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# Cranial Electrotherapy Stimulation

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**H**arnessing electricity for medicinal purposes predates Benjamin Franklin and his famous kite experiment. The ancient Greeks used the shock of a torpedo ray fish (also known as an electric eel), which can deliver up to 220 volts for pain relief during surgery and childbirth, as well as for the treatment of headaches. Scribonius Largus, the court physician to the Roman emperor Claudius, was the first to record such use of electricity to treat headaches and gout pain in 46 AD (Bullock, Hopkins, Popper, & Ray, 2005). Fast forward 2 millennia and practitioners are now using an elegant version of microcurrent to treat the body and mind. Cranial electrotherapy stimulation (CES) is a Food and Drug Administration (FDA)–approved modality for the treatment of anxiety, insomnia, and depression (Cranial electrotherapy stimulator, 21 *Code of Federal Regulations* [CFR], § 882.5800, 2013). CES research has made remarkable advances over the last 100 years, paralleling the direction of modern health care science, with the most recent studies being double-blind, sham-controlled randomized clinical trials (RCT), the gold standard in evidence-based medicine.

As Henry Nasrallah pointed out in his description of the future of behavioral health, neurostimulation for brain repair is one of the top six trends in clinical practice, along with pharmacogenomics, targeting neuroplasticity

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and unravelling the connection between physical and mental disorders (Nasrallah, 2009). CES offers a noninvasive, safe, and effective form of neurostimulation that can be performed by the clinician, or the patient at home, and is cost-effective. This is in stark contrast to vagal nerve stimulation (VNS) and to deep brain stimulation (DBS), which requires neurosurgery, or transcranial magnetic stimulation (TMS), which is cost-prohibitive for most patients as it is not covered by insurance and must be performed in the practitioner's office. All of these modalities also have a much bigger adverse-effects profile than CES.

This chapter covers the history of CES and the clinical evidence supporting its use in practice, including safety, effectiveness, and the scope of applications. We also explain the logistics of including this technology in a practitioner's armamentarium and what it takes to develop a CES treatment room to multiply the efforts of your practice.

## Cranial Electrotherapy Stimulation Past to Present

Electromedicine may have begun with the ancient Greeks and Romans, but it wasn't considered a viable option by practitioners in the United States until the 1970s. However, CES started in Russia in the 1950s and gained popularity in parts of Europe, where it was originally called "electrosleep" before making its way to the United States in the 1960s. Psychopharmaceutical treatment was not prevalent then, so intense interest was generated by the possibilities that this new method offered for treating difficult psychiatric cases. Clinical studies commenced with the intent of discovering the best waveform configuration, mechanisms of action, safety profile, and potential clinical usefulness.

In 1978, the FDA's Neurological Panel suggested the modality be called cranial electrotherapy stimulation, rather than "electrosleep." The FDA also determined that CES would only be available by prescription, making the United States one of only two countries in which an order from a licensed health care practitioner must be obtained for its use. This restriction continues today (Cranial electrotherapy stimulator, 21 CFR, § 882.5800, 2013). However, a license to order pharmaceuticals is not required—practitioners can use and order a CES device for a patient if their license allows them to diagnose and treat the particular condition. Currently, psychologists are the largest group of practitioners and researchers who utilize CES.

As technology has progressed over the decades, so have CES devices. This progression started with early 1970s CES units, which were the size of a carry-on suitcase designed to be used by practitioners in a clinical setting. It required tying a band around the head to hold wet sponges initially directly on the eyes, then against the forehead or temples, to deliver the treatment (Kirsch, 2002). Today, CES devices (Alpha-Stim, Nexalin, and CES Ultra) have made significant technological strides—the size of the equipment has been reduced to the size of a smartphone with digital LCD screens designed to be quick and easy to use by a practitioner or by the patient at home. The current is now delivered via electrodes that clip onto the earlobes, as

opposed to the antiquated 1970s sponges. Besides being easier to use and having an appearance similar to earbud headphones, the earlobes provide a better electrode placement because they drive the current more directly to the target areas in the brain stem that control emotions (e.g., hypothalamus, limbic system). Figure 5.1 illustrates the technological advances to the Alpha-Stim CES device since it was first introduced in 1981.

## How Cranial Electrotherapy Stimulation Works

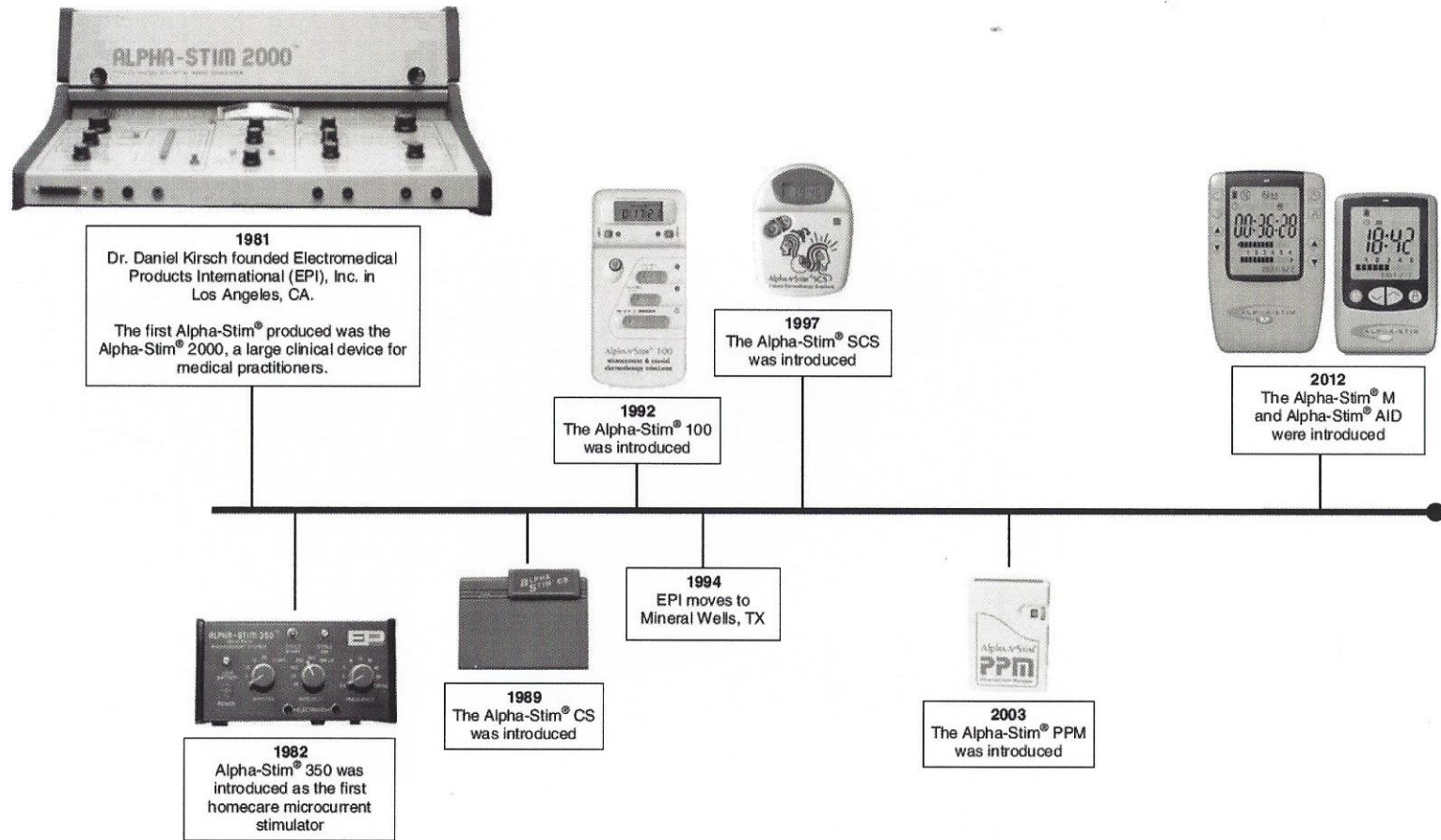
The mechanisms of action of CES have not been clearly elucidated; however, several mechanisms have been postulated. CES is thought to be derived from a direct mode of action, and, thus, it has been described largely from a neurobiological standpoint with respect to its effect on electrical brain activity, neurotransmitters, and hormones. Table 5.1 summarizes some of the mechanistic studies carried out to better understand the physiological responses to CES since 1967.

In the past decade, research has shifted to imaging studies to increase knowledge about the physiological processes that occur during CES. A functional magnetic resonance imaging (fMRI) study by Feusner et al. (2012) found that CES causes cortical deactivation in the midline frontal and parietal regions of the brain of anxiety patients after just one 20-minute treatment. A second fMRI study reported decreased activity in the pain processing regions of the brain in patients with fibromyalgia (Taylor, Anderson, Riedel, Lewis, & Bourguignon, 2013; Taylor, Anderson, Riedel, Lewis, Kinser, et al., 2013).

The most recent fMRI study to date (Qiao et al., 2015) showed balancing of nerve clusters in Tourette's patients under 12 years old, confirming the putative mechanism of brain balancing, or normalization, proposed by Giordano (Kirsch, 2006). In this Tourette's study, after a series of Alpha-Stim CES treatments, subjects exhibited altered spontaneous functional connectivity in brain areas within cortico-striato-thalamo-cortical (CSTC) circuits involved in motor generation or control. The functional activity and connectivity in motor pathways was suppressed, while activations in the control portions of the CSTC loop were increased. There was also a decrease in the Yale Global Tic Severity Scale indicating a decrease in motor and vocal tics from baseline to the end of 24 weeks of CES treatment that was highly significant ( $p < .01$ ) for both the subset of subjects ( $n = 8$ ) who had fMRIs and the total group ( $N = 42$ ). The authors, in China and the United States, concluded that the normalization of the balance between motor and control portions of the CSTC circuit may result in the recovery of adolescents with Tourette's syndrome.

Electroencephalogram analysis of subjects who received one 20-minute treatment of CES showed significant increases in alpha activity (increased relaxation) and decreases in delta activity (increased alertness) and theta activity (increased ability to focus; Kennerly, 2004). The changes in brainwave patterns are thought to represent a calm, relaxed, alert state. These imaging changes, coupled with the older neurochemical research, help to explain the positive clinical responses reported with CES in mood and sleep disorders.

FIGURE 5.1



Technological advances to the Alpha-Stim cranial electrotherapy stimulation device since it was first introduced in 1981. From *History of the waveform: The clinical history of the Alpha-Stim® waveform technology*. Retrieved from <http://www.alpha-stim.com/healthcare-professionals/history-of-the-waveform/>. Copyright 2017 by Electromedical Products International, Inc. Adapted with permission.

TABLE 5.1

## Summary of Mechanistic Cranial Electrotherapy Stimulation Research

Findings	Study type	Reference
Increase neurotransmitter release and resynthesis	Open label	Siegesmund et al., 1967
Increased inhibitory process resulting in analgesia and sleep	Open label	Pozos et al., 1968 Pozos et al., 1969
Increase blood serotonin levels	Pilot study	Shealy et al., 1989
Increased MAO-B and GABA	Double blind	Krupitsky et al., 1991
Increased serotonin and beta-endorphins in spinal fluid	Open label	Liss & Liss, 1996
Increased GABA and beta-endorphins	Open label	Shealy et al., 1998
Increased alpha and decreased delta activity on qEEG	Open label pilot study	Kennerly, 2004
Cortical deactivation in frontal and parietal regions on fMRI	Open label	Fuesner et al., 2012
Decreased pain processing in fibromyalgia patients on fMRI	Double blind	Taylor, Anderson, Riedel, Lewis, & Bourguignon, 2013
Balancing of cortical brain clusters in adolescent Tourette's patients on fMRI	Double blind	Qiao et al., 2015

## Safety of Cranial Electrotherapy Stimulation

The FDA cleared CES for the treatment of anxiety, depression, and insomnia in 1979. CES is noninvasive and has an excellent safety profile. The FDA publicly commented on CES safety in an announcement in the *Federal Register* reclassifying CES to a Class II device and stating that “in terms of safety, there is little evidence of device risk,” and “in general, CES devices appear to have a favorable long-term safety profile” (Kux, 2016). The only precautions to CES include pregnancy and having a pacemaker, spinal cord stimulator, or other implanted electrical device (Phillips, 1997). Adverse effects of CES occur infrequently and are mild and self-limiting. These include vertigo, skin irritation at the electrode sites, and headaches. Headaches and vertigo are usually experienced when the current is set too high for a particular individual. These effects resolve when the current is reduced or within minutes to hours following treatment. Skin irritation at the electrode site can be avoided by moving electrodes around slightly during treatments. No serious adverse effects have ever been reported from using CES (Kirsch, 2002). In an Alpha-Stim survey of service members and veterans, 99% of subjects ( $n = 152$ ) considered CES technology to be safe (Kirsch, Price, Nichols, Marksberry, & Platoni, 2014). An important safety benefit of CES is that it leaves the user alert and relaxed after treatment, in contrast to drugs that can have adverse effects on service members' ability to function on missions that require intense focus and attention (Kennerly, 2006).

## Evidence Base for Cranial Electrotherapy Stimulation

In the last 5 years, CES studies have been carried out at major American medical institutions (e.g., Walter Reed National Military Medical Center, MD Anderson Cancer Center, The University of Texas Health Science Center, UCLA's David Geffen School of Medicine, the University of Virginia). At the time of this writing, over 60% of Alpha-Stim CES sales in the United States go to the U.S. Department of Defense and Veterans Affairs Medical Centers, both of which are conducting well-planned research projects. The uptick in research is not confined to the approved indications of anxiety, insomnia, and depression, but also includes treatment areas such as restless leg syndrome, attention-deficit/hyperactivity disorder, fibromyalgia, the aforementioned Tourette's syndrome, and addictions. The exploration of these off-label treatment areas is an indicator that CES is still in the infancy stage and that researchers are just starting to understand the normalization effects of CES to the brain.

### ANXIETY

In a double-blind, sham-controlled RCT that studied anxiety and depression, 115 subjects suffering from a treatment-resistant anxiety disorder, many with comorbid depression, received 5 weeks of active or sham CES (Barclay & Barclay, 2014). The Hamilton Anxiety Rating Scale (HAM-A; Hamilton, 1959) and Hamilton Depression Rating Scale (HAM-D; Hamilton, 1960) were obtained at baseline and at the end of weeks 1, 3, and 5. At the end of the study, when compared with scores at baseline, anxiety and depression scores decreased significantly in the treatment group but not in the sham group. The CES treatment group decreased their initial anxiety scores by 50% in 83% of the subjects ( $p = .001$ ) and in 82% of the initial depression scores ( $p = .001$ ). In the CES treatment group, the decrease in anxiety scores was more than 3 times that of the sham group, and the decrease in depression scores was more than 12 times the decrease seen in the sham control.

The results reported by Barclay and Barclay (2014) are consistent with seven similar double-blind, sham-controlled RCTs using CES to treat acute and chronic anxiety disorders (Cork et al., 2003; Hill, 2015; Lee et al., 2013; Mellen & Mackey, 2008; Strentzsch, 2008; Voris, 1995; Winick, 1999). These anxiety studies represent a unique cross-section of patients, including college students, preoperative and dental anxiety patients, sheriff and security officers, people with chronic mental illness, outpatient psychology and psychiatry patients, and chronic pain patients. The diversity of patient populations studied sheds light on the potential uses for CES.

In an RCT ( $n = 120$ ) comparing the effects of paroxetine (Paxil) with paroxetine and CES in anxiety patients over a 6-week period, there was significantly more improvement ( $p < .01$ ) in the CES group on the HAM-A (L. Lu & Hu, 2014) than in the group that took paroxetine alone (although both groups improved significantly). The CGI-SI, as a secondary measure, confirmed the between-group differences in favor of the CES group ( $p < .05$ ).

Four additional single-blind RCTs on anxiety yielded significant findings in favor of the treatment group (Chen et al., 2007; Gibson & O'Hair, 1987; Kim et al., 2008; Kolesos, Osionwo, & Akkhighbe, 2013). Four open-label and retrospective analyses also reported that CES significantly decreased anxiety (Gong et al., 2016; Libretto, Hilton, Gordon, Zhang, & Wesch, 2015; X. Y. Lu, Wang, Li, Zhang, & Liu, 2005; Overcash, 1999).

A prominent research and academic psychiatrist has said that "CES melts away anxiety" (M. Woodbury, personal communication to the FDA at the American Psychiatric Association annual meeting, New Orleans, May 2010). Indeed, the effects in state or situational anxiety are almost immediate in most people, or at least achievable within a single 20- to 40-minute treatment session. CES is used as an anxiolytic by dentists just prior to and throughout procedures (Kolesos, Osionwo, & Akkhighbe, 2013; Winick, 1999), as well as by physicians and psychologists (Lee et al., 2013). A single treatment can increase alpha brain waves, while decreasing delta and theta waves (Kennerly, 2004).

Achieving significant effects in trait anxiety or generalized anxiety disorder (GAD) could take up to 6 weeks of treatment. Two or three treatments per week are usually sufficient. After the anxiety is under control, CES may be used on an as-needed basis.

### *Clinical Vignette: Generalized Anxiety Disorder*

Donald is a 55-year-old man with long-standing GAD. He had suffered with worsening anxiety for more than 20 years, and, during most of that time, he had seen a psychiatrist who prescribed several anxiolytics, sleep medications, and an antidepressant. Donald felt as though these medications had little effect; however, he continued to take them as directed. He also saw a psychologist who instructed him on relaxation techniques and deep breathing. Over the period of a year, after a minor cardiac event, the patient's anxiety worsened. He became increasingly anxious, which led to panic attacks and other disruptions in daily life, and he began to demonstrate agoraphobic behavior (his leg was shaking and both his family life and career began to erode).

He learned about CES through a new psychologist he was referred to by a friend, and together they decided to try a series of treatments in the office. The first few CES treatments took place during the patient's normal cognitive behavioral therapy (CBT) visit each week, and each visit tended to calm him down. Donald called it his "brain spa" time. After the encouraging preliminary results seen in the office trial, the psychologist instructed Donald on how to properly use the device and ordered one for 20-minute daily home use. At first, Donald was concerned the CES device was making him worse, because more suppressed negative feelings were coming to the surface. The psychologist explained that CES helps to normalize the brain, which can include processing previously repressed feelings, and advised him to continue CES therapy on a reduced schedule of two to three 20-minute treatments per week. After 1 month, Donald reported a decrease in his anxiety, an improved sex life, and the ability to do more tasks that require concentration. He also noted a higher overall quality of life, and his family noticed the positive changes in him as well. He was then instructed to continue using CES one or two times a week and whenever he started

to feel stressed. After 6 weeks, his leg stopped shaking and by 90 days, Donald considered himself cured of his anxiety.

## DEPRESSION

Two double-blind, sham-controlled RCTs using Alpha-Stim CES technology yielded significant findings for depression in favor of the treatment group in (a) 115 GAD patients ( $p < .001$ ) with comorbid depression (Barclay & Barclay, 2014), and (b) in 21 sheriff officers ( $p < .01$ ) in Alabama (Mellen & Mackey, 2009). In addition, Chen et al. (2007), in a single-blind, sham-controlled RCT of 60 children ages 8 to 16 with mixed anxiety-depression disorder, reported that CES significantly decreased depression ( $p < .001$ ) in the treatment group, when compared with the sham group. Six open-label studies and retrospective analyses reported that CES significantly decreased depression from baseline to the endpoint of the study (Amr, El-Wasify, Elmaadawi, Roberts, & El-Mallakh, 2013; Bystritsky, Kerwin, & Feusner, 2008; Gong et al., 2016; Libretto et al., 2015; Lichtbroun, Raicer, & Smith, 2001; X. Y. Lu et al., 2005).

Similar to the course of treatment in trait anxiety, CES could take 3 to 6 weeks of treatment to notice significant effects in depressed patients. When depression is comorbid with anxiety, the anxiety also may not show improvement for the first week or two. Two or three treatments per week are usually sufficient at first, although some cases require daily treatment. After the first 6 weeks, the schedule may be reduced to one to two treatments per week.

## Insomnia

One double-blind, sham-controlled RCT using Alpha-Stim CES technology ( $n = 46$ ) for 8 weeks found that CES significantly ( $p < .001$ ) decreased insomnia in favor of the treatment (Taylor, Anderson, Riedel, Lewis, & Bourguignon, 2013; Taylor, Anderson, Riedel, Lewis, Kinser, et al., 2013). Another double-blind, sham-controlled, randomized, 5-day study of military service members in a partial psychiatric hospitalization program ( $n = 57$ ) using Alpha-Stim CES technology reported significant improvements ( $p < .04$ ) on Days 1 and 4, and almost significant findings ( $p = .079$ ) on Day 5 (Lande & Gragnani, 2013). In that study, the actively treated service members slept 43 minutes more, and the sham-treated subjects slept 19 minutes less, per night, over the 5-day period. An open-label study of pain patients also found that CES significantly improved sleep (Lichtbroun et al., 2001).

Insomnia has a wide range of etiologies, and, depending on the cause and comorbid conditions, it can take anywhere from one treatment to 2 months of treatments before an improvement is seen. The 20- to 60-minute treatment session should be done at least 3 hours before going to bed, as CES has the paradoxical effect of increasing alertness immediately following a treatment. However, some people can use it when waking in the night and fall back asleep while the treatment is still active (the device will turn itself off at the conclusion of the preset treatment period).

## FIBROMYALGIA

There have been three studies of the use of Alpha-Stim CES on fibromyalgia patients conducted at major U.S. universities. In a double-blind, sham-controlled RCT of CES for fibromyalgia ( $n = 46$ ), subjects in the active CES and sham groups were instructed to use the device for 60 continuous minutes each day for 8 weeks (Taylor, Anderson, Riedel, Lewis, & Bourguignon, 2013). Pain was decreased significantly in the active group ( $p = .023$ ) but not in the sham group.

In a 6-week study, a 3-week double-blind, sham-controlled RCT of CES for fibromyalgia ( $n = 60$ ) was followed by a 3-week open-label crossover arm in which subjects in the sham and control groups could elect to participate in a more typical treatment course of CES (Lichtbroun et al., 2001). Results were significant in the CES group over the sham-treated group for sleep quality ( $p = .02$ ), anxiety ( $p = .04$ ), anger ( $p = .04$ ), tender point scores ( $p = .02$ ), self-rated pain ( $p = .004$ ), fatigue ( $p = .03$ ), feelings of well-being ( $p = .007$ ), and quality of life ( $p = 0.001$ ). Changes in depression, vigor, and confusion were not significant in this study. The findings for anxiety and sleep quality in this study were consistent with the findings of other Alpha-Stim studies indicating CES significantly decreases anxiety and improves sleep quality.

The third double-blind, sham-controlled RCT of CES evaluated the effect of a specified treatment course of CES for patients with fibromyalgia (Cork et al., 2003). This 6-week study included a 3-week, double-blind, randomized, sham-controlled arm, followed by a 3-week, open-label arm in which subjects in the sham group participated in a usual course of treatment of CES. Results were significant in the CES group over the sham-treated group for anxiety ( $p = .001$ ), tender point scores ( $p = .001$ ), self-rated pain ( $p = .001$ ), but changes in functional impairment as measured by the Oswestry test (Fairbank & Pynsent, 2000) were not significant.

With these three RCT trials and one fMRI study showing decreased activity in the pain-processing regions of the brain (e.g., cingulate gyrus, insula, prefrontal cortex) in patients with fibromyalgia (Taylor, Anderson, Riedel, Lewis, Kinser, et al., 2013), there is more evidence that CES is a more effective treatment for fibromyalgia than any other intervention. Fibromyalgia patients must have patience in both treatment duration and course. Because they are particularly sensitive to the current, they must use a low level of current (e.g., 100 microamperes) for at least an hour per day. Then, it will be approximately 3 to 4 weeks before they begin to notice significant improvements in pain levels, sleep patterns, and mood.

## POSTTRAUMATIC STRESS DISORDER

Posttraumatic stress disorder (PTSD) can take many forms, with some patients suffering from debilitating anxiety, depression, anger, headaches, and depression. As these symptoms manifest and worsen over time, we see stress levels increase, relationships deteriorate, and quality of life erode. Patients are often prescribed several medications to address each one of their symptoms. This polypharmacy approach dramatically increases the risks of harmful side effects.

The Warrior Combat Stress Reset Program (WCSRP) at Fort Hood, Texas, has been using Alpha-Stim CES since 2008. This integrative program was evaluated by a third party for effectiveness for treating PTSD (Libretto et al., 2015). The evaluation results were very positive, with significant reduction ( $p < .001$ ) reported in PTSD, depression, anxiety, and pain. The WCSRP is an integrative program that uses individual and group therapy sessions, acupuncture, massage, yoga, CES, and other treatment modalities to treat PTSD patients who have recently returned from deployment. The goal is to prepare them to return to combat. Patient satisfaction for each modality was also measured, with Alpha-Stim CES scoring 100% in the final year of the evaluation.

A case series conducted at Creighton University tested the utility of CES in treating PTSD symptoms in two war veterans (Bracciano et al., 2012). The patients reported significant reduction in PTSD symptoms after 28 days of treatment, going from 34 to 13 and 29 to 10 on the PTSD Symptom Scale-Interview (PSS-I; Foa, Riggs, Dancu, & Rothbaum, 1993). There were also noticeable reductions in hyperarousal, avoiding certain situations and flashbacks.

A service member and veteran survey examined the perceptions of the effectiveness and safety of CES in 152 respondents (Kirsch et al., 2014). The findings were not only highly significant overall, but unexpectedly, the CES-plus-medication group did not do as well as the CES-only group treatment in anxiety, PTSD, insomnia and depression.

Victims of domestic violence also often experience PTSD in a manner similar to service members. A brief 5-day study was conducted with 10 women who were victims of domestic violence and living in a shelter (Mellen, Case, & Ruiz, 2016). The average age was 45 years, and most reported either being married to or living with the abuser. Two of three scales in the Behavior Rating Inventory of Executive Function—Adult Version (BRIEF-A; Roth, Isquith, & Gioia, 1996) found significant reductions in stress levels for the 10 sheltered residents. These were the Global Executive Composite Score ( $p = .028$ ) and the Behavior Regulation Scale ( $p = .009$ ); Metacognition fell just out of range ( $p = .06$ ). The nine clinical measures of the Brief Symptom Inventory (Derogatis, 1993) did not quite achieve statistical significance either within the 5-day course of therapy, however, the trend lines indicated positive changes in all nine of the clinical variables, suggesting movement toward more normalized functioning in each category. Specifically, there were reductions seen in somatization and obsessive-compulsive thinking; reduced levels of depression, anxiety, hostility; and improved ability to relate interpersonally. There were also reductions in phobic anxiety, paranoid ideation, and psychoticism. The authors concluded that CES may contribute to reductions in psychological stress experienced by victims of domestic abuse. The results from the BRIEF-A suggest improvements in global functioning within the cortical and subcortical areas of the brain that may improve victims' abilities to think more clearly and make better decisions. PTSD patients should expect to use CES daily until the symptoms subside and then continue on a reduced schedule indefinitely.

## Incorporating Cranial Electrotherapy Stimulation Into Clinical Practice

Mental health practitioners should begin by learning about CES. There are free live webinars and recorded training sessions are given frequently. There is a test after the webinar that earns a certificate of proficiency in continuing medical education and offers continuing education credits in some fields. Practitioners can then implement CES as a treatment option for patients with anxiety, insomnia, and/or depression, as well as for so-called off-label uses, either as a first-line treatment or a synergistic modality used with CBT, eye movement desensitization and reprocessing, biofeedback or neurofeedback, hypnosis, prolonged exposure, meditation, or talk therapy. Some clinicians have their patients use the CES device in the waiting room, prior to treatment, although more commonly CES is applied during a talk session (as it tends to open up the patient to talk more freely). Once positive results are seen, the practitioner can write an order for either the purchase or rental of a CES device for the patient's home use. There are practitioners who order CES devices in quantity to have on hand to immediately dispense them when it is indicated. Many of these practitioners usually pass along most, if not all, of the bulk discount to their patients as a courtesy.

A newer concept being adopted by some practitioners is to have a specialized CES treatment room with five to 10 comfortable chairs where patients can come in and use CES whenever they feel the need. This concept was first implemented in an army hospital in Texas, because it was the most cost-effective way to administer treatment to the most service members, using the minimal number of staff. One room monitor can supervise 10 chairs per seating, with up to three seatings per hour, or 240 treatments per 8-hour shift. From there, it was taken up by a Veterans Affairs Medical Center where Alpha-Stim CES was studied along with four other devices for safety, effectiveness, veteran compliance, and practicality (Tan, Dao, Smith, Robinson, & Jensen, 2010). Although the veterans were trained in the use of all five devices, and were encouraged to use any one at each visit, they chose CES 73% of the time. Of course, the government does not charge service members or veterans for health care, but this same concept can be quite lucrative when applied to a private practice, clinic, or hospital for a very nominal fee to the patient. And there is no impending shortage of patients with mood and sleep disorders. Using a figure of just \$20 as the lowest reasonable fee for this service, and assuming a maximum capacity of 240 treatments per day, such a room would generate gross revenues of \$4,800 per day, or \$1,267,200 per year. The costs would be one employee, 10 comfortable lounge or massage chairs, and 10 CES devices, which cost under \$1,000 each. Of course there would also be replenishable supplies (e.g., electrodes, conducting solution, batteries), but those costs are negligible. Realistically, the room would not likely be at full capacity for 22 days per month as calculated into the above numbers. So, a practitioner is more likely to make \$250,000 to \$500,000 annual net income from a CES treatment room. Once an order is provided for the patients to use or purchase a CES device,

they like the low cost and convenience of such a therapy room and tend to refer their friends. The \$20 cost is cheaper than a few drinks at a bar, and the mood-enhancing effects are better and certainly healthier.

Using CES is easy. The ear clip electrodes have replaceable pads that are moistened with a specialized conducting solution and then clipped onto the earlobes. The device is then turned on, and the current is slowly raised until the patient experiences an altered state, typically described as a light or floating feeling. If the current is uncomfortable, it can be reduced. As a rule of thumb, people who can comfortably tolerate 250 microamperes or more can complete a treatment in 20 minutes. Under 250 microamperes usually requires longer treatment, generally 30 to 40 minutes or until at least 2 minutes after the patient feels light. If the patient feels heavy, continue treatment until that gives way to a light feeling. The same procedure is used for all indications, as CES tends to have a balancing or normalizing effect on the brain.

## Conclusion

CES is a well-researched, safe, effective, and cost-effective means to manage mood and sleep disorders. With mental health care moving away from pharmaceuticals and toward a new set of devices, it is time for CES to be the first-line of treatment for many disorders, as it is safer and at least as effective as other forms of therapy.

## Essential Resources

The American Institute of Stress Learning Center, <http://www.stress.org>.

Electromedical Products International, Inc., manufacturer of Alpha-Stim technology, <http://www.alpha-stim.com>

Kirsch D. L. (2002). *The science behind cranial electrotherapy stimulation* (2nd ed.). Edmonton, Alberta, Canada: Medical Scope.

Kirsch, D. L., & Marksberry, J. A. (2015). The evolution of cranial electrotherapy stimulation for anxiety, insomnia, depression and pain and its potential for other indications. In Rosch, P. J. (Ed.), *Bioelectromagnetic and subtle energy medicine* (2nd ed.). Boca Raton, FL: CRC Press.

## References

- Amr, M., El-Wasify, M., Elmaadawi, A. Z., Roberts, R. J., & El-Mallakh, R. S. (2013). Cranial electrotherapy stimulation for the treatment of chronically symptomatic bipolar patients. *The Journal of ECT*, 29, e31–e32. <http://dx.doi.org/10.1097/YCT.0b013e31828a344d>
- Barclay, T. H., & Barclay, R. D. (2014). A clinical trial of cranial electrotherapy stimulation for anxiety and comorbid depression. *Journal of Affective Disorders*, 164, 171–177. <http://dx.doi.org/10.1016/j.jad.2014.04.029>

- Bracciano, A. G., Chang, W.-P., Kokesh, S., Martinez, A., Meier, M., & Moore, K. (2012). Cranial electrotherapy stimulation in the treatment of posttraumatic stress disorder: A pilot study of two military veterans. *Journal of Neurotherapy*, 16, 60–69. <http://dx.doi.org/10.1080/10874208.2012.650100>
- Bullock, T. H., Hopkins, C. D., Popper, A. N., & Fay, R. R. (2005). *Electroreception*. New York, NY: Springer.
- Bysritsky, A., Kerwin, L., & Feusner, J. (2008). A pilot study of cranial electrotherapy stimulation for generalized anxiety disorder. *The Journal of Clinical Psychiatry*, 69, 412–417. <http://dx.doi.org/10.4088/JCP.v69n0311>
- Chen, Y., Yu, L., Zhang, J., Li, L., Chen, T., & Chen, Y. (2007). Results of cranial electrotherapy stimulation to children with mixed anxiety and depressive disorder. *Shanghai Archives of Psychiatry*, 19, 203–205.
- Cork, R. C., Wood, P., Ming, N., Shepherd, C., Eddy, J., & Price, L. (2003). The effect of cranial electrotherapy stimulation (CES) on pain associated with fibromyalgia. *The Internet Journal of Anesthesiology*, 8(2), 1–8.
- Cranial electrotherapy stimulator, 21 C.F.R. § 882.5800 (2013).
- Derogatis, L. R. (1993). *BSI Brief Symptom Inventory: Administration, scoring, and procedure manual* (4th ed.). Minneapolis, MN: National Computer Systems.
- Electromedical Products International, Inc. (2017). *History of the waveform: The clinical history of the Alpha-Stim® waveform technology*. Retrieved from <http://www.alpha-stim.com/healthcare-professionals/history-of-the-waveform/>
- Fairbank, J. C. T., & Pynsent, P. B. (2000). The Oswestry Disability Index. *Spine*, 25, 2940–2953.
- Feusner, J. D., Madsen, S., Moody, T. D., Bohon, C., Hembacher, E., Bookheimer, S. Y., & Bysritsky, A. (2012). Effects of cranial electrotherapy stimulation on resting state brain activity. *Brain and Behavior*, 2, 211–220. <http://dx.doi.org/10.1002/brb3.45>
- Foa, E., Riggs, D., Dancu, C., & Rothbaum, B. (1993). Reliability and validity of a brief instrument for assessing post-traumatic stress disorder. *Journal of Traumatic Stress*, 6, 459–474. <http://dx.doi.org/10.1007/BF00974317>
- Gibson, T. H., & O'Hair, D. E. (1987). Cranial application of low level transcranial electrotherapy vs. relaxation instructions in anxious patients. *American Journal of Electromedicine*, 4, 18–21.
- Gong, B. Y., Ma, H. M., Zang, X. Y., Wang, S. Y., Zhang, Y., Jiang, N., . . . Zhao, Y. (2016). Efficacy of cranial electrotherapy stimulation combined with biofeedback therapy in patients with functional constipation. *Journal of Neurogastroenterology and Motility*, 22, 497–508. <http://dx.doi.org/10.5056/jnm15089>
- Hamilton, M. (1959). The assessment of anxiety states by rating. *British Journal of Medical Psychology*, 32, 50–55. <http://dx.doi.org/10.1111/j.2044-8341.1959.tb00467.x>
- Hamilton, M. (1960). A rating scale for depression. *Journal of Neurology, Neurosurgery, and Psychiatry*, 23, 56–62. <http://dx.doi.org/10.1136/jnnp.23.1.56>
- Hill, N. T. (2015). *The effects of alpha stimulation on induced anxiety* (Master's thesis). Available from Digital Commons @ ACU, Electronic Theses and Dissertations. (Paper 6).
- Kennerly, R. (2004). qEEG analysis of cranial electrotherapy: A pilot study. *Journal of Neurotherapy*, 8(2), 112–113.

- Kennerly, R. (2006). *Changes in quantitative EEG and low resolution tomography following cranial electrotherapy stimulation* (Unpublished doctoral dissertation). University of North Texas, Denton.
- Kim, H. J., Kim, W. Y., Lee, Y. S., Chang, M. S., Kim, J. H., & Park, Y. C. (2008). The effect of cranial electrotherapy stimulation on preoperative anxiety and hemodynamic responses. *Korean Journal of Anesthesiology*, 55, 657–661. <http://dx.doi.org/10.4097/kjae.2008.55.6.657>
- Kirsch, D. L. (2002). *The science behind cranial electrotherapy stimulation* (2nd ed.). Edmonton, Alberta, Canada: Medical Scope.
- Kirsch, D. L. (2006). Cranial electrotherapy stimulation for the treatment of anxiety, depression, insomnia and other conditions. *Nature Medicine*, 23, 118–120.
- Kirsch, D. L., Price, L. R., Nichols, F., Marksberry, J. A., & Platoni, K. T. (2014). Military service member and veteran self reports of efficacy of cranial electrotherapy stimulation for anxiety, posttraumatic stress disorder, insomnia, and depression. *US Army Medical Department Journal*, Oct–Dec, 46–54.
- Kolesos, O. N., Osionwo, H. O., & Akkhighbe, K. O. (2013). The role of relaxation therapy and Cranial Electrotherapy Stimulation in the management of dental anxiety in Nigeria. *ISOR Journal of Dental Practices*, 10, 51–57.
- Krupitsky, E. M., Burakov, A. M., Karan-ova, G. F., Katsnelson, J. S., Lebedev, V. P., Grinenko, A. J., & Borodkin, J. S. (1991). The administration of transcranial electric treatment for affective disturbances therapy in alcoholic patients. *Drug and Alcohol Dependence*, 27, 1–6. [http://dx.doi.org/10.1016/0376-8716\(91\)90080-I](http://dx.doi.org/10.1016/0376-8716(91)90080-I)
- Kux, L. (2016). Neurological devices; Reclassification of cranial electrotherapy stimulator intended to treat insomnia and/or anxiety; Effective date of requirement for premarket approval for cranial electrotherapy stimulator intended to treat depression. *Federal Register Number*: 2016-01173.
- Lande, R. G., & Gragnani, C. (2013). Efficacy of cranial electric stimulation for the treatment of insomnia: A randomized pilot study. *Complementary Therapies in Medicine*, 21, 8–13. <http://dx.doi.org/10.1016/j.ctim.2012.11.007>
- Lee, S.-H., Kim, W.-Y., Lee, C.-H., Min, T.-J., Lee, Y.-S., Kim, J.-H., & Park, Y.-C. (2013). Effects of cranial electrotherapy stimulation on preoperative anxiety, pain and endocrine response. *The Journal of International Medical Research*, 41, 1788–1795. <http://dx.doi.org/10.1177/0300060513500749>
- Libretto, S., Hilton, L., Gordon, S., Zhang, W., & Wesch, J. (2015). Effects of integrative PTSD treatment in a military health setting. *Energy Psychology*, 7, 33–44. <http://dx.doi.org/10.9769/EPJ.2015.11.01.SL>
- Lichtbroun, A. S., Raicer, M.-M. C., & Smith, R. B. (2001). The treatment of fibromyalgia with cranial electrotherapy stimulation. *Journal of Clinical Rheumatology*, 7, 72–78. <http://dx.doi.org/10.1097/00124743-200104000-00003>
- Liss, S., & Liss, B. (1996). Physiological and therapeutic effects of high frequency electrical pulses. *Integrative Physiological and Behavioral Science*, 31, 88–96.
- Lu, L., & Hu, J. A. (2014). Comparative study of anxiety disorders treatment with paroxetine in combination with cranial electrotherapy stimulation therapy. *Medical Innovation of China*, 11, 080–082.

- Lu, X. Y., Wang, A. H., Li, Y., Zhang, J. S., & Liu, B. X. (2005). Safety and effectiveness of Cranial Electrotherapy Stimulation in treating children with emotional disorders. *Chinese Journal of Clinical Rehabilitation*, 9, 96–97.
- Mellen, R. R., Case, J., & Ruiz, D. J. (2016). Cranial Electrotherapy Stimulation (CES) as a treatment for reducing stress and improving prefrontal cortex functioning in victims of domestic violence. *International Association for Correctional and Forensic Psychology Newsletter*, 48, 12–15.
- Mellen, R. R., & Mackey, W. (2008). Cranial electrotherapy stimulation (CES) and the reduction of stress symptoms in a sheriff's jail security and patrol officer population: A pilot study. *American Jails*, 22, 32–38.
- Mellen, R. R., & Mackey, W. (2009). Reducing sheriff's officers' symptoms of depression using Cranial Electrotherapy Stimulation (CES): A control experimental study. *The Correctional Psychologist*, 41, 9–15.
- Nasrallah, H. A. (2009). Psychiatry's future is here: Here are 6 trends that will affect your practice. *Current Psychiatry*, 8, 16–18.
- Overcash, S. J. (1999). Cranial Electrotherapy Stimulation in patients suffering from acute anxiety disorders. *American Journal of Electromedicine*, 16, 49–51.
- Phillips, P. (1997, July 25). 510(k) (Number: K903014). Retrieved from [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn\\_template.cfm?id=k903014](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn_template.cfm?id=k903014)
- Pozos, R. S., Richardson, A. W., & Kaplan, H. M. (1968). Low wattage electroanesthesia in dogs: Modification by synaptic drugs. *Anesthesia and Analgesia*, 47, 342–344. <http://dx.doi.org/10.1213/00000539-196807000-00007>
- Pozos, R. S., Richardson, A. W., & Kaplan, H. M. (1969). Mode of production and locus of action of electroanesthesia in dogs. *Anesthesia and Analgesia*, 48, 342–345. <http://dx.doi.org/10.1213/00000539-196905000-00007>
- Qiao, J., Weng, S., Wang, P., Long, J., & Wang, Z. (2015). Normalization of intrinsic neural circuits governing Tourette's Syndrome using Cranial Electrotherapy Stimulation. *IEEE Transactions on Biomedical Engineering*, 62, 1272–1280. <http://dx.doi.org/10.1109/TBME.2014.2385151>
- Roth, R. M., Isquith, P. K., & Gioia, G. A. (1996). *BRIEF-A: Behavior rating inventory of executive function—Adult version*. Psychological Assessment Resources: Lutz, FL.
- Shealy, C. N., Cady, R. K., Culver-Veehoff, D., Cox, R., & Liss, S. (1998). Cerebrospinal fluid and plasma neurochemicals: Response to Cranial Electrical Stimulation. *Journal of Neurological and Orthopedic Surgery and Medicine*, 18, 94–97.
- Shealy, C. N., Cady, R. K., Wilkie, R. G., Cox, R., Liss, S., & Clossen, W. (1989). Depression: A diagnostic, neurochemical profile and therapy with cranial electrotherapy stimulation (CES). *The Journal of Neurological & Orthopaedic Medicine & Surgery*, 10, 319–321.
- Siegesmund, K. A., Sances, A., Jr., & Larson, S. J. (1967). The effects of electrical currents on synaptic vesicles in monkey cortex. In A. M. Wageneder and S. T. Schuy (Eds.), *Electrotherapeutic sleep and electroanesthesia proceedings* (Vol. 1, pp. 31–33). Amsterdam, The Netherlands: Excerpta Medica Foundation.
- Strentzsch, J. A. (2008). *An examination of cranial electrotherapy stimulation (CES) on alpha-amylase levels, cortisol levels and state-trait anxiety scores in the chronically mentally ill*

- (Doctoral dissertation, Saint Mary's University). Retrieved from <https://www.stress.org/an-examination-of-cranial-electrotherapy-stimulation-ces-on-alpha-amylase-levels-cortisol-levels-and-state-trait-anxiety-scores-in-the-chronically-mentally-ill/>
- Tan, G., Dao, T. K., Smith, D. L., Robinson, A., & Jensen, M. P. (2010). Incorporating complementary and alternative medicine (CAM) therapies to expand psychological services to veterans suffering from chronic pain. *Psychological Services, 7*, 148–161. <http://dx.doi.org/10.1037/a0020304>
- Taylor, A. G., Anderson, J. G., Riedel, S. L., Lewis, J. E., & Bourguignon, C. (2013). A randomized, controlled, double-blind pilot study of the effects of Cranial Electrical Stimulation on activity in brain pain processing regions in individuals with fibromyalgia. *EXPLORE: The Journal of Science and Healing, 9*, 32–40. <http://dx.doi.org/10.1016/j.explore.2012.10.006>
- Taylor, A. G., Anderson, J. G., Riedel, S. L., Lewis, J. E., Kinser, P. A., & Bourguignon, C. (2013). Cranial electrical stimulation improves symptoms and functional status in individuals with fibromyalgia. *Pain Management Nursing, 14*, 327–335. <http://dx.doi.org/10.1016/j.pmn.2011.07.002>
- Voris, M. D. (1995). *An investigation of the effectiveness of cranial electrotherapy stimulation in the treatment of anxiety disorders among outpatient psychiatric patients, impulse control parolees, and pedophiles*. Corpus Christi, TX: Delos Mind/Body Institute Newsletter.
- Winick, R. L. (1999). Cranial Electrotherapy Stimulation (CES): A safe and effective low cost means of anxiety control in a dental practice. *General Dentistry, 47*, 50–55.