

Original Article

Theta-transcranial alternating current stimulation (tACS) to enhance sleep and mood symptoms in insomnia disorder: A randomized, single-blind, parallel-group, sham-controlled study

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Abstract

This research investigated whether transcranial alternating current stimulation (tACS) could help reduce symptoms of insomnia. Thirty individuals diagnosed with insomnia were recruited from various psychiatric clinics in Ahvaz, Iran, and assigned to two groups: 15 in the real stimulation group and 15 in the sham stimulation group. Participants received tACS at theta frequency targeting the dorsolateral prefrontal cortex (DLPFC) with the anode placed at F3 and the cathode at F4 for 10 consecutive days. All participants were evaluated before and after the intervention using the Insomnia Severity Index (ISI), the Beck Depression Inventory (BDI), and the Beck Anxiety Inventory (BAI). The results of the mixed-model ANOVA indicated a significant difference between the active tACS group and the sham tACS group regarding the reduction of insomnia severity ($p < 0.001$). Additionally, a significant difference in the reduction of depression was observed between the two groups ($p < 0.006$), while no significant difference in anxiety was found ($p > 0.419$). Real tACS demonstrated greater efficacy compared to sham tACS in improving symptoms of insomnia as well as depression. The results indicate that tACS targeting the DLPFC has the potential to serve as an effective and safe intervention for chronic insomnia over the course of 10 sessions.

Keywords

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Introduction

Insomnia is a widespread sleep disorder that affects millions worldwide, considerably influencing both sleep quality and duration (Lee et al., 2025). It is estimated that around 10% of adults experience insomnia disorder, while 15 to 20% occasionally face insomnia symptoms (Morin & Buysse, 2024). This condition can result in various physical and mental health issues, including impaired daytime performance, depression, anxiety, cognitive deterioration, and a reduced quality of life (Ishak et al., 2012; Ariapooran & Batouei, 2025). Cognitive Behavioral Therapy for Insomnia (CBT-I) is regarded as the primary treatment option, whereas medication serves as an adjunctive therapy (Morin and Buysse, 2024). Despite the effectiveness of both CBT-I and pharmacological treatments for insomnia, they often come with challenges such as limited availability or significant side effects (Ong et al., 2008; Sasai et al., 2010). These shortcomings in current treatment methods underscore the necessity for new therapeutic strategies.

Transcranial alternating current stimulation (tACS) is a non-invasive brain stimulation technique that delivers weak alternating electrical currents to the scalp to modulate brain oscillations (Elyamany et al., 2021). tACS has been studied across a variety of frequencies, including standard EEG frequencies from 0.1 Hz to 80 Hz, and extends into the 'ripple' frequency range (80–200 Hz), which can influence cortical excitability (Antal & Paulus, 2013). It has also been explored as a potential method to affect sleep (Shao et al., 2024; Simons et al., 2024; Zhu et al., 2024). Although numerous studies have been conducted, many are limited by small sample sizes or short durations (Motamedi et al., 2023; Robinson et al., 2018), which is insufficient for confirming clinical efficacy. Some research has shown significant effects of tACS on insomnia with larger participant numbers and adequate study durations (Wang et al., 2020; Zhu et al., 2024). However, these studies utilized a higher current intensity (15 mA) than the generally recommended range of 2–4 mA (Kunz et al., 2017), leaving the effectiveness of tACS at lower intensities uncertain. Additionally, while these studies encompass various frequencies, few have compared the

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optimal frequency for treating insomnia (Simons et al., 2024). The studies indicated that stimulation of the dorsolateral prefrontal cortex (DLPFC) with low frequencies (1 Hz) could enhance sleep architecture and quality (Babiloni et al., 2021). Considering that the theta rhythm is well recognized as a marker of sleepiness during wakefulness and the initial phases of spontaneous sleep onset, the theta band may serve as a viable target for modulation (Finelli et al., 2000). Furthermore, irregularities in neural oscillatory activity in the theta band have been noted in individuals with insomnia (Zhao et al., 2021). Previous studies have also demonstrated that 5 Hz transcranial alternating current stimulation (tACS) applied to the dorsolateral prefrontal cortex (DLPFC) prior to sleep can speed up the onset of sleep in healthy subjects (Xie et al., 2021). Additionally, theta-tACS during waking hours has been associated with increased sleep pressure and enhanced slow-wave activity during subsequent sleep (D'Atri et al., 2019). Thus, targeted modulation of theta activity at specific frequencies could provide therapeutic benefits for those with insomnia.

Considering the inconsistent findings in previous studies regarding optimal parameters, and the potential safety concerns associated with high-intensity stimulation, there is a critical need to evaluate safer, low-intensity protocols that target specific sleep mechanisms. While the theta band has been a focus of interest, the slow-oscillation frequency (approx. 0.5 Hz) represents the fundamental rhythm of deep, restorative sleep, yet its direct clinical application in insomnia remains underexplored. Validating the efficacy of low-intensity stimulation at this specific frequency is essential, as it could offer a novel, non-pharmacological, and well-tolerated therapeutic avenue for patients who do not respond to standard treatments. Therefore, the present study sought to bridge this gap by investigating the effectiveness of low-intensity transcranial alternating current stimulation (tACS) at 0.5 Hz. Our hypothesized that stimulation at this slow frequency, by mimicking natural sleep rhythms, would lead to significantly greater improvements in sleep quality and a reduction in insomnia symptoms compared to the sham condition.

Method

Participants

This research utilized a randomized, single-blind, parallel-group design. A total of thirty patients diagnosed with chronic insomnia (mean age = 35.59 years) were recruited through convenience sampling from various psychiatric clinics in Ahvaz, Iran. The diagnosis of insomnia was established by an experienced psychiatrist based on clinical interviews and confirmed to be the primary complaint, ensuring the exclusion of comorbid psychiatric conditions. Participants were randomly assigned to either the real stimulation group (n=15) or the sham group (n=15) using a block randomization method. The inclusion criteria were: (1) a diagnosis of chronic insomnia according to the DSM-5-TR; (2) age between 18 and 60 years; (3) no history of neurological conditions, brain surgery, epilepsy, seizures, head trauma, or metallic implants; and (4) the absence of any other

concurrent psychiatric disorders. This clinical trial received approval from the Ethics Committee of Islamic Azad University, Ardabil Branch (Ethics code: IR.IAU.ARDABIL.REC.1404.040), and all participants provided written informed consent prior to enrollment.

Instrument

Insomnia Severity Index:

The ISI, designed by Morin (1993), is a brief self-assessment tool that measures insomnia symptoms and their negative impacts on individuals' lives over the past two weeks. This tool consists of 7 questions that evaluate the severity of insomnia. Each question is scored on a 5-point Likert scale ranging from 0 to 4, and the total score of the questionnaire, derived from the sum of the scores, ranges from 0 to 28. A higher score on this questionnaire indicates more severe insomnia. Scores of 0-7 indicate no insomnia, scores of 8-14 indicate insomnia below the clinical threshold, scores of 15-21 indicate moderate insomnia, and scores of 22-28 indicate severe insomnia (Morin et al., 2011). The validity of this tool has been confirmed in various studies conducted in Iran (Motevalizadeh et al., 2022).

Beck Anxiety Inventory (BAI):

The Beck Anxiety Inventory (BAI) includes 21 items rated on a Likert scale from 0 to 3, producing raw scores that range from 0 to 63, which indicate the presence of anxiety. The Persian version of this inventory has demonstrated high internal consistency (Cronbach's alpha = 0.92) and acceptable test-retest reliability ($r = 0.83$) (Kaviani & Mousavi, 2008). This inventory is particularly useful for assessing the effectiveness of anxiety treatments (Leyfer et al., 2006), and the anxiety levels measured have been found to correlate with OCD symptoms (Velloso et al., 2016).

Beck Depression Inventory-II (BDI-II):

The BDI-II (Beck et al., 1996) is a self-report questionnaire that consists of 21 items designed to assess the feelings of the individual over the past two weeks. The internal consistency of the BDI-II has been reported to range from 0.7 to 0.92, and its test-retest reliability coefficient is 0.93 over a one-week period (Beck et al., 1988). In this research, a native language version of the BDI-II with reliable psychometric properties was used (Ghassemzadeh et al., 2005). Scores of 20 and above on the BDI-II suggest moderate to severe depression. The Persian version of the BDI-II has a reported Cronbach's alpha of 0.94 (Alipoor & Nori, 2006).

tACS:

tACS was applied using a single-channel electrical stimulator (NeuroStim 2, Madineh Teb, Iran) with two sponge electrodes (35 cm²; 7 × 5 cm) soaked in saline solution (0.9% NaCl). The stimulation duration was 30 minutes with a current intensity of 2 mA, including a 30-

second ramp-up and ramp-down. Participants in the real tACS group received stimulation at a frequency of 0.5 Hz. The anode was placed over F3 (left DLPFC) and the cathode over F4 (right DLPFC) according to the International 10-20 System. This montage was selected to target the dorsolateral prefrontal cortex (DLPFC), a key region involved in sleep regulation and arousal control, consistent with protocols used in previous successful sleep modulation studies (Xie et al., 2021). The intervention consisted of 10 sessions. A survey on potential side effects was conducted following each tACS session.

Procedure

Prior to the experiment, participants underwent a screening process to confirm eligibility and provided informed consent. Following the baseline clinical and cognitive assessments (pre-intervention), participants entered the treatment phase. The intervention consisted of 10 daily sessions performed consecutively over 10 days. To minimize circadian rhythm variability, all sessions were scheduled at the same time of day for each participant (between 16:00 and 20:00). During each session, participants were seated in a comfortable armchair in a quiet, dimly lit room. The skin at the electrode sites (F3 and F4) was cleaned with alcohol to ensure electrical impedance remained below 10 k Ω . Participants were instructed to relax, keep their eyes open to avoid drowsiness, and refrain from mentally demanding tasks during the 30-minute stimulation. In the sham condition, the device delivered current only during the initial and final 30 seconds (ramp-up and ramp-down) to mimic the skin sensations of the real stimulation, remaining off for the rest of the duration. Throughout the study, participants were kept unaware of their group assignment and the study's specific hypotheses. Post-intervention assessments were conducted immediately after the final session. None of the participants received concurrent psychotherapy during the trial.

The data analysis was performed using the SPSS statistical software, version 26.0 (IBM, SPSS, Inc., Chicago, IL). The distribution of the data was assessed for normality and variance homogeneity using the Shapiro-Wilk and Levene tests. A repeated measures ANOVA with a 2 $\times$ 2 design was

carried out. Prior to conducting the ANOVA, Mauchly's test was utilized to evaluate the sphericity of the data. If this assumption was not met, a Greenhouse-Geisser correction was applied. Following any significant findings from the ANOVA, Fisher's LSD post hoc tests (two-tailed and paired samples) were conducted for further analysis.

Results

Demographic and Baseline Characteristics

To ensure the comparability of the study groups, demographic characteristics including age, gender, and education level were analyzed prior to the intervention using independent samples t-tests for continuous variables and Chi-square tests for categorical variables. The results indicated no statistically significant differences between the real stimulation and sham groups at baseline. Regarding age, the mean in the real stimulation group was 35.20 (SD = 4.50) years, compared to 36.10 (SD = 4.20) years in the sham group ($t = -0.56$, $p = 0.58$). In terms of gender distribution, the real group consisted of 7 males (46.7%) and 8 females (53.3%), while the sham group comprised 8 males (53.3%) and 7 females (46.7%), with no significant difference observed ($\chi^2 = 0.13$, $p = 0.71$). Similarly, regarding education, the real group had an average of 14.50 (SD = 2.10) years of education, and the sham group had 14.20 (SD = 2.30) years, showing no significant disparity ($t = 0.37$, $p = 0.71$). These findings confirm that the randomization process was successful and the groups were homogenous concerning demographic variables at the study's outset. Prior to conducting the Repeated Measures ANOVA, preliminary analyses were performed to ensure no violations of the assumptions of normality and homogeneity of variance. The Shapiro-Wilk test indicated that the data for Insomnia Severity, Depression, and Anxiety were normally distributed for both groups ($p > 0.05$). Additionally, Levene's test for equality of variances showed no significant differences in error variances across groups ($p > 0.05$). Box's M test was also used to verify the assumption of homogeneity of covariance matrices, which was satisfied ($p > 0.001$). Therefore, the data were deemed suitable for parametric analysis.

Table 1. Means and SDs of, Insomnia Severity, Depression and Anxiety Before and Immediately After Interventions

Measure	Time	Group		p-value
		Active tACS M (SD)	Sham tACS M (SD)	
Insomnia severity	Pre-intervention	25.13 (2.38)	24.80 (1.97)	0.680
	Post-intervention	16.13 (5.16)	22.66 (1.49)	
Depression	Pre-intervention	24.46 (5.23)	27.53 (6.01)	0.147
	Post-intervention	17.66 (4.63)	25.73 (6.12)	
Anxiety	Pre-intervention	18.80 (3.56)	17.26 (1.75)	0.146
	Post-intervention	17.26 (1.75)	15.40 (1.91)	

The results of the 2 (Active tACS, sham tACS) $\times$ 2 (pre, post) mixed model ANOVA conducted for the Insomnia severity revealed significant main effects of stimulation ($F_1 = 13.006$, $p < 0.001$, $\eta^2 = 0.31$), time ($F_1 = 56.86$, $p < 0.001$, $\eta^2 = 0.670$) and a significant stimulation $\times$ time interaction ($F_1 = 21.63$, $p = 0.001$, $\eta^2 = 0.43$). The results of post hoc comparisons revealed that Active tACS

stimulation significantly reduced Insomnia severity as compared to sham tACS ($p_{\text{post-intervention}} = 0.001$). Comparisons between pre-to post intervention conditions within treatment groups showed a significant reductions of Insomnia severity scores were obtained in the Active tACS ($t_{\text{post}} = 7.05$, $p < 0.001$). (Fig1, Table 2).

The results of the 2 (Active tACS, sham tACS) $\times$ 2 (pre, post) mixed model ANOVA conducted for the depression (BDI-II) score revealed significant main effects of stimulation ($F_1 = 8.85$, $p < 0.006$, $\eta^2 = 0.24$), time ($F_1 = 31.64$, $p < 0.001$, $\eta^2 = 0.53$) and a significant stimulation $\times$ time interaction ($F_1 = 10.69$, $p = 0.003$, $\eta^2 = 0.27$). The results of post hoc comparisons revealed that

Active tACS stimulation significantly reduced BDI-II score as compared to sham tACS ($p_{\text{post-intervention}} = 0.006$). Comparisons between pre-to post intervention conditions within treatment groups showed a significant reduction of BDI-II scores were obtained in the Active tACS ($t_{\text{post}} = 6.17$, $p < 0.001$). (Fig1, Table 2).

Table 2. Results of the Mixed Model ANOVAS for Effects of Group (Active Tacs, Sham Tacs) and Time (Pre-Intervention, Post-Intervention) on Measures

Measure	Source	df	F	p-value	partial η^2
Insomnia severity	time	1	56.86	<0.001	0.670
	group	1	13.006	<0.001	0.317
	time $\times$ group	1	21.63	<0.001	0.436
Depression	time	1	31.64	<0.001	0.531
	group	1	8.85	<0.006	0.240
	time $\times$ group	1	10.69	<0.003	0.276
Anxiety	time	1	37.37	<0.001	0.272
	group	1	0.67	0.419	0.023
	time $\times$ group	1	12.52	<0.001	0.309

Also, the results of the 2 (Active tACS, sham tACS) $\times$ 2 (pre, post) mixed model ANOVA conducted for the anxiety level (BAI) revealed no significant main effects of stimulation ($F_1 = 0.67$, $p > 0.419$, $\eta^2 = 0.023$), but revealed significant of stimulation in time ($F_1 = 37.37$, $p = 0.001$, $\eta^2 = 0.27$) and stimulation $\times$ time interaction ($F_1 = 12.52$, $p = 0.001$, $\eta^2 = 0.30$). Comparisons between pre-to post

intervention conditions within treatment groups showed a significant reduction of BAI scores were obtained in the Active tACS ($t_{\text{post}} = 5.27$, $p < 0.001$) (Fig1, Table 2).

Side Effects and Baseline Evaluation

The participants experienced the stimulation without any issues, and there were no reported adverse effects during or after the stimulation, confirming the safety of the intervention.

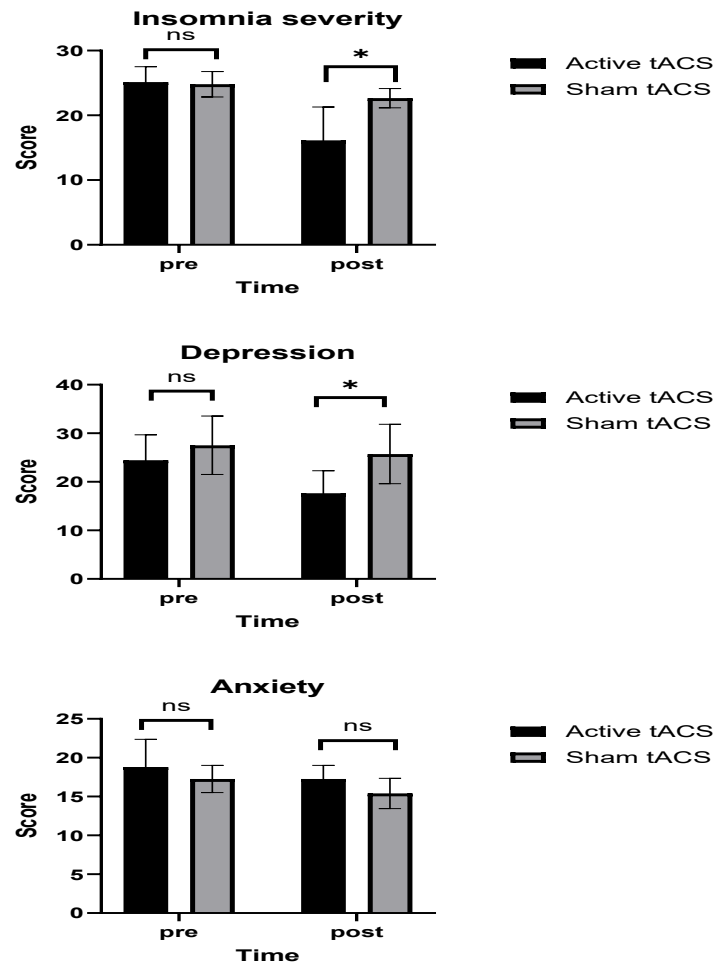


Figure 1. The impact of Active tACS on Insomnia severity, Depression and Anxiety

Note: tACS = Transcranial Alternating Current Stimulation; Asterisks [*] represent a statistically significant difference between sham conditions and active protocols; ns = nonsignificant

Discussion

This study evaluated the safety, feasibility, and efficacy of tACS for the treatment of chronic insomnia in adult patients. The study consisted of 10 sessions, with each session lasting 30 minutes over a consecutive 10-day period. Participants in the treatment group demonstrated a significant improvement in insomnia and depression issues compared to the sham stimulation group. The findings of the present study align with previous research results, which indicated that frequency-specific modulation of theta activity (in DLPFC) may have a therapeutic effect on patients with insomnia disorder (Shao et al., 2024). The neurological mechanisms associated with insomnia disorder are quite complex and are linked to abnormal brain function and neural oscillations. Based on the current understanding of the principles of NIBS techniques, tACS possesses the ability to specifically modulate neural oscillations by directly targeting frequencies. This capability may facilitate achieving more precise brain modulation in patients with insomnia disorder, potentially leading to better or quicker results (Shao et al., 2024).

To explain the findings of the current study, the hyperarousal hypothesis can be utilized. Recent research has indicated that individuals with insomnia exhibit unique electroencephalographic patterns in both sleep and wakefulness, which can be interpreted as signs of hyperarousal. During the EEG recordings taken in the wakeful resting state, these patients tend to show increased power in high-frequency ranges and decreased power in low-frequency ranges (Kwan et al., 2018). Specifically, there is less power observed in the narrow upper alpha band and more power in a broader beta range (Colombo et al., 2016). Evidence suggests that these characteristics can account for hyperarousal, with a decrease in theta power and an increase in beta power recognized as features associated with this condition (Wolynczyk-Gmaj & Szelenberger, 2011; Zakibakhsh, et al., 2024). Therefore, stimulating the frontal area with tACS at 5 Hz may help improve insomnia.

Additionally, recent clinical uses of tACS have demonstrated promising outcomes in reducing negative symptoms associated with various psychiatric disorders, including depression (Zhou et al., 2024). Abnormalities in theta band power (4–7 Hz) have also been observed in Major Depressive Disorder (MDD). Early research indicated that there was an increase in frontal-midline theta power during resting state in MDD patients; this increase was found in the anterior cingulate cortex (ACC) and indicated difficulties in emotion regulation (Jaworska et al., 2012). In summary, clinical studies of tACS have shown promising improvements in reducing MDD symptoms. However, it should be noted that the underlying mechanisms of modulation in these studies have varied and have led to different results (Pan et al., 2023).

Despite the promising findings, this study has several limitations that should be acknowledged. First, the evaluation of sleep quality relied primarily on subjective self-report questionnaires (ISI and PSQI). While these tools

are valid, future studies should employ objective measures such as polysomnography (PSG) or actigraphy to validate the neurophysiological changes associated with tACS. Second, the neural mechanisms underlying the efficacy of 0.5 Hz stimulation remain to be fully elucidated; incorporating EEG biomarkers or neuroimaging could clarify how this specific frequency modulates brain oscillations. Third, the sample size was relatively small, and the follow-up period was limited. Future research with larger cohorts and longitudinal designs is necessary to determine the long-term durability of the effects. Finally, while this study used a fixed frequency of 0.5 Hz, investigating personalized frequency tACS (based on individual peak frequencies) could potentially result in more robust and enduring enhancements in sleep quality.

Conclusion

In conclusion, this study provides preliminary evidence supporting the efficacy of low-intensity transcranial alternating current stimulation (tACS) at 0.5 Hz for the treatment of chronic insomnia. Our findings demonstrate that entraining brain oscillations at this slow-wave frequency can significantly reduce insomnia severity and improve sleep quality compared to sham stimulation. Although tACS is not yet a standard clinical treatment, this research proposes a specific, safe, and non-invasive protocol that could serve as a viable therapeutic option, particularly for patients seeking alternatives to pharmacological interventions. Validating this protocol in broader clinical settings may pave the way for tACS to become a routine intervention in sleep medicine.

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Disclosure Statement

The authors declare that they have no competing interests.

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