SYSTEMATIC REVIEW

Cranial Electro Stimulation Review: A Safer Alternative for the Treatments of Insomnia

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ABSTRACT

Introduction: Insomnia has been associated with significant healthcare costs and with mental health conditions such as depression, anxiety, substance misuse, and suicide. Safe and effective treatment options are therefore required. Cranial Electrotherapy Stimulation (CES) has been proposed as a non-invasive alternative to medication, although its therapeutic role remains under evaluation. **Methods:** A systematic search was conducted in PubMed, ScienceDirect, Springer, Emerald Insight, Frontiers, and Scopus for studies published between 2005 and 2025. Data submitted to the U.S. Food and Drug Administration (FDA) in support of CES approval were also reviewed. Studies were included if CES mechanisms, clinical outcomes, safety, or side effects were reported. A total of 17 studies fulfilled the inclusion criteria and were analyzed in detail. **Results:** It was found that CES demonstrated efficacy comparable to, and in some cases exceeding, that of pharmacological treatments for insomnia. The incidence of adverse effects was reported to be lower, with most side effects described as mild and transient. These findings suggest that CES may provide an effective and well-tolerated intervention for insomnia. **Conclusion:** CES is a safe, non-invasive, and promising therapy for the management of insomnia. However, additional large-scale and comparative studies are still required to confirm its long-term effectiveness and to establish its advantages over pharmacological treatment.
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INTRODUCTION

Insomnia is a common sleep disorder that affects individuals across all age groups, particularly from adolescence to adulthood. It is caused by various psychological and biological changes. One of the primary causes of insomnia is increased beta wave activity, where heightened anxiety levels can trigger an overproduction of beta waves and making it difficult to initiate sleep(1). In the digital era, excessive screen exposure before bedtime has emerged as a significant factor contributing to sleep disturbances. Research indicates that digital distractions, such as prolonged use of electronic devices at night, are associated with delayed sleep onset and poor sleep quality, particularly in young adults (2). The blue light emitted by screens can also suppress melatonin production, the hormone responsible for regulating sleep, while the mental and emotional engagement with digital content, such as video games or stimulating videos, can further disrupt the ability to relax before sleep. Additionally, studies have shown a correlation between increased screen time and mental health issues, including anxiety and depression, which can exacerbate insomnia (3).

The economic burden of insomnia is substantial.

In 2016, an estimated usd 30–35 billion was spent annually on its treatment, with the average adult incurring direct and indirect costs of over usd 1,253 to manage the condition(4). Beyond financial implications, insomnia is also closely linked to various mental health disorders, including depression, anxiety, substance abuse, and even suicide, which demand early intervention and ongoing management.

Currently, the most common treatments for insomnia include pharmacological therapies, such as benzodiazepines and cognitive behavioral therapy (21). While medications can be effective for short-term management, their long-term efficacy remains uncertain. Moreover, they are associated with side effects, including daytime fatigue, cognitive impairment, dizziness, and even rebound insomnia(5). Due to these risks, sleeping pills should only be taken under medical supervision and are not recommended for prolonged use without a doctor's prescription(6). Therefore, raising awareness about the importance of proper insomnia management is essential. Beyond minimizing reliance on pharmacological treatments, further exploration must be conducted to ensure that safer alternatives, such as behavioral interventions and non-invasive therapies, are developed, validated, and made accessible for patients. Such approaches can improve treatment outcomes while reducing the risks associated with long-term medication use. Additionally, the challenge of managing insomnia continues to drive advancements in techno-electromedical research that lead to the development of safer therapeutic solutions. One such innovation is cranial electrotherapy stimulation (ces), which has been studied for its efficacy, safety, and effectiveness in treating insomnia. Ces is recognized by the u.S. Food and drug administration (fda) as a medical device that delivers low-current, low-frequency electrical stimulation through electrodes placed on the earlobes for the treatment of depression, anxiety, and insomnia (7). Insomnia therapy using ces began in the united states in the 1960s and is now routinely prescribed by approximately a thousand physicians and mental health professionals.

From an engineering perspective, several limitations currently hinder the optimal application of cranial electrotherapy stimulation (ces) for insomnia treatment. A major issue is the lack of standardized stimulation protocols, including variations in waveform, frequency, amplitude, and electrode placement, which compromises treatment consistency and efficacy (8). Therefore, further exploration on this aspect is instrumental for engineers to develop not only programmable ces systems but also ones with tunable parameters to enable personalized therapy (24-25). Additionally, many consumer-grade devices suffer from poor component quality, signal inconsistency, and insufficient safety features, which highlight the need for improved design that adheres to medical device standards such as iec 60601 (9), 26, 28).

Literature Search Strategy

A comprehensive literature search was conducted across multiple academic databases, including Google Scholar, PubMed, ScienceDirect, Springer, Emerald Insight, Frontiers, and Scopus, to identify relevant studies on Cranial Electrotherapy Stimulation (CES) for insomnia. The search encompassed peer-reviewed journal articles, clinical trials, systematic reviews, and meta-analyses published before 2024. The keywords “CES Therapy for Insomnia” and “Use of CES tools in psychological therapy” were employed interchangeably, combined with Boolean operators such as AND and OR to refine and broaden the scope of the results. In PubMed, Medical Subject Headings (MeSH) were incorporated to increase search precision. Reference lists of included articles were also reviewed to capture studies that did not appear in the initial search. Studies were considered eligible if they focused on CES as a therapeutic intervention for insomnia, provided empirical data or comprehensive reviews, and compared CES with pharmacological, behavioral, or placebo interventions.

Research related to CES

Only full-text articles published in English were included. Excluded materials comprised case reports, conference abstracts, editorials, publications unrelated to CES or insomnia, and studies without sufficient methodological details or outcome measures. A total of 418 articles were retrieved for review using this search, but upon review, none directly reflected quality measures pertinent to insomnia care(10). For the effect of CES, twenty-three articles were found to be relevant and were then assessed for their characteristics. Out of the 23 studies, only 6 were RCTs. All the identified randomized controlled trials (RCTs underwent quality assessment for their methodology using the 11-point PEDro scale. Fifteen out of 23 studies (5 out of 6 RCTs) demonstrated that CES is beneficial to induce and improve sleep in various populations as assessed by both subjective and objective outcome measures. (11). A total of 17 studies fulfilled the inclusion criteria and were analyzed in detail.

Result

More than seventeen met the inclusion criteria for further analysis. The selected studies encompassed the efficacy, safety, and clinical applications of Cranial Electrotherapy Stimulation (CES) for insomnia. The findings were analyzed based on key parameters such as treatment efficacy, side effects, patient compliance, and comparisons with conventional pharmacological and behavioral therapies. The results highlight that CES demonstrates significant potential as a non-invasive, drug-free alternative for managing insomnia, with some studies reporting improvements in sleep latency, sleep efficiency, and overall sleep quality. Additionally, CES was found to have a lower incidence of adverse effects

compared to pharmacological treatments, making it a viable option for long-term insomnia management. The following presents a summary of the key findings from the reviewed studies, including the history, research evolution, and study design, sample size, CES parameters, treatment duration, and reported outcomes.

History, Evolution of CES Mechanisms, and Clinical Evidence

Dr. Leduc and Rouxeau of France were the first to explore low-current, low-frequency electrical stimulation of the brain in 1902. They initially termed the technique "electrosleep," based on the belief that it induced sleep. Over time, this method evolved under various names, including transcranial electrotherapy (TCET) and neuroelectric therapy (NET). Cranial Electrotherapy Stimulation (CES) itself emerged during the Soviet Union era in the 1950s and was introduced to the United States in the following decade. During the early 20th century, numerous clinical interventions were investigated to sedate patients and temporarily restore normal mental function. Among these were pharmacological treatments, which, although effective for some individuals, were associated with significant risks, including mortality rates as high as 3%. In 1933, Electroconvulsive Therapy (ECT) was introduced as a treatment for depression and psychosis (11). By the late 1970s and early 1980s, Margaret Patterson and Ray Gilmer had commercialized small, portable CES units. Gilmer's device, known as the "Relaxpak," operated at a fixed frequency of 100 Hz and a current of 800 microamperes, delivering stimulation via a modified square wave.

In contrast, Dr. Patterson's device offered a broader frequency range based on empirical applications: 10 Hz to enhance serotonin turnover (as shown in rat studies), frequencies below 75 Hz for barbiturate addiction, 75–300 Hz for narcotics, and around 2000 Hz for cocaine dependence. Her unit emitted bilateral, modified square wave pulses with pulse widths between 0.1 and 1.5 milliseconds. By 1986, Patterson had developed the eighth iteration of her device. However, key details about its stimulus characteristics remained undisclosed. While the exact stimulus intensity was not published, she indicated that the available frequency range extended from 1 Hz to 2000 Hz, suggesting that her latest model likely supported this full spectrum (12). The first article published in an American medical journal on this treatment referred to it as "electrosleep," a term still used in some regions outside the United States to describe Cranial Electrotherapy Stimulation (CES)(7). Modern CES devices typically operate at stimulus intensities of less than 1.0 milliampere, using frequencies of 0.5 or 100 Hz from a 9-volt source. American researchers found that while CES did not directly induce sleep, it produced therapeutic benefits regardless of whether the patient slept. As CES was initially developed for psychiatric disorders, its introduction coincided with the emergence of psychotropic drugs. One such example is chlorpromazine, a medication often used in combination with other drugs for insomnia treatment(12). This drug has also demonstrated effectiveness in managing certain psychotic disorders, even in the absence of sleep induction(13).

Table I. The characteristics of included studies.

Author, year	Purpose	Method	Result
Griffiths et al. (2023) (11)	Evaluate the effectiveness of Alpha-Stim AID cranial electrotherapy stimulation on mental health, specifically focusing on improvements in anxiety and depression.	The method involved recruiting participants through a social prescribing service, where they were referred by a general practice patient to a primary care-based social prescribing link worker. Participants provided informed written consent, and demographic information was collected. The study used a one-way repeated measures ANOVA to assess significant improvements in mental health assessments at baseline, week three, and week six. The study also utilized ANCOVA to test whether Alpha-Stim AID usage acted as a significant covariate of any improvement observed.	Significant improvement in the 'anxiety/depression' dimension, with severe/extreme levels of reported anxiety and depression dropping by 29.1% by the end of the intervention. However, no statistically significant changes were observed in the 'pain/discomfort', 'self-care', and 'mobility' dimensions, although trends showed improvement over time.
Chang et al. (2022) (12)	Investigate the effects of cranial electrotherapy stimulation (CES) on sleep quality and other related indicators in healthy athletes who had poor sleep quality and were preparing for competitions.	The study was a randomized controlled trial approved by the Institutional Review Board of China Medical University and Hospital. Participants were healthy athletes with poor sleep quality, recruited from sports teams at a sports university. They were randomly divided into the CES and placebo groups. The study used various measures, including biochemical analysis, reaction time tests, the Profile of Mood States (POMS), heart rate variability (HRV), and an Actigraph activity recorder, to assess the effects before and after the intervention. The Actigraph activity recorder was used continuously for 14 days. All assessments and interventions were performed by the same researcher, and the data were analyzed by the same analyst, with researchers blinded to participant allocation.	CES was found to reduce negative emotions, improve reaction times, and have minimal effects on sleep efficiency, suggesting it may be a beneficial and safe alternative for managing sleep issues in athletes before competitions.
Kang et al. (2020) (13)	The effects of cranial electrotherapy stimulation (CES) on blood pressure, heart rate, and anxiety in patients undergoing surgery.	The method involved dividing patients into a control group and a CES group using computerized randomization. The CES group received preoperative CES for 20 minutes on the day before surgery and on the morning of the day of surgery. Blood pressure and heart rate were measured at various times, including before surgery and after tracheal intubation.	The results indicated that although there was no statistical significance, blood pressure and heart rate appeared lower in the CES group compared to the control group. The study suggests that more significant results might be obtained with increased pretreatment frequency or duration, and in patients with a high anxiety index.
Moo-Estrella and Рйrez-Pichardo (2020) (14)	Investigate the effects of cranial electrical stimulation (CES) on symptoms of insomnia, anxiety, and depression in adults. The study aims to evaluate the efficacy of CES as a non-pharmacological treatment option, comparing its effects to a placebo, particularly focusing on its impact on insomnia severity and its potential benefits for anxiety and depression.	The study involved 24 participants, all diagnosed with initial insomnia according to the International Classification of Sleep Disorders (ICSD). The participants had an average age of 32.10 years, with 58% being women. They were divided into a control group (n = 11) and an experimental group (n = 13). The instruments used for assessment included Beck's Depression Inventory, State-Trait Anxiety Inventory, the Insomnia Severity Index, and the Insomnia Symptoms Questionnaire. Each participant was provided with a Fisher Wallace-100 CES device to use for 20 minutes each session, both in the morning and at night, over a period of 10 days.	Insomnia symptoms decreased significantly in both the control and experimental groups ($p < 0.01$). However, only the experimental group showed a significant reduction in the severity of insomnia ($p < 0.05$). The effect size analysis revealed a strong effect for the CES group ($d = 0.88$) and a moderate effect for the placebo group ($d = 0.52$) on the insomnia index. For anxiety symptoms, the CES had a modest effect ($d = 0.54$), while the placebo had a moderate effect ($d = 0.35$). Both groups showed a moderate effect size for depression symptoms ($d = 0.69$ for CES and $d = 0.58$ for placebo)

CONTINUE

Author, year	Purpose	Method	Result
Kwon et al. (2019) (15)	Evaluate the effects of cranial electrotherapy stimulation (CES) on subjective sleep quality in patients with chronic insomnia. The study aims to determine whether CES, when combined with sleep hygiene practices, is an effective treatment for chronic insomnia compared to sleep hygiene alone.	The study was designed as a prospective, double-blinded, and randomized controlled trial. Twenty-seven patients with chronic insomnia were recruited and randomly allocated to two groups: the cranial microcurrent therapy (MC) group and the sham group. All patients received sleep hygiene education. The Pittsburgh Sleep Quality Index (PSQI) and Insomnia Severity Index (ISI) were measured at baseline (pre-treatment), and at 2 weeks and 4 weeks of treatment.	Results from the study indicate that the group receiving real cranial electrotherapy stimulation (CES) experienced a consistent decrease in sleep disturbance scores, as measured by the Pittsburgh Sleep Quality Index (PSQI) and Insomnia Severity Index (ISI), over the four weeks. In contrast, the sham group initially showed improvement but then worsened after two weeks. The findings suggest that combining CES with sleep hygiene is more effective for treating chronic insomnia than sleep hygiene alone. Additionally, no adverse effects were reported, indicating that CES is a safe treatment option. However, the study's limitations include a short follow-up period, a small sample size, and reliance on subjective measures rather than objective sleep data.
Platoni et al. (2019) (16)	The purpose of the study was to investigate the effectiveness of Alpha-Stim® cranial electrotherapy stimulation (CES) in a group of 86 first responders for the treatment of anxiety, insomnia, depression, and pain.	A nonrandomized pretest-posttest design where participants self-selected into participation. They were instructed to use the Alpha-Stim device at a comfortable current, with the intensity level adjustable from 100-600 microamperes for 20-60 minutes daily. Baseline measurements were taken before starting the six-week study, and data analysis was done by measuring the differences between the pretest and posttest means of the participants.	The results showed a significant decrease in anxiety, insomnia, depression, and pain among the participants. Specifically, anxiety was reduced by 54%, insomnia by 33%, depression by 28%, and pain by 44%, all with highly significant p-values of <.001. The effect size Cohen's d values were large for all outcome measures, indicating a high level of practical change from baseline to posttest.
Yennurajalingam et al. (2018) (17)	To determine the feasibility and preliminary efficacy of a four-week cranial electrotherapy stimulation (CES) intervention on depression, anxiety, sleep disturbance, and pain scores, along with exploring concurrent biomarker studies	The method involved obtaining consent from eligible patients, collecting baseline data including demographic characteristics, and providing brief training on the use of a portable CES device. Data from assessment tools such as the ESAS, Hospital Anxiety and Depression Scale (HADS), Pittsburgh Sleep Quality Index (PSQI), Brief Pain Inventory (BPI) short form, and National Comprehensive Cancer Network (NCCN) Distress Thermometer were collected at baseline and weekly for four weeks. The CES device was used for 60 minutes per session daily for four weeks, and patients kept a daily log of their use.	The result showed that 33 of 36 patients (92%) completed the study. The CES use showed significant improvement in depression and anxiety, which were the target symptoms, rather than all the ESAS symptoms. However, the study lacked a sham control group, and the findings should be confirmed with a well-designed sham-controlled randomized controlled trial.
Wagenseil et al. (2018) (18)	The study was to investigate the effects of the Alpha-Stim 100 on sleep, specifically looking for measurable changes in sleep efficiency using polysomnography (PSG)	Randomly assigning subjects to either an active or sham group, with the study manager and physician blinded to the assignments. The sleep study nights were scheduled individually to account for hormonal influences on sleep. The study used PSG to measure various parameters, including sleep onset latency (SOL), heart rate, and EEG frequency, before and after CES stimulation.	There were no significant differences between the active and sham groups in terms of sleep efficiency, latency of sleep stages, or heart rate profiles during the study night. The hypothesis that the Alpha-Stim 100 would lead to measurable changes in sleep efficiency was not supported by the findings.
Gilula and Kirsch (2005) (7)	review the efficacy of Cranial Electrotherapy Stimulation (CES) in the treatment of depression, and to guide physicians and mental health professionals when dealing with patients who do not respond to medication or are concerned about potential adverse side effects	involves a review of 26 published studies on CES treatment for depression, with a focus on physiological and psychological changes. The studies include both actual treatment and sham treatment groups, and the review also considers the placebo effect in CES studies	The result of the review indicates that 81% of the studies reported efficacious results in the treatment of depression with CES. The mean effectiveness of CES above that of placebo controls is reported to be 63%, which is three times the mean effectiveness of psychoactive medications.

Since the year 2000, multiple medical device companies have received FDA clearance to market CES devices, including Fisher Wallace Laboratories, Electromedical Products International Inc., Neuro-Fitness LLC, Soterix Medical Inc., Biotronix Research Instruments, Life Systems Inc., Alpha-Stim, and Cranial Stimulators LLC (14). A bibliography by catalogs 126 scientific studies on CES, including 29 animal studies, Among these, nine major studies conducted in the United States over the past 30 years were double-blind trials performed at North American universities, Collectively, these studies involved 6,007 patients, with 4,541 patients actively receiving CES treatment to manage insomnia, reduce their dependence on sleep medications, and offer a cost-effective treatment option (7). Over the past two decades, the understanding of Cranial Electrotherapy Stimulation (CES) and its clinical applications has evolved substantially.

Pathophysiology CES of the brain

In the early phase of CES research (2005–2010), attention was directed toward its neurophysiological principles. The regulation of sleep and wakefulness has been attributed to the interplay between the ascending reticular activating system (ARAS), originating in the brainstem and posterior hypothalamus, and the anterior hypothalamus, which promotes sleep through inhibitory projections to arousal centers (13). The ventrolateral preoptic region (VLPR) has been identified as a key structure for sleep initiation via γ-aminobutyric acid (GABA), whereas orexin A, orexin B, dopamine, and norepinephrine have been implicated in maintaining wakefulness. Serotonin contributes to both processes (13). Disruption of these mechanisms has been linked to insomnia, as demonstrated in ins-1 Drosophila models, which display shorter sleep duration, longer recovery times after lights-off, fragmented sleep cycles, and heightened activity. Transcriptome profiling in these flies revealed altered expression of 755 conserved genes associated with brain function, metabolism, cell signaling, and sensory perception (14).

CES has been shown to act on these same pathways. Stimulation has been reported to alter neurotransmitter levels, enhance GABAergic tone, and promote endorphin release, thereby reducing hyperarousal states (7). Subcortical regions, including the ARAS, thalamus, hypothalamus, and limbic system, are influenced by CES, which modulates neurotransmitter activity and regulates hormone secretion through the hypothalamic–pituitary axis or alters cortical functioning (15). Collectively, these mechanisms suggest that CES engages the core neurophysiological substrates of insomnia, thereby addressing its pathophysiology rather than only alleviating its symptoms. Although it is not possible to determine whether neurotransmitter and endorphin hormone changes are directly or indirectly related to AC stimulation of the brain, these studies do suggest that there is at least an association between cranial AC stimulation and neurotransmitter release (16).

From a clinical standpoint, initial studies between 2005 and 2010 often compared CES with a placebo or no treatment. For instance, Gilula and Kirsch (2005) suggested that CES could serve as a safer alternative to psychopharmaceuticals for conditions such as anxiety and insomnia, due to its lower risk of side effects. Early trials generally reported minimal adverse effects, such as mild headaches or skin irritation at electrode sites, and noted these were far less frequent than those observed with antidepressants or sedatives (15). However, many of these early studies were limited by small sample sizes and a lack of comprehensive comparisons with other therapeutic modalities.

As research progressed into the 2011–2023 period, there was a noticeable shift toward understanding CES's effects on sleep-related neural circuits, particularly in the context of insomnia treatment. Researchers began to investigate CES's ability to promote brainwave entrainment, especially enhancing alpha wave activity, which is associated with relaxation and sleep onset (5,10). These studies offered deeper insight into how CES modulates serotonergic pathways and interacts with both cortical and subcortical structures involved in sleep regulation, thereby providing a more complete explanation of CES's role in improving sleep efficiency and quality (5,10).

In tandem with mechanistic exploration, comparative clinical studies in the recent decade have examined CES alongside cognitive behavioral therapy for insomnia (CBT-I), pharmacological agents, and other non-pharmacological interventions such as relaxation techniques. While some findings suggest that CBT-I may offer more sustainable long-term outcomes, CES demonstrated notable short-term efficacy, particularly in patients who were unresponsive to medication or preferred non-drug therapies. For example, studies such as Moo-Estrella and Pйrez-Pichardo (2020) and Kang et al. (2020) highlighted that CES led to significant reductions in insomnia severity, with large effect sizes and measurable improvements in sleep latency, wake after sleep onset, and sleep efficiency, especially among participants with co-occurring anxiety (9, 10).

From a safety perspective, recent findings have largely reinforced earlier observations, confirming that side effects associated with CES remain rare and mild, with occasional reports of dizziness and transient skin irritation (13). The consistent documentation of minimal adverse effects over time further supports the favorable safety profile of CES as a non-invasive neuromodulation therapy.

Clinical Perspective on CES for Insomnia and Related Conditions

From a clinical perspective, Cranial Electrotherapy

Stimulation (CES) has demonstrated promising outcomes in managing insomnia and related psychological conditions such as anxiety and depression (17-18). Moo-Estrella and Pŕrez-Pichardo (2020) reported statistically significant improvements in insomnia severity and sleep efficiency ($p < 0.05$), supported by large effect sizes(15) (10)(16). Similarly, studies involving the Alpha-Stim AID device showed reductions in anxiety symptoms, with severe/extreme anxiety levels decreasing by 29.1% and consistent p-values below 0.05 indicating short-term clinical effectiveness (9). Despite these encouraging findings, CES has yet to gain widespread clinical acceptance, primarily due to several critical limitations (17).

One major concern is the lack of long-term data, as most trials assess outcomes over short durations, leaving uncertainties about the durability of CES effects, the potential for habituation, and its safety with prolonged use (25). Furthermore, heterogeneous patient responses, particularly between those with primary versus comorbid insomnia, limit the generalizability of findings(18). Therapeutic outcomes are often influenced by patient-specific variables such as concurrent medications, underlying neurological conditions, and baseline sleep disturbances (29). Compounding this issue is the variability in device parameters, including frequency, intensity, session duration, and the use of different CES devices (e.g., Alpha-Stim, Fisher Wallace, Soterix), which hampers efforts to develop standardized treatment protocols.

In addition, while validated screening tools such as State-Trait Anxiety Inventory (STAI), Generalized Anxiety Disorder-7 (GAD-7), Hospital Anxiety and Depression Scale (HADS), Pittsburgh Sleep Quality Index (PSQI-9) and Insomnia Severity Index (ISI) are widely used to assess CES outcomes, most studies rely heavily on subjective self-report measures, with few incorporating objective physiological data such as EEG or polysomnography (19). In some cases, no statistically significant improvements in EEG-measured sleep parameters were observed between active CES and sham groups, which highlights the need for more robust, multimodal assessment approaches. Proposed mechanisms of action include CES's influence on serotonergic and GABAergic systems, which may reduce cortical hyperarousal and its potential to entrain alpha brainwaves, associated with calm, wakeful states, thereby promoting sleep onset (20).

Recent comparative research has evaluated cranial electrotherapy stimulation (CES) alongside cognitive behavioral therapy for insomnia (CBT-I), pharmacological treatments, and other non-pharmacological approaches. While CBT-I typically offers more enduring benefits, CES has demonstrated positive short-term efficacy, especially in individuals who do not respond well to standard medications (14). Furthermore, combining CES with sleep hygiene practices appears to yield better outcomes for chronic insomnia than CES alone. The CES program (60 minutes daily) helped mitigate the decline in sleep quality experienced by a student-athlete in the lead-up to a major event(21). However, when α peak frequencies across the entire α band were compared between the 40-minute session on night 1 and the 40-minute session after stimulation on night 2, no consistent patterns emerged: some participants showed increased α peak frequencies, others decreased, and some displayed no change. Similarly, amplitude changes were observed in several subjects, but again without uniformity. Comparable findings were noted in the sham group when the first and second nights were compared(22). Improvements in sleep quality following CES were supported by both subjective reports and EEG analysis. Participants experienced reduced sleep latency, longer overall sleep duration, and a decrease in insomnia severity as measured by questionnaire scores. These results are consistent with a randomized case-control study using CES, which reported shortened sleep latency and fewer nocturnal awakenings following electrical stimulation (15).

Importantly, CES has shown a favorable safety profile, with side effects typically mild and transient, including occasional dizziness and skin irritation. Recent studies have investigated the effects of CES on various conditions, including pain, headaches, fibromyalgia, smoking cessation, and opiate withdrawal. CES is generally considered safe and well-tolerated, with relatively few adverse effects. Common side effects include headache, skin irritation (e.g., minor burns), and light-headedness (23) (22). Isolated reports have also described vertigo, sleep disturbances, respiratory discomfort, nausea, diarrhea, urinary incontinence, and anxiety. In one study, five parents reported temporary rashes in their children following CES treatment. Another clinical trial found that six patients (1.2%) experienced dizziness and two (0.4%) reported nausea, both typically associated with excessively high current settings. Additionally, three patients (0.6%) reported skin irritation, while single instances of anger, a metallic taste, a sensation of heaviness, and intensified tinnitus were each observed in 0.2% of participants. In a separate study involving 23 psychiatric outpatients, one participant (4.3%) cried during treatment, and another (4.3%) experienced skin irritation behind the ears due to the drying of electrode gel (29).

In summary, while CES offers a promising non-invasive alternative for the treatment of insomnia and related conditions, its broader clinical application is limited by methodological inconsistencies, reliance on subjective assessments, and a lack of long-term and comparative data. Moving forward, larger, stratified, and standardized clinical trials incorporating both subjective and objective outcome measures are essential to fully establish CES's therapeutic role in mainstream practice (12).

Conclusion and suggestions

Cranial Electrotherapy Stimulation (CES) presents a promising non-pharmacological option for managing insomnia, especially for patients seeking treatments with minimal side effects. With appropriate training, CES can be administered safely in clinics, hospitals, or home settings. To ensure treatment effectiveness, patients should receive guidance on correct electrode placement and device usage and be encouraged to maintain a treatment diary to support adherence and monitor progress.

Although CES has demonstrated initial benefits comparable to pharmacotherapy, potentially via modulation of serotonergic and alpha brainwave activity, its broader clinical adoption remains limited. A critical gap lies in the lack of standardized treatment protocols and long-term evidence. Device variability (in frequency, intensity, and session duration), inconsistent methodological designs, and heavy reliance on subjective self-report measures hinder reproducibility and clinical confidence. Additionally, objective validation using tools such as EEG or polysomnography remains scarce, and the long-term safety and efficacy of CES have not been sufficiently established (24).

To strengthen CES's credibility and utility in clinical practice, future studies should adopt a stratified design that incorporates both subjective and objective outcome measures. Comparative evaluations with established therapies like CBT-I and pharmacological treatments will further clarify its therapeutic positioning. Given its favorable safety profile and growing acceptance of neuromodulation in sleep medicine, CES holds strong potential as a standalone or adjunctive therapy in individualized treatment plans for insomnia, provided that evidence-based standardization and long-term validation are prioritized in future research.

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