, Inc. (EPI) is a leading medical device company in non-invasive brain stimulation for psychiatric disorders and microcurrent therapy for pain management. The company is the manufacturer of Alpha-Stim, a prescription medical device available in more than 50 countries worldwide (prescription not required outside the U.S.).

Alpha-Stim is FDA cleared to provide fast, safe, and effective treatment of anxiety and insomnia via cranial electrotherapy stimulation (CES) and pain via microcurrent electrical therapy (MET).

Learn more at www.alpha-stim.com.

ALPHA-STIM®