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

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Summary
Objectives: This pilot study examined the potential efficacy of cranial electric stimulation for the treatment of insomnia.
Design: The researchers tested the hypothesis through a randomized, double-blind, and placebo controlled clinical trial. The researchers approached eligible subjects who scored 21 or above on the Pittsburgh Insomnia Rating Scale. The researchers then randomly assigned the subjects to receive either an active or sham device. Each study subject received 60 min of active or sham treatment for five days. Following each intervention the subjects completed a sleep log, as well as three and ten days later.
Setting: The researchers conducted the study among active duty service members receiving mental health care on the Psychiatry Continuity Service (PCS), Walter Reed National Military Medical Center in Bethesda, MD.
Main outcome measures: The study's primary outcome variables were the time to sleep onset, total time slept, and number of awakenings as reported by the subjects in the serial sleep logs. The researchers identified a nearly significant increase in total time slept after three cranial electric stimulation treatments among all study subjects. A closer examination of this group revealed an interesting gender bias, with men reporting a robust increase in total time slept after one treatment, decay in effect over the next two interventions, and then an increase in total time slept after the fourth treatment. The researchers speculate that the up and down effect on total time slept could be the result of an insufficient dose of cranial electric stimulation.

Nearly everyone can recall a particularly poor night's sleep. Perhaps a troubling day at work or an anxiety laded looming event launches incessant bedtime ruminations that prevent the peaceful prerequisite. Even so, for most people a restful night's rest is the norm. For another group, affecting anywhere from 10 to 35% 0f Americans, each night brings tossing, turning, and all manner of sleep related turmoil.[1] In the beginning, the insomniac probably turns to readily available home remedies and nonprescription retail nostrums. The failure of these interventions to produce

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a restorative night's sleep often drives the sufferer to consider other options.

When home remedies fail the chronic insomniac seeks relief most commonly from alcohol, prescription medications, or both. In one study, 15% of chronic insomniacs reported using alcohol to initiate sleep.[2] Prescription medication choices broadly include benzodiazepines, nonbenzodiazepines, and antidepressants. There appears to be a long term trend favoring antidepressants, perhaps out of concern for benzodiazepine misuse.[3] In a similar manner, prescriptions for nonbenzodiazepine sedative hypnotics surged 30-fold between 1994 and 2007, far outpacing benzodiazepine use.[4] The perpetual use of prescription medications, averaging nearly four years for some chronic insomniacs, bolsters the concern for misuse.[5] Another troubling trend is the association between sedative-hypnotic sleep medications and suicidality.[6]

Chronic insomnia by itself is bad enough but the suffering is greatly magnified when the condition coexists with another problem. Both sleep latency and short sleep each independently exacerbates depression and delays a return to a normal mood state.[7] A pattern of poor sleep preceding a traumatic event increases the likelihood of post-traumatic stress disorder (PTSD).[8] The increasing recognition of an association between insomnia, nightmares, and other sleep problems with suicidal ideation has positive clinical relevance.[9,10] Insomnia is also over represented among individuals with physical conditions such as heart disease, high blood pressure, stomach ulcers, and asthma.[11]

The pervasiveness of chronic insomnia, and concerns about long term medication use and misuse, inspires clinicians' interest in nonpharmacologic treatments. Of particular note are highly efficacious behavioral interventions such as stimulus control and sleep restriction.[12] Cognitive behavior therapy is another evidence based treatment for chronic insomnia.[13] Rigorous studies examining the plethora of complementary and alternative therapies for insomnia are few and far between. Where such studies exist, there is some evidence that acupressure, tai chi, and yoga may be effective insomnia treatments.[14]This study examines a relatively unusual treatment approach using cranial electric stimulation (CES). CES involves the administration of miniscule electrical currents, often no more than 1 or 2 mA, to the head of individuals suffering from depression, anxiety, and insomnia.[15] Using tiny amounts of electrical energy for therapeutic effect has a rich history but modern practices date to the mid-twentieth century. At that time, clinicians referred to the practice as electrosleep therapy. A small, early randomized controlled trial of electrosleep technology reported a transient improvement with insomnia but a worsening of primary depression.[16] In another study from the same era, a researcher conducted a small double blind study specifically examining the impact of electrosleep on sleep latency.[17] The researcher reported a significant decline in sleep latency and an overall improvement in sleep efficiency. Yet another study found electrosleep therapy ineffective.[18] A few years later, a small double blind study reported an enduring improvement among insomnia subjects from electrosleep therapy that lasted for two years after initial treatment.[19]

Researchers published a meta-analysis of ''the most carefully conducted randomized controlled trials of CES versus sham treatment''.[20] With that rigorous approach the researchers identified 18 studies. In all but two studies the researchers were not blinded. With that limitation in mind, the meta-analysis resulted in CES being superior to sham only for the treatment of anxiety. The controversy over the efficacy of CES continued when another group of researchers criticized the methodology of this meta-analysis.[21]

Interest in CES continues unabated. Review articles tout the benefits, emphasizing the safety of the clinical practice and suggesting a role in reducing long term medication use.[22] Another reviewer, while not specifically commenting on the efficacy of CES for insomnia, once again commented on the need for sound methodological research.[23] Researchers in another study mounted an effort in that direction and through a randomized, double-blind controlled, clinical trial reported a ''trend toward statistically significant differences in reports of daily disturbances of sleep...'' with active CES treatment.[24]

The investigators in this study used the Alpha-Stim SCS cranial electrotherapy stimulator manufactured by Electromedical Products International, Inc. (2201 Garrett Morris Parkway, Mineral Wells, TX 76067-9034). When used in clinical practice the Alpha-Stim SCS cranial electrotherapy stimulator produces asymmetric rectangular electrical waves with a pulsed frequency of 0.5 Hz/s and 10 to 500 μA continuously adjustable current. The current is transmitted from the device through wires that terminate in conductive ear clips. The ear clips are attached to the person's earlobes.[25]

The exact mechanism of action of CES is not fully understood. Researchers have theorized that CES may affect endorphin release or modulate neurotransmitter activity. Placement of the electrodes on the earlobes probably permits the microcurrent to travel across local cranial nerves to the brainstem, thalamus and cortex. Functional magnetic resonance imaging (fMRI) suggests that CES results in cortical deactivation in the midline prefrontal and parietal areas of the brain. Researchers speculate that the brain deactivation may decrease obsessive worry and increase focused attention.[26] Electroencephalographic analysis also suggests that CES decreases anxiety by increasing alpha waves.[27,28] Ruminations and anxiety both inhibit sleep and the putative mechanisms of action of CES on brain activity in decreasing both would suggest a favorable outcome for the chronic insomniac. The researchers' objective was to test the efficacy of CES for insomnia through a randomized, double-blind, and placebo controlled pilot clinical trial.

Method

The researchers conducted the study among active duty service members receiving mental health care on the Psychiatry Continuity Service (PCS), Walter Reed National Military Medical Center in Bethesda, MD. The PCS provides evidenced based care in a multidisciplinary setting for service members needing a partial hospital level of care. Common diagnoses include combat related post-traumatic stress disorder (PTSD), mood disorders, substance disorders, and to a lesser degree psychosis. The researchers' recruited subjects