

ALPHA-STIM CRANIAL ELECTROTHERAPY STIMULATION: THE NEW RX FOR ANXIETY, INSOMNIA, DEPRESSION AND PAIN MANAGEMENT

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The impact of multiple deployments into the wartime theater, continued exposure to combat, endless family separations, and returning to the home front to face economic hardships only convey a small portion of those stressors to which our men and women in uniform are exposed. There is, however, a proven, safe, and effective means of re-establishing a healthier perspective on life. Alpha-Stim® cranial electrotherapy technologies (CES) are a group of prescription medical devices cleared by FDA and the DoD/VA for use as stand-alone or complementary therapies for anxiety, insomnia, depression and pain management. The three Alpha-Stim devices are all pocket-sized and work through ear clip electrodes to deliver a very low level current of less than 1 milliampere directly into the brain for 20 to 60 minute sessions. For pain management, electrode patches or probes offer rapid and cumulative relief.

The proprietary Alpha-Stim waveform is supported by more scientific research than any other therapeutic medical device. The research section of www.alpha-stim.com contains more than 55 studies and reviews, including meta-analyses revealing more robust effect sizes than seen with most other interventions for the four indications. Side effects are rare, minor, and self-limiting consisting of headaches (0.10% in CES studies involving 10,556 subjects) and skin reactions at the electrode sites (0.07%).

The brain functions electrically and can be readily altered by electrical interventions. Alpha-Stim technology is believed to affect the limbic system, the reticular activating system and the hypothalamus, and to stimulate regions that control pain messages, neurotransmitter formation, and hormone production via the hypothalamic-pituitary axis. Alpha-Stim treatments induce significant changes in the electroencephalogram (EEG), increasing alpha (8-12 Hz) relative power and decreasing relative power in the delta (0-3.5 Hz) and beta (12.5-30 Hz) frequencies. Increased alpha correlates with improved relaxation and increased mental alertness or clarity. Decreased delta waves suggest reduced drowsiness. Beta reductions exhibited were primarily between 20-30 Hz. Decreases in 20-30 Hz correlate with reductions in anxiety, ruminative thought, and obsessive/compulsive-like behaviors. Low-resolution electromagnetic tomography (LORETA) and functional magnetic resonance imaging (fMRI) studies showed that the proprietary Alpha-Stim waveform reached all cortical and subcortical areas of the brain, producing changes consistent with anxiolytic effects.

A series of meta-analyses published over the past few years in the journal *Practical Pain Management* also reconfirmed findings in the research and identified robust effect sizes for the indications of CES. Large effect sizes (>50% improvement) are well established across a number of randomized clinical trials (double blind studies) and open clinical trials using Alpha-Stim in the treatment of a wide variety of psychological and physical disorders. A meta-analysis of CES for depression that included 20 studies encompassing 975 subjects revealed a mean effect size of .50 (equivalent to 50% improvement, considered a large effect size). A meta-analysis of CES for anxiety, which included 41 studies comprising 2,049 participants, revealed a mean effect size

of .57. A recent study of CES involving subjects diagnosed with chronic and pervasive anxiety (Generalized Anxiety Disorder) demonstrated a 50% average reduction in self-reported anxiety. A meta-analysis of 20 studies involving 1,083 participants that received CES for insomnia achieved a mean effect size of .64.

Pain management is usually accomplished within 2 to 5 minutes, using probes for a simple 4-step procedure. This treatment application is referred to as microcurrent electrical therapy (MET) and usually produces a significant reduction of pain within 2 to 5 minutes. It should be applied 2 or 3 times a week for chronic pain or on an as-needed basis. Compared to other pain management interventions, results are more stable and long-lasting, without the risks of such negative side effects such as tolerance and addiction to narcotic analgesics.

Electromedical Products International, Inc. (EPI) of Mineral Wells, Texas, was founded in Los Angeles in 1981 and is now the world's leader in cranial electrotherapy stimulation and microcurrent technology. In 1992, Alpha-Stim was introduced to Kuwait to help their soldiers and citizens cope with the aftermath of the war. Following the events of 9/11, the company dedicated substantial resources to the war effort by focusing research and teaching of pain and stress management through electrical interventions for the benefit of our Service Members. Since 2005 Alpha-Stim has been included in the Federal Supply Schedule for the DoD and VA (Contract No. V797P-4800a). The U.S. Army is currently utilizing Alpha-Stim technology broadly in the practice of complementary medicine. Multiple studies involving Alpha-Stim CES technology are currently being conducted for the treatment of PTSD within the DoD. Additionally, the Department of Veterans Affairs has conducted multi-site studies that had good outcomes with large effect sizes (.73) using Alpha-Stim for pain management in veterans with spinal cord injuries. In 2008, government business accounted for 13.2% of Alpha-Stim sales in the USA, and that figure rose to 21.5% for the first half of 2009.

Licensed practitioners within the DoD or VA who would like to try Alpha-Stim for their patients may request a no cost 60-day loan (one time only). During and subsequent to this free trial, competent and friendly clinical support specialists are available to answer any questions and to provide technical support. DVD educational programs are also available upon request. Visit the practitioners section of www.alpha-stim.com for complete prescribing information. This website also contains many research abstracts and articles, professional endorsements, print media, and provides several links to radio and television broadcasts worldwide. Call 1-800-FOR-PAIN to request a free practitioner's information kit, loaner devices, or to schedule a visit from one of our certified customer service representatives (on-site visits available in most areas).

Dr. Kirsch is the recipient of the 2008 Richard S. Weiner Pain Educator of the Year Award by the American Academy of Pain Management. In addition to being a research and practice consultant for the DoD and VA, he teaches within the Compassion Fatigue and Substance Abuse Programs for the Army.