

CES in the Treatment of Insomnia: A Review and Meta-analysis

Cranial Electrotherapy Stimulation (CES) is an effective, established treatment for insomnia that avoids polypharmacy interactions for pain patients taking medications while simultaneously reducing anxiety, depression, and pain.

By Daniel L. Kirsch, PhD, DAAPM, FAIS and Marshall F. Gilula, MD



Daniel L. Kirsch, PhD, DAAPM, FAIS



Marshall F. Gilula, MD

Primarily insomnia is a complaint lasting for at least one month, of difficulty initiating and/or maintaining sleep or of the presence of non-restorative sleep as defined by the Diagnostic and Statistical Manual of Mental Disorders.¹ Primary insomnia is categorized as a Primary Sleep Disorder, under the category of “Dyssomnias” in the

DSM-IV-TR. The diagnostic criteria for primary insomnia is summarized in Table 1.²

The International Classification of Sleep Disorders Revised (ICSD-R) uses the term “psychophysiologic insomnia” for a complaint of insomnia, and for the associated decreased functioning during wakefulness. The ICSD-R defines insomnia of six months duration as chronic.³

The DSM criteria also reflects the now widely-accepted use of polysomnography (PSG) which has enlarged the scope of differential diagnosis when assessing insomnia. The DSM-IV-TR categorizes all sleep disorders as either dyssomnias or parasomnias.⁴ Parasomnias include diagnoses of Nightmare Disorder, Sleep Terror Disorder, Sleep-walking Disorder, or “not otherwise specified” conditions such as REM sleep behavior disorder and sleep paralysis. Sleep paralysis can be an exaggeration of a relatively nonpathologic hypnagogic event, or can be a common component of Narcolepsy, which itself is one of the dyssomnias. A list of some common dyssomnias is shown in Table 2.

Estimates of the number of people in the U.S. who suffer from insomnia range from 18 million to 24 million in adulthood, and up to 20% in later life, or 7 million in people 65 years of age and older, with women being about two times as likely to develop insomnia as men.^{5,6}

Theoretically, “nonrestorative” or nonrefreshing sleep is definable as some impairment in daytime functioning but is not always easy to demonstrate clinically. It has been difficult to demonstrate systematic impairment of daytime function in insomniacs. Some PSG studies have shown clear differences between the sleep of insomniacs and normal subjects.⁷ However, there is one large study which shows extensive overlap in PSG indicators of sleep between insomnia patients and normal con-

trols.⁸ So controversy exists whether patients with insomnia complaints and response to hypnotics differ from controls in any PSG measures of sleep and daytime function.⁹

The significance of insomnia also relates to whether it occurs at the beginning, the end, or in the middle of the course of the usual sleep period. Traditionally, insomnia has been classified into three main types: delayed sleep onset, impaired sleep continuity, and early-morning awakening.¹⁰ Insomnia can be a feature of many major psychiatric disorders but is not regarded as a necessary diagnostic criterion for any particular disorder. Insomnia can be the sole symptom of depression, and can be a risk factor for the development or recurrence of some psychiatric disorders. Paradoxically, sleep loss can be both a symptom and a treatment of major depression.¹¹

The primary function of sleep is to ensure adequate cortical function when awake.¹² According to one theory, two processes

TABLE 1. DSM-IV-TR DIAGNOSTIC CRITERIA FOR PRIMARY INSOMNIA

A. Difficulty initiating or maintaining sleep, or nonrestorative sleep, for at least one month
B. Sleep disturbance (or associated daytime fatigue) causes clinically significant distress or impairment in social, occupational, or other important areas of functioning
C. Sleep disturbance does not occur exclusively during the course of Narcolepsy, Breathing-Related Sleep Disorder, Circadian-Rhythm Sleep Disorder, or a Parasomnia
D. Sleep disturbance does not occur exclusively during the course of another mental disorder such as Major Depressive Disorder, Generalized Anxiety Disorder, or a delirium.
E. The disturbance is not due to the direct physiological effects of a substance (such as a drug of abuse or a medication) or a general medical condition

TABLE 2. LISTING OF DSM-IV-TR MAIN DYSSOMNIAS

A. 307.42 Primary Insomnia
B. 307.44 Primary Hypersomnia
C. 347.00 Narcolepsy
D. 780.57 Breathing-Related Sleep Disorder
E. 327.xx Circadian Rhythm Sleep Disorder
.31 Delayed Sleep Phase Type
.35 Jet Lag Type
.36 Shift Work Type

interact in normal sleep production. The sleep homeostat drives the sleep-wake schedule toward a balanced requirement (prolonged wakefulness incurs a “sleep debt”), and an internal circadian timer regulates the 24 hour biological clock’s sleep-wake cycle.¹³ Together, the two processes regulate not only the amount of sleep but the quality of sleep as well. The two processes also differ across the life span, with young children requiring longer periods of sleep with more rapid eye movement (REM) sleep than do adults as the homeostatic drive declines with age.¹⁴

There is no absolute technique for falling asleep and staying asleep. Sleep is generally regarded as a passive process in which internal and external cues enable autonomic conditions for sleep. According to the inhibition model, there is both a physiological de-arousal, and a cognitive de-arousal, allowing sleep to occur.^{15,16}

Sleep will usually not occur during cognitive arousal. According to Freud, the first step in becoming an insomniac is to worry that one will not sleep when one goes to bed. Recent research

has borne out the fact that worries of any kind—but certainly a fear of not falling asleep and worrying about the resulting consequences of this for one’s life the next day—clearly deactivates the cognitive de-arousal required for sleeping.¹⁷

When asked what kinds of thoughts they have when they attempt to sleep, insomniacs provide a long list, typically including planning, thinking things out—especially with a negative emotional content, fear of not sleeping, plus concentrating on worrisome changes that are operative in their lives. When people who have no problems falling asleep are asked what they think about when they go to bed at night, many answer, “nothing especially.”

While medications are often used to treat insomnia, those in the class of benzodiazepine and related chemical structures have limited usefulness over the long range since they tend towards tachyphylaxis (rapidly decreasing response following initial doses) and produce tolerance. The use of cognitive behavior therapy for enhancing sleep is often suggested since it may identify the things that the insomniac is doing to defeat the brain’s attempt to de-arouse.¹⁸

People also sleep poorly due to illnesses, especially pain, depression, chronic medication effects, sleep apnea, anxiety, other stress related disorders, and other sleep disorders that can be diagnosed with PSG. These should all be addressed and evaluated as part of any therapy that is provided to the insomniac.

Of additional interest in electromedicine is that the head in the awake person has a negative ionic charge anteriorly and a positive ionic charge posteriorly. Those charges reverse, both when the person is asleep, and when under general anesthesia. The person whose head remains negative anteriorly will not sleep well until such electrical conditions reverse.¹⁹

Treating Insomnia with CES

Cranial electrotherapy stimulation (CES) is the FDA recognized generic category for medical devices using microcurrent levels of electrical stimulation applied across the head via transcutaneous electrodes for the treatment of anxiety, insomnia, and depression. Ear clip electrodes, moistened with an appropriate conducting solution, are applied for 20 minutes to an hour or more on an initial daily basis for a week or two, followed by a reduced schedule of 2 or 3 treatments a week until the insomnia is resolved, and then further reduced to an as-needed (p.r.n.) basis.

When CES first came to the U.S.A. in the 1960s it was called “Electrosleep.” The intent of electrosleep was to put patients to sleep when the current was turned on. That rarely occurred regardless of the waveform parameters.

Confirming Kratzenstein’s observation in 1743 that putting electricity in his body during the day helped him sleep at night,²⁰ research has revealed that CES, while not directly inducing sleep, helps to improve the quality of night time sleep, regardless of what time of day CES is used.

In one study, ten patients were allowed to sleep in a sleep lab that monitored their EEG overnight. Half were given CES and half were given sham CES. After 30 minutes of stimulation daily for ten days, it was found that those patients receiving actual CES went to sleep faster, awoke fewer times during the night, spent more time in Stage IV sleep, and reported feeling more rested the following morning. At two year follow up, the CES treated patients were still sleeping normally, while the sham

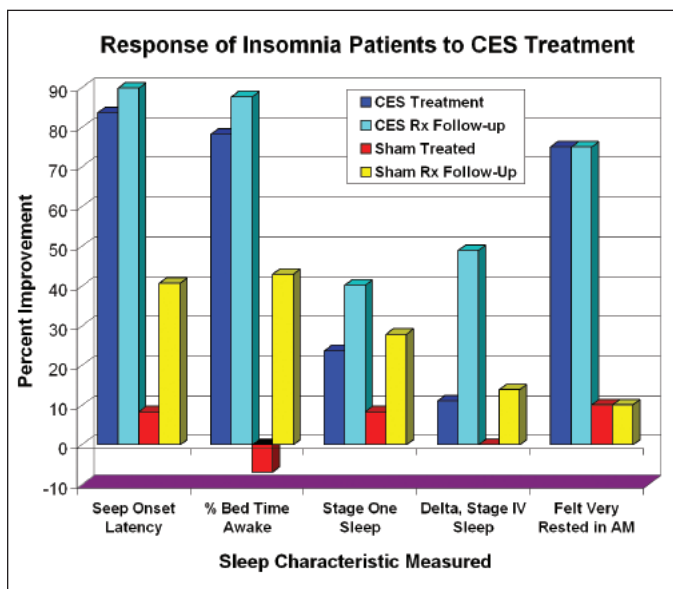


FIGURE 1. The results of a double blind CES study on insomnia, with two year follow up. While the sham group did improve over the two year period except in restoration (feeling rested in AM), the treatment group did significantly better in all areas and those effects were maintained or improved at follow up.

treated patients were not, as shown in Figure 1.^{21,22}

To understand insomnia, we need to understand the distinction between the different stages of sleep, which are studied using polysomnography (PSG) and electroencephalography (EEG). PSG is a combination of multiple channels of neurophysiologic information. An 18 channel device might typically include six channels of scalp EEG, two channels of left and right eye movements, electrocardiogram (ECG), 2-3 channels of electromyogram (EMG), oxygen saturation, and other channels representing movements of the mouth, chest, and abdomen. EEG examinations usually involve a larger number of EEG channels but may also contain ECG, and some of the other PSG-type information detailed above as well as photic stimulation recording and intranasal or sphenoid electrodes for special localization studies.

Brain wave frequencies and the presence or absence of REM sleep have been used to divide sleep into two broad categories.²³ Rapid eye movements (REM) were defined as “regularly recurrent periods of altered ocular motility during sleep.” This prompted a dichotomy of two different types of sleep: (1) Non-REM (“slow sleep”) and (2) REM sleep (“paradoxical sleep” or “fast sleep”).

The basic brain wave frequencies are of course the same in both EEG and PSG, but the look and feel of the recordings is quite different. The brain waves are grouped into four frequency bands of cycles per second, or Herz (Hz): (1) Delta: under 4 Hz, (2) Theta: 4-7 Hz, (3) Alpha: 8-13, and (4) Beta: 14 Hz and above. The modern terminology of four sleep stages includes (1) Drowsiness, (2) Light sleep, (3) Deep sleep, and (4) Very deep sleep.²⁴ Sleep stages have both clinical and electrographic correlates. In Stage I, in which there is a feeling of drowsiness, the alpha rhythm becomes flatter, a dropout of the higher frequencies occurs, and, some theta frequencies begin to appear in the electrodes that cover the vertex of the skull. Stage II is characterized as light sleep, theta waves predominate instead of alpha waves, and the EEG recording shows the same vertex waves, and other electrographic structures called “sleep spindles” and “K-Complexes.” Stage III is a deeper stage of sleep. The EEG record shows much slowing, and theta and delta waves (0-4 Hz) predominate while the record continues to show some of the same electrographic structures seen in Stage II. Stage IV is the deepest and most restful stage of sleep. High amplitude, low-frequency delta waves predominate. Conventional EEG lab studies usually do not show this stage because the recordings are usually less than one hour in duration and it often takes more than one hour to go into Stage IV sleep.

CES Research

Research has revealed that a series of CES treatments not only facilitates sound, restful sleep, but can effectively treat stress in the process, as measured by various psychometric scales of depression and anxiety.

Feighner studied 21 long term insomniacs and employed a global rating scale of sleep. From the change in sleep pattern observed, a two-tailed t test of probability result was obtained at the .0002 level. As this study utilized a crossover design, this change was computed on the first group of treated patients prior to the crossover.²⁵

Flemenbaum studied 28 outpatients who had suffered from insomnia for 3 to 4 years. They were provided with five, 30

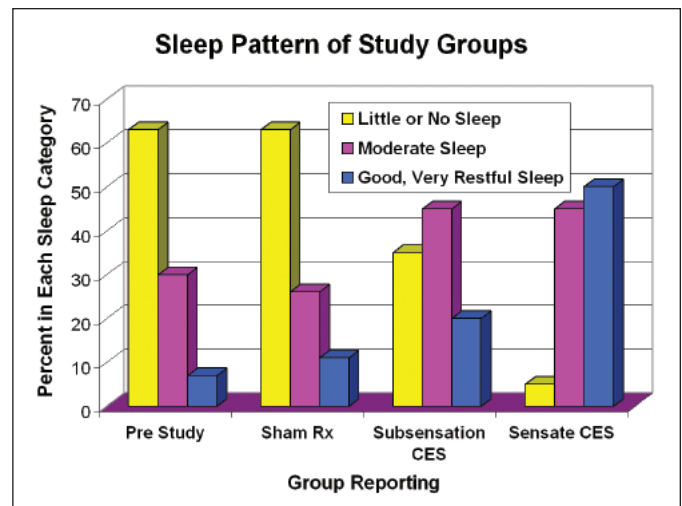


FIGURE 2. Sleep patterns in fibromyalgia patients showing improvement from subsensory CES in the double blind group, and “sensate” CES in the sham group after they were crossed over to an open clinical trial.

minute CES treatments. The results, scored on a global rating scale, indicated a 50% improvement in their sleep and that persisted six months later.²⁶

Frankel added a most unusual study to the CES insomnia literature in that half of the patients were treated with 100 Hz, while the other half were treated with 15 Hz. The two groups were then subjected to a crossover. It was never explained why those two different frequencies were chosen and, in the data analysis, why they were never broken down separately. He combined data from both the 100 Hz and 15 Hz patients before the crossover, then again following the crossover so that any treatment effects from either frequency could not be ascertained separately.²⁷

Gomez studied self withdrawal from methadone maintenance with 28 heroin addicts in a VA hospital. It was discovered that the treated patients, but not the controls, significantly reduced their PRN sleep medication requests beginning the third night of the ten day treatment.²⁸

Hearst gave 28 psychiatric outpatients five 30 minute CES treatments or sham treatments, and had both physicians and the patients complete a global rating of sleep. The treated patients scored 42% higher than did the controls on sleep improvement.²⁹

Hozumi studied a group of 27 inpatients with multi-infarct dementia, giving them either real or sham CES for 20 minutes daily for two weeks. They found that in addition to significantly improving their sleep, CES was significantly effective in improving sleep related behavioral disorders such as nocturnal wandering and nocturnal delirium.³⁰

Kirsch compiled physicians’ ratings for 500 patients treated with Alpha-Stim CES. Within this group, 135 complained of persistent sleep problems, and although they were treated for various lengths of time, 79% said they had experienced significant improvement of 25% or greater. The average improvement among the overall group was 62%.³¹

Lichtbroun did two double-blind studies of fibromyalgia patients who customarily have very poor sleep. Following one hour of actual CES daily for three weeks, the first group of 30 improved 72%. Following the same treatment protocol, the second 60 patients rated their sleep as being 82% improved, while there were no significant changes in the sham treated groups.^{32,33}

Figure 2 shows the sleep patterns in this 60-subject Alpha-Stim CES fibromyalgia study.³³ It can be seen that the sleep of CES-treated patients improved greatly both during the subsensory double-blind phase of the study and following the one way crossover where the sham treated controls self-treated with CES at home above the subsensory level using the normal protocol to regulate treatment time and current level. The graph in Figure 2 also indicates that the stronger stimulus levels used in the crossover open clinical trial phase achieved better sleep results than with subsensory stimulation. This would be more consistent with actual clinical practice results than with the restricted subsensory current level used in double-blind research.

Moore gave 17 patients five days of CES, 30 minutes per day in a crossover design. The first group to get treatment prior to the crossover reported a 46% improvement on self rated sleep scales.³⁴

Patterson published two CES studies that address insomnia. One was a seven year retrospective review of 186 addicts and the other was a small 18 patient study of addicts. Sleep improvement of 56% was found in the first group, and 55% in the second group.^{35,36}

Philip withdrew patients from anti-depressant medication so they could be given electroconvulsive therapy (ECT). CES was successfully used to withdraw from the drugs for one week. Philip was totally unaware of the ability of longer term CES to effectively treat depression, so while the patients got through their drug abstinence period successfully with 42% better sleep, they were still given ECT.³⁷

Rosenthal completed three studies with 9, 18, and 22 patients respectively, in which a clinical rating scale was used to assess changes in sleep behavior. Patients were treated for 30 minutes a day for five days with CES or sham CES. CES treated patients in these studies experienced 50%, 60% and 81% sleep improvement.³⁸⁻⁴⁰

Straus gave CES or sham CES to 34 inpatients who suffered from insomnia, and compared the effects of CES with phenobarbital for inducing sleep. Sleep improved among the CES-treated patients over the one to two week treatment period approximately 33%. In this study CES was found to be as efficacious as phenobarbital in inducing sleep, but without the adverse side effects.⁴¹

Tyers completed two studies with fi-

TABLE 3. PATIENT'S SELF-REPORTED RESULTS FROM USING CES THREE WEEKS OR MORE

Diagnosis	Number	%Female	Age	Weeks Used	Improvement
Insomnia only Range Average	69	59%	3 – 81 yrs 47.86 yrs	0 – 52 wks 6.79 wks	0 – 99% 75-99%
Insomnia & Anxiety and/or Depression Range Average	88	59%	24 – 86 yrs 49.37 yrs	1 – 28 wks 5.71 wks	0 – 100% 75-99%
Insomnia & Pain Range Average	143	78%	21 – 85 yrs 50.66 yrs	0 – 78 wks 9.68 wks	1% - 99% 75-99%
Total Insomnia Range Average	300	68%	3 – 86 yrs 49.66 yrs	0 – 78 wks 7.95 wks	0 – 100% 75-99%
Mean Effect Size: $r = .87$					

bromyalgia patients. He gave them CES for one hour a day for three weeks. A ten point self-rated sleep questionnaire was completed pre- and post-study. Results of one study of 20 severe pain patients showed that sleep improved 79% on average, while sleep of 56 patients in the second study improved by 53%.^{42,43}

Three hundred surveys had been sent in by patients diagnosed with insomnia. In this group, Alpha-Stim CES had been used for a minimum of three weeks. Patient responses were analyzed to assess their perception of CES's effectiveness in the treatment of their sleep disorder.⁴⁴ Among the people who listed insomnia as a major diagnosis were those who also included comorbidities such as anxiety or depression, while still others listed pain as their major accompanying symptom. The results were broken down into several sub-categories of insomnia as shown in Table 3, where it can be seen that patients reported an average of 87% improvement.

Meta-analysis

Table 4 lists the studies that have been found in which CES was used to treat insomnia.

Meta-analysis is a statistical method of combining the results of several studies that address a set of related research hypotheses. Our meta-analysis of CES calculates the percent of patients improving versus the percent not improving to yield the treatment effect size r , which is equal to the amount of patient improvement

given as percentage. These results can be compared with the accepted standardized ratings of $r = .10$ for small effect, $r = .30$ for medium effect and $r = .50$ for large effect. Table 5 shows a meta-analysis of the studies in Table 4, minus the study by Frankel that did not present treatment results prior to the crossover, and therefore could not be used. All resulting data were converted to Zr scores as previously described for the purpose of combining the effects from the various studies.^{45,46}

The summary at the end of Table 5 indicates that the mean effect size from all 20 studies combined (7 of which were double blind), was a strong $r = .64$. The standard deviation, or distribution of effect sizes around the mean effect size was .36, so 99% of effect sizes gained from all future meta-analyses will be expected to fall between $r = .41$ and $r = .87$ (the confidence interval). Clearly, CES can be an effective treatment for insomnia, with the added benefit that it has minimal negative side effects, it is less expensive than medications and has no cross-reactions with the plethora of medications used for insomnia, and can be used over a long period of time without becoming addictive.

Discussion

There have been more than 20 sleep studies done with CES for insomnia as the primary diagnosis or as a secondary diagnosis to addictions or other forms of stress or pain related disorders. These studies demonstrate that CES can be an excellent

TABLE 4. LIST AND DESCRIPTION OF INSOMNIA STUDIES

Author	Primary Diagnosis	Blinding			Study Design	Outcome Measure
		Patient	Therapist	Assessor		
Feighner ²⁵	Insomniacs	Yes	No	Yes	Crossover 2 wks/2 wks	Global Rating Scale
Flemenbaum ²⁶	Insomniacs	No	No	No	Open Clinical	Clinical Rating Scale
Franke ²⁷	Insomniacs	No	No	No	Crossover 3 wks/3 wks	Psychology Tests/Biochem.
Gomez ²⁸	Drug Abstinence Syndrome	Yes	No	No	Single Blind	PRN Medication
Hearst ²⁹	Insomniacs	Yes	No	No	Single Blind	Clinical Rating Scale
Hozumi ³⁰	Multi-Infarct Dementia	Yes	?	?	Double Blind	EEG/Clinical Rating Scale
Kirsch ³¹	Insomniacs	No	No	No	Post Treatment Physician Survey	Physician's Rating
Lichtbroun ³²	Fibromyalgia	Yes	Yes	Yes	Double Blind Placebo Controlled	Self Rating Scale
Lichtbroun ³³	Fibromyalgia	Yes	Yes	Yes	Double Blind Placebo Controlled	Self Rating Scale
Moore ³⁴	Insomniacs	Yes	No	Yes	Crossover 1 wk/1wk	Self Rating Scale
Patterson ³⁵	Drug Abstinence Syndrome	No	No	Yes	Post Rx Physician Survey	Clinical & Self Rating Scales
Patternson ³⁶	Drug Abstinence Syndrome	Yes	Yes	Yes	Double Blind	Clinical Rating Scale
Philip ³⁷	Drug Abstinence Syndrome	Yes	Yes	No	Double Blind	Self Rating Scale
Rosenthal ³⁸	Insomniacs	No	No	No	Open Clinical	Clinical Rating Scale
Rosenthal ³⁹	Insomniacs	Yes	No	No	Single Blind	Clinical Rating Scale
Rosenthal ⁴⁰	Insomniacs	Yes	No	Yes	Double Blind	Clinical Rating Scale
Smith ⁴⁴	Insomniacs	No	No	No	Patient Self Report Survey	Self Rating Scales
Straus ⁴¹	Insomniacs	Yes	No	Yes	Crossover 2wk/2wk	Clinical Rating Scale
Tyres ⁴²	Fibromyalgia	No	No	No	Open Clinical	Self Rating Scale
Tyres ⁴³	Fibromyalgia	No	No	No	Open Clinical	Self Rating Scale
Weiss ²¹	Insomniacs	Yes	Yes	No	Double Blind	EEG/Self Rating Scale

treatment for insomnia in those patients who can accept and adapt to the modality. CES also has the additional benefit of helping to reduce dependence on drugs.³⁷

When the problem of studies done with a crossover design is counteracted by utilizing the results prior to the first crossover, Frankel conducted the only study in the CES literature that appears to have demonstrated no benefits of CES for insomnia, and this result very likely is due to experimental design difficulties.

Frankel described his group as suffering from "primary insomnia," and that has proven confusing. In fact, he recruited subjects from newspaper advertisements seeking people who had trouble sleeping. Weiss selected his subjects in exactly the

same way, and yet obtained very robust results, that held up over a 24 month follow up period.^{21,22}

Several studies have been included in which stimulation was given for only 30 minutes for five days, along with studies that provided one hour of stimulation for three weeks. No attempt has been made to separate out those two ends of the treatment spectrum to see if there is additional benefit from longer periods of treatment. The primary reason is that not separating them can be viewed as a conservative meta-analysis strategy. Even when including all these studies in a meta-analysis, CES emerges as a very robust treatment for insomnia. Finally, as with all meta-analyses, a statistical check was made to test for heterogeneity

of variance, and none was found, meaning that those treated for one week were not statistically distinct from those treated for longer periods of time. This suggests that one week of CES is quite possibly all that is required to initiate a significant improvement in this debilitating disorder, at least for some patients. Others, especially those with comorbidities may need considerably longer treatment to produce a sustained effect; possibly as much as two months of daily treatment.

Clinical Procedures and Considerations

CES may result in very vivid dreams, especially in post traumatic stress disorder patients. It is best to warn patients of this. Some individuals may panic after using CES for the first time in the mistaken belief that CES is adversely affecting them. They report having extremely vivid dreams and erroneously conclude that something must be going wrong. On the other hand, those who have been warned in advance are able to relax and enjoy the experience—only regretting it when their dreams return to normal after the first week or two.

A small percentage of people cannot use CES prior to going to sleep since it also induces an alert state of mind that can cause some people to remain wide awake because of their stimulated thought processes. On the other hand, the vast majority of people have better results using CES within three hours of going to sleep. If they wake up during the night they can remoisten the electrodes and turn the device back on for another treatment. This typically causes them to resume sleeping. A problem can occur after their sleep is normalized, usually by the end of the first or second week of use. If they continue to use CES immediately prior to sleep, a paradoxical alerting reaction may occur that again, could cause alertness instead of helping them sleep. At that point it is best to defer CES usage to the morning, and no more than two or three times per week.

Patients who are trying to eliminate benzodiazepines should do so very slowly, of course, and under the supervision of their physician because of withdrawal-induced insomnia and anxiety symptoms. CES will stimulate endorphin production,⁴⁷ but it can take a few days for the endorphin level to elevate sufficiently to modulate the norepinephrine in the brain, so the patient will be more agitated (and alert) during these few days. Sleep will worsen accordingly. The patient should be counseled regarding this process and encouraged to wait it out. It will certainly help if the drug is withdrawn slowly over weeks, using CES to help the brain normalize as the drug is withdrawn. As CES has been shown to potentiate the uptake and utilization of psychoactive medications, it may be prudent to reduce any ongoing sleep medication by at least one-third when CES is being added to pharmaceutical regimens.^{48,49} However, any long-term or short-term reduction of medications requires active participation of the patient in making this decision. Following this pattern will enhance the patient's sense of well-being as well as a sense of control over two different disturbing problems: the insomnia as well as the challenging medications often used to treat insomnia.

In addition to CES, cognitive behavioral therapy (CBT) is another treatment modality that may offer clear advantages over medications.⁵⁰ One study randomly treated 48 chronic insomniacs with CBT, Zopiclone (similar to Lunesta), or inactive placebo for six weeks. At the end of treatment and then six months later, sleep records (ambulatory PSG used in the home bedroom

TABLE 5. META-ANALYSIS OF CES INSOMNIA STUDIES SHOWN IN TABLE 4.

Author	Number of Patients			Statistic Reported	Zr Equivalent
	CES	Sham	Total		
Feighner	10	9	19	59% Imp.	.678
Flemenbaum	28	none	28	P<.01	.511
Gomez	14	14	28	93% Imp.	1.650
Hearst	14	14	28	42% Imp.	.448
Hozumi	14	13	27	P<.05	.388
Kirsch	135	none	135	62% Imp	.725
Lichtbroun	10	20	30	72% Imp	.908
Lichtbroun	20	40	60	82% Imp	.875
Moore	17	17	34	P<.05	.343
Patterson	186	none	186	56% Imp	.633
Patterson	8	10	18	P<.02	.590
Philip	10	11	21	P<.05	.448
Rosenthal	9	none	9	50% Imp	.549
Rosenthal	12	6	18	60% Imp	.693
Rosenthal	11	11	22	81% Imp	1.127
Smith	300	none	300	87% Imp	.811
Straus	17	17	34	P<.05	.343
Tyres	20	none	20	79% Imp	1.071
Tyres	60	none	60	53% Imp	.590
Weiss	5	5	10	P<.001	1.528
Total	900	187	1083		14.909
					Mean .746
					Effect Size r = .64
					Standard Deviation .36
					Standard Error of the Mean .08
					Confidence Interval, p<.01, r = .41 to r = .87

setting) were obtained. The authors stated, "For most outcomes, zopiclone did not differ from placebo...patients receiving CBT had better sleep efficiency using polysomnography than those taking zopiclone." Another source paraphrased the study as, "CBT raised the patients' average slow-wave sleep 27 percent by the end of treatment, and had increased it 34 percent six months later. Patients who took the sleeping pill had a big drop in the amount of slow-wave sleep. They had 20 percent less slow-wave sleep at the end of treatment, and six months later, they had 23 percent less slow-wave sleep."⁵¹

In tandem with CES, CBT may also offer clear advantages for some patients over soporifics and hypnotic medications used to

TABLE 6. ADDING CES TO CBT PRINCIPLES FOR INSOMNIA TREATMENT
(Modified from Sivertsen, et al.)

A. Sleep Hygiene: How lifestyle habits and environment affect sleep.
B. Sleep Restriction: Strict schedule of bed times and wake times with no midday naps.
C. Stimulus Control: Associate being in bed only with going to sleep. For appropriate patients, may also associate CES with going to sleep or better overall sleep even if CES is used during the day (patient who are "activated" by CES). Appropriate patients may use CES during sleep continuity disturbances at night.
D. Cognitive behavioral therapy: Control thoughts about sleeping or not sleeping; minimize worry about adverse health effects from insomnia.
E. Progressive relaxation techniques: CES can induce a state of deep muscular relaxation as well as helping one to learn the difference between tension and relaxation. CES is optimally combined with slow, deep, abdominal breathing. But not at bedtime for all patients.

promote sleep (Table 6). The concomitant use of CES, a neuroelectric modality, and CBT, a behaviorally-oriented form of psychotherapy gives the physician an even wider potential range of clinical effectiveness for dealing with insomnia. When possible, combining CES and CBT can facilitate less continuous and therefore more effective application of soporific and hypnotic medications. Intermittent use of hypnotics minimizes the negative consequences of adding tolerance and addiction to the problems of insomnia. ■

Daniel L. Kirsch, PhD, DAAPM, FAIS is an internationally renowned authority on electromedicine with 34 years of experience in the electromedical field. He is a board-certified Diplomate of the American Academy of Pain Management, Fellow of the American Institute of Stress, Member of the International Society of Neuronal Regulation, and a Member of Inter-Pain (an association of pain management specialists in Germany and Switzerland). He served as Clinical Director of The Center for Pain and Stress-Related Disorders at Columbia-Presbyterian Medical Center, New York City, and of The Sports Medicine Group, Santa Monica, California. Dr. Kirsch is the author of two books on CES titled, The Science Behind Cranial Electrotherapy Stimulation, 2nd Ed. published by Medical Scope Publishing Corporation, Edmonton, Alberta, Canada in 2002; and Schmerzen lindern ohne Chemie CES, die Revolution in der Schmerztherapie, Internationale Ärztgesellschaft für Energiemedizin,

Austria 2000 (in German). Dr. Kirsch is a research consultant to the US Army and VA Medical Centers and currently spends much of his time giving lectures at national military conferences and grand rounds at Army hospitals. Best known for designing the Alpha-Stim CES and MET line of medical devices, Dr. Kirsch is Chairman of Electromedical Products International, Inc. of Mineral Wells, Texas, USA with additional offices in Europe and Asia. Dr. Kirsch can be reached at dan@epii.com.

Marshall F. Gilula, M.D. is a Diplomate of the American Board of Psychiatry and Neurology and a Diplomate of the American Board of Medical Electroencephalography. He is also a board-certified Instructor in Biofeedback and Neurotherapy (NBCB). In 1978 he was a US-USSR NIMH Exchange Scientist working with cranial electrotherapy stimulation and general psychophysiology techniques at the P.K. Anokhin Institute, Soviet Academy of Medical Sciences, Moscow. In 1983 Dr. Gilula was the first Motoyama-Ben Tov Fellow at the Institute of Life Physics, Tokyo (Mitaka-shi), Japan and researched neuroelectric methodology and the EEG of altered states with Professor Hiroshi Motoyama. Dr. Gilula has had four years of residency and postdoctoral fellowship training in psychiatry and over seven years of postdoctoral training in neurology (neurophysiology and epilepsy). He has 40 years of experience in clinical psychiatry, and was in the Department of Neurology at the University of Miami Miller School Of Medicine from 1999 through 2003. Dr. Gilula was a Senior Fellow, Miami Center for Patient Safety, Department of Anes-

esthesiology, University of Miami from 2003 through 2005. Dr. Gilula is President and CEO of the Life Energies Research Institute in Miami. He can be reached at mgilula@mind-spring.com.

References

- American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders (DSM-IV)*. American Psychiatric Association. Washington, DC. 1994
- Diagnostic Criteria From DSM-IV-TR. American Psychiatric Association: *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision*. American Psychiatric Association. Washington, DC. 2000. p 267.
- American Sleep Disorders Association. *International Classification of Sleep Disorders: Diagnostic and Coding Manual. Revised Ed.* ASDA. Rochester, MA. 1997.
- DSM-IV-TR. Op.Cit. pp 267-276.
- Bixler EO, Kales A, Soldatos CR, Kales JD and Healy B. Prevalence of sleep disorder in the Los Angeles metropolitan area. *American Journal of Psychiatry*. 1979. 136:1257-62.
- U.S. Government, Bureau of the Census. U.S. Census figures. 2000.
- Zorich F, Kribbs N, Roehrs T, et al. Polysomnographic and MMPI characteristics of patients with insomnia. In: Hindmarch I, Ott H, and Roth T, eds. *Sleep, Benzodiazepines, and Performance*. Springer-Verlag. Heidelberg, Germany. 1984. pp 165-172.
- Roth T, Roehrs TA, Vogel GW, et al. Evaluation of hypnotic medications. In: Prien RF, Robinson DS, eds. *Clinical Evaluation of Psychotropic Drugs, Principles and Guidelines*. Raven Press. New York, NY. 1995. pp 579-592.
- Roehrs T and Roth T. Hypnotics: Efficacy and Adverse Effects. In: Kryger MH, Roth T, and Dement WC, eds. *Principles and Practice of Sleep Medicine, Third Edition*. W.B. Saunders Company. Philadelphia. 2000. pp 414-418.
- Aldrich MSS. *Cardinal Manifestations of Sleep Disorders*. In: Kryger MH, Roth T, and Dement WC, eds. Op. Cit. 2000. pp 526-533.
- McCall WV and Reynolds D. *Psychiatric Disorders and Insomnia*. In: Kryger MH, Roth T, and Dement WC, eds. Op. Cit. 2000. pp 640-646.
- Horne J. *Why We Sleep*. Oxford Univ. Press. Oxford. 1998. p 319.
- Dement W. The effect of dream deprivation. *Science*. 1960. 191:1705-1707.
- Buysse DJ. Rational pharmacotherapy for insomnia: time for a new Paradigm. *Sleep Medicine Review*. 2000. 4:521-27.
- Espie CA. Insomnia: conceptual issues in the development, persistence, and treatment of sleep disorder in adults. *Annual Review of Psychology*. 2002. p 10.
- Wegner DM. Sleep stage responses of older and younger subjects after sleep deprivation. *Electroencephalography and Clinical Neurophysiology*. 1994. 52:368-371.
- Ansfield ME, Wegner DM, and Bowser R. Ironic effects of sleep urgency. *Behavior Research and Therapy*. 1996. 34:523-531.
- Kripke D. Hypnotic drugs: deadly risks, doubtful benefits. *Sleep Medicine Review*. 2000. 4:5-20.
- Becker RO and Selden G. *The Body Electric*. William Morrow. New York. 1985. p 116.
- Kratzenstein CG Schreiben von dem Nutzen der Electricitaet in der Arzneiwissenschaft. Halle. 1745.
- Weiss MF. The treatment of insomnia through use of electrosleep: an EEG study. *Journal of Nervous and Mental Disease*. 1973. 157(2):108-120.

22. Cartwright RD and Weis MF. The effects of electrosleep on insomnia revisited. *Journal of Nervous and Mental Disease*. 1975. 16(2):134-137.
23. Aserinsky E and Kleitman N. Regularly occurring episodes of eye mobility and concomitant phenomena during sleep. *Science*. 1953. 118:273-274.
24. Dement W and Kleitman N. Cyclic variations in EEG during sleep and their relation to eye movements, body motility and dreaming. *Electroencephalogr Clin Neurophysiol*. 1957. 9:673-690.
25. Feighner JP, Brown SL, and Olivier JE. Electro-sleep therapy: a controlled double-blind study. *Journal of Nervous and Mental Disease*. 1973. 157(2):121-128.
26. Flemenbaum A. Cerebral electrotherapy (electrosleep): an open clinical study with a six month follow-up. *Psychosomatics*. 1974. 15(1):20-24.
27. Frankel BL, Buchbinder R, and Snyder F. Ineffectiveness of electrosleep in chronic primary insomnia. *Archives of General Psychiatry*. 1973. 29:563-368.
28. Gomez E and Mikhail AR. Treatment of methadone withdrawal with cerebral electrotherapy (electrosleep). *British Journal Psychiatry*. 1978. 134:111-113.
29. Hearst ED, Cloninger CR, Crews EL, and Cadoret RJ. Electro-sleep therapy: a double-blind trial. *Archives of General Psychiatry*. 1974. 30(4):463-466.
30. Hozumi SH, Hori M, Okawa Y, Hishikawa and Sato K. Favorable effect of transcranial electrostimulation on behavior disorders in elderly patients with dementia: a double-blind study. *International Journal of Neuroscience*. 1996. 88:1-10.
31. Kirsch DL. *The Science Behind Cranial Electrotherapy Stimulation*. Medical Scope Publishing. Edmonton, Alberta, Canada. 2002. p 164.
32. Lichtbroun AS, Raicer MM et al. *The use of Alpha Stim Cranial Electrotherapy Stimulation in the Treatment of Fibromyalgia*. Presented at the 15th Annual International Symposium on Acupuncture and Electro-Therapeutics. Columbia University. New York City. October 21-24, 1999.
33. Lichtbroun AS, Raicer MM et al. The treatment of fibromyalgia with cranial electrotherapy stimulation. *Journal of Clinical Rheumatology*. 2001. 7(23):72-78.
34. Moore JA, Mellor CS, Standage KF, and Strong H. A double-blind study of electro-sleep for anxiety and insomnia. *Biological Psychiatry*. 1975. 10(1):59-63.
35. Patterson MA, Firth J, and Gardiner R. Treatment of drug, alcohol and nicotine addiction by neuroelectric therapy: Analysis of results over 7 years. *Journal of Bioelectricity*. 1984. 3(1&2):193-221.
36. Patterson MA, Flood NV, and Patterson L. Neuroelectric therapy (NET) in addiction detoxification. *Subtle Energies*. 1992. 3(3):1-22.
37. Philip P, Demotes-Mainard J, Bourgeois M, and Vincent JD. Efficiency of transcranial electrostimulation on anxiety and insomnia symptoms during a washout period in depressed patients; a double-blind study. *Biological Psychiatry*. 1991. 29:451-456.
38. Rosenthal SH and Wulfsohn NL. Electro-sleep: a preliminary communication. *Journal of Nervous and Mental Disease*. 1970. 151(2):146-151.
39. Rosenthal SH and Wulfsohn NL. Studies of electro-sleep with active and simulated treatment. *Current Therapeutic Research*. 1970. 12(3):126-130.
40. Rosenthal SH. Electro-sleep: A double-blind clinical study. *Biological Psychiatry*. 1972. 49(2):179-185.
41. Straus B, Elkind A, and Bodian CA. Electrical induction of sleep. *American Journal of Medical Sciences*. 1964. 248:514-520.
42. Tyres S and Smith RB. Treatment of fibromyalgia with cranial electrotherapy stimulation. *Original In-tervist*. 2001. 8(3):15-17.
43. Tyres S and Smith RB. A comparison of cranial electrotherapy stimulation alone or with chiropractic therapies in the treatment of fibromyalgia. *The American Chiropractor*. 2001. 23(2):39-41.
44. Smith RB. Is microcurrent stimulation effective in pain management? An additional perspective. *American Journal of Pain Management*. 2001. 11(2):64-68.
45. Kirsch DL and Gilula M. A review and meta-analysis of cranial electrotherapy stimulation in the treatment of anxiety disorders – Part 1. *Practical Pain Management*. 2007. 7(2):40-47.
46. Kirsch DL and Gilula M. Cranial electrotherapy stimulation in the treatment of anxiety disorders: statistical considerations – Part 2. *Practical Pain Management*. 2007. 7(3):22-39.
47. Gold MS, Pottash ALC, Sternbach H, Barbaban J and Annitto W. Anti-withdrawal effects of alpha methyl dopa and cranial electrotherapy. *Society for Neuroscience*. 12th Annual Meeting. 1982.
48. Stanley TH, Cazalaa JA, Limoge A, and Louville Y. Transcutaneous cranial electrical stimulation increases the potency of nitrous oxide in humans. *Anesthesiology*. 1982. 57:293-297.
49. Childs A. Droperidol and CES in organic agitation. *Clinical Newsletter*, Austin Rehabilitation Hospital. Austin, Texas. 1995.
50. Sivertsen B, Omvik S, Pallesen S, et al. Cognitive Behavioral Therapy vs Zopiclone for Treatment of Chronic Primary Insomnia in Older Adults: A Randomized Controlled Trial. *JAMA*. 2006. 295:2851-2858.
51. DeNoon DJ. *Insomnia: Talk Therapy Beats Sleeping Pills*. <http://www.foxnews.com/story/0,2933,201216,00.html?sPage=fnc.health.neurologicalillnesses>. Accessed Online 5/26/07.

Experts in topical anesthetics for over 100 years



Gebauer Company has been supporting the medical community for over 100 years. From the turn of the 20th century when we introduced the first easy-to-use pharmaceutical grade ethyl chloride to today, medical and physical therapy professionals have relied on our expertise and experience in topical anesthetics, because they know Gebauer is a name they can trust.



Gebauer Company
The Most Trusted Name In Skin
Refrigerants For Over 100 Years!®

800.321.9348 • www.gebauer.com