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Electrical vestibular nerve stimulation as a novel therapeutic approach for insomnia: a systematic review and meta-analysis

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Abstract

Background Insomnia affects over 850 million adults globally, representing a significant public health burden. Current treatments, including cognitive behavioral therapy for insomnia (CBT-I) and pharmacological interventions, face accessibility barriers and safety concerns, respectively. Electrical vestibular nerve stimulation (VeNS) has emerged as a promising non-invasive neuromodulation technique, leveraging connections between the vestibular system and sleep-regulating brain regions. This systematic review and meta-analysis aimed to evaluate the effect of VeNS on insomnia severity in adults with clinically significant insomnia.

Methods Following PRISMA guidelines, we systematically searched multiple databases up to July 19, 2025. Eligible studies included adults (≥ 18 years) with clinically significant insomnia (ISI ≥ 15) receiving transcutaneous VeNS versus sham stimulation. The primary outcome was the change in Insomnia Severity Index (ISI), a validated subjective measure scale. Secondary outcomes included the Pittsburgh Sleep Quality Index (PSQI) and quality of life measures, all assessed through self-reported instruments.

Results Three randomized controlled trials encompassing 289 participants met the inclusion criteria. VeNS demonstrated a statistically significant reduction in insomnia severity compared to sham control (ISI mean difference: -3.65 [95% CI: -6.84, -0.46]). Secondary analysis revealed significant improvements in sleep quality (PSQI mean difference: -0.98 [95% CI: -1.88, -0.08]).

Conclusions VeNS demonstrated statistically significant improvements in insomnia and sleep quality. However, the findings should be interpreted cautiously given the small number of available trials, reliance on subjective outcome measures, considerable heterogeneity, and limited safety data. Larger standardized trials are needed to establish its clinical utility and optimal implementation.

Clinical trial number Not applicable.

Keywords Electrical vestibular nerve stimulation, Galvanic vestibular stimulation, Insomnia, Neuromodulation

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Background

Insomnia represents one of the most prevalent health conditions worldwide, affecting more than 850 million adults aged 20 and older, which accounts for approximately 16.2% of the global population. Nearly half of these individuals, around 415 million, suffer from severe insomnia, imposing substantial burdens on both personal well-being and healthcare systems [1].

The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) defines insomnia disorder as dissatisfaction with sleep quality and/or quantity. It is characterized by difficulty falling asleep, staying asleep, or returning to sleep after early-morning awakening, occurring three nights per week, and causing distress in daily life [2]. Research has shown that insomnia significantly impacts quality of life, cognitive performance, and physical health [3, 4]. It is also linked to a wide range of comorbidities, including depression, anxiety, chronic pain, hypertension, vasomotor symptoms, and substance use disorders [5].

Current evidence-based treatments include cognitive behavioral therapy for insomnia (CBT-I) and pharmacological interventions. Although international guidelines recommend CBT-I as the first-line treatment given its proven effectiveness in addressing nighttime symptoms, daytime impairment, and associated comorbidities [6], significant barriers limit accessibility. These include provider shortages in some regions, high costs, and the need for extended time and effort [7]. Similarly, pharmacological approaches, though effective in the short term, carry risks of dependence, tolerance, cognitive impairment, and rebound insomnia, limiting their suitability for long-term management [8].

Electrical vestibular nerve stimulation (VeNS), also referred to in some literature as galvanic vestibular stimulation (GVS), has emerged as a promising non-invasive neuromodulation technique for various neurological and psychiatric conditions [9]. For insomnia, the neurobiological rationale for its use stems from extensive anatomical connections between the vestibular system and sleep-regulating brain regions. Vestibular signals travel via the vestibulocochlear nerve to the vestibular nuclei along the lateral wall of the fourth ventricle. From there, projections extend to multiple regions, including the intergeniculate leaflet (IGL), ventral lateral geniculate nucleus (VGL), and the locus coeruleus (LC), forming a network that conveys both photic and non-photic inputs to the suprachiasmatic nucleus. Additionally, reciprocal projections with lateral hypothalamic orexin neurons further connect the vestibular input to the sleep-wake regulating regions. Building on these multi-synaptic circuits and supported by evidence that rocking movements promote sleep, vestibular nerve stimulation has been explored as an interventional approach to improve insomnia [10–13].

Transcutaneous VeNS is delivered via electrodes placed over the mastoid processes, providing low-level electrical stimulation to vestibular nerves. This approach offers potential advantages, including non-invasive delivery, minimal side effects, and the possibility of home-based administration [9, 14].

Krone et al. [15] conducted a systematic review evaluating various non-invasive brain stimulation techniques for insomnia, including transcranial magnetic stimulation, transcranial electrical stimulation, and forehead cooling. At the time of their review, evidence for vestibular stimulation was limited to a single uncontrolled pilot study. More recently, Galin et al. [13] systematically reviewed the effects of vestibular stimulation on circadian rhythms and sleep. They evaluated multiple modalities, including mechanical stimulation (rotary chairs, rocking devices) and electrical stimulation, across controlled and non-controlled trials. Beneficial effects were reported, particularly for objective polysomnographic sleep parameters following mechanical stimulation; however, evidence supporting electrical vestibular nerve stimulation remained limited.

To address this methodological gap, the present systematic review focuses specifically on adults with clinically significant insomnia (ISI ≥ 15) and includes only sham-controlled randomized controlled trials rather than incorporating uncontrolled and non-randomized designs used in prior reviews. It focuses exclusively on electrical vestibular nerve stimulation (VeNS) rather than combining electrical and mechanical vestibular stimulation modalities. Moreover, it provides a quantitative meta-analysis to estimate pooled treatment effects on insomnia severity, measured by the Insomnia Severity Index (ISI) as the primary outcome, and on sleep quality, measured by the Pittsburgh Sleep Quality Index (PSQI) as the secondary outcome.

Methods

This systematic review was carried out in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [16]. It followed the methodological framework outlined in the Cochrane Handbook for Systematic Reviews of Interventions [17], and the study protocol was prospectively registered in PROSPERO (Registration number: CRD420251107128).

Inclusion criteria

Studies satisfying the following criteria were included in this review:

- **Population**: Adults (≥ 18 years) with clinically significant insomnia (Insomnia Severity Index ≥ 15), including both community-dwelling and clinical populations.
- **Intervention**: Transcutaneous electrical vestibular nerve stimulation delivered via electrodes placed bilaterally over mastoid processes, with any stimulation frequency or intensity.
- **Comparator**: Sham VeNS controls using identical-appearing devices that deliver lower frequencies and minimal vestibular stimulation for a few seconds before switching off.
- **Outcome measures**: Studies reporting quantitative outcomes for insomnia severity using the Insomnia Severity Index (ISI).
- **Study design**: Randomized, double-blind, sham-controlled, parallel-group trials.

We excluded studies that were: (a) non-randomized controlled trials, single-arm studies, observational studies, and letters to the editor; (b) conference abstracts, theses, or studies not published in English; (c) studies involving individuals with ISI scores < 15 indicating mild or no insomnia, or studies exclusively involving healthy volunteers without insomnia complaints; (d) studies investigating invasive vestibular stimulation procedures, mechanical vestibular stimulation without electrical component, or VeNS combined with other active neuromodulation techniques where effects could not be isolated; and (e) studies that lacked adequate reporting of primary outcomes or with data that could not be extracted.

Information sources and search strategy

We conducted comprehensive searches of multiple electronic databases up to July 19, 2025. The databases included PubMed/MEDLINE, the Cochrane Central Register of Controlled Trials (CENTRAL), Web of Science, Scopus, and ClinicalTrials.gov. The search strategy combined terms related to vestibular stimulation and insomnia. For PubMed, the search strategy was: ("vestibular stimulation" OR "vestibular nerve stimulation" OR "electrical vestibular stimulation" OR "VeNS" OR "galvanic vestibular stimulation") AND (insomnia OR "sleep disorder" OR "sleep quality" OR "sleep disturbance" OR "sleep problem"). Similar strategies were adapted for other databases. Full details of the search strategies for other databases are provided in Supplementary File 1.

Screening and study selection process

We employed Rayyan [18] to assist with the semi-automated screening of the literature search results. The screening process was carried out in two stages. In the first stage, titles and abstracts were assessed to identify studies that appeared to meet the inclusion criteria. In the second stage, full-text articles of the selected records were retrieved and evaluated for eligibility based on our predefined criteria. Two independent reviewers (M.M and M.A.T.M) conducted the initial screening, and any disagreements were addressed through discussion. If consensus was not achieved, a third reviewer (A.Z) was consulted. The entire study selection process was tracked and documented using a PRISMA flowchart.

Data extraction

Data extraction for all included studies was performed independently by three reviewers (M. M, E.G, and M.A.T.M) using a standardized Excel sheet. The extracted data included: (a) details of the study design and methodology, (b) baseline characteristics of the study participants, and (c) outcome data deemed reliable for inclusion in the analysis.

Risk of bias assessment

The risk of bias in the included studies was assessed using version 2 of the Cochrane Risk of Bias (RoB 2) tool [19]. This tool evaluates potential sources of bias across five key domains: the randomization process, deviations from intended interventions, missing outcome data, measurement of outcomes, and selection of the reported results. Two reviewers (Y.A and M.A.T.M) independently conducted the assessments, and any disagreements were resolved through discussion with a third reviewer (M.M.E) to ensure consistency and accuracy in the evaluation.

Outcomes

The primary outcome measured in this review was the Insomnia Severity Index (ISI). It is a self-report tool consisting of seven items that assess subjective insomnia symptoms, related distress, and the impact on daily life. Each item is scored on a 5-point Likert scale (from 0 to 4), with a total score ranging from 0 to 28. Higher scores indicate more severe insomnia [20].

The secondary outcomes included the Pittsburgh Sleep Quality Index (PSQI) and quality of life measures. The PSQI is a validated 7-component questionnaire that evaluates overall subjective sleep quality within the past month, with a total score higher than 5 corresponding to poorer sleep [21].

Quality of life was assessed using different validated instruments across studies: the Short Form Survey-36 (SF-36) in two studies, which evaluates eight health-related domains, including physical functioning, energy/fatigue, and emotional well-being [22]; and the World Health Organization Quality of Life- Brief Version scale (WHOQOL-BREF) [23] along with the Depression,

Anxiety and Stress Scale-21 (DASS-21) [24] in another study [25].

Data synthesis and statistical analysis

The main effect measures were the pooled mean differences in change scores (from baseline to post-treatment) for the ISI and the global PSQI scores between the VeNS and Sham groups. The mean change and standard deviation of change (SD change) within each group were used whenever clearly reported. In Curry et al. [26], the change in mean ISI score from baseline and the 95% confidence interval (95% CI) were shown only in figures, so the Plot-Digitizer [27] was used. Two reviewers (R. Akwan and M. Mahmoud) independently extracted the data from the figures, with consistent results upon comparison. The extracted 95% CIs were then used to calculate the SD of change using standard formulas. The same formulas were also applied in studies that reported the mean change and 95% CI numerically in text to calculate the corresponding SD of the change score. All procedures and formulas followed the guidelines in the Cochrane Handbook for Systematic Reviews of Interventions [17]. Outcomes not included in the meta-analysis were presented narratively.

Heterogeneity was assessed using Chi-square and I^2 statistics, with significant heterogeneity defined by a p-value less than 0.1 and an I^2 greater than 50%. When heterogeneity was encountered, a random-effects model was used, and a sensitivity analysis (if applicable) was performed to further evaluate the observed heterogeneity. Otherwise, a fixed-effects model was applied. All analyses were conducted using RevMan version 5.4 for Windows.

Publication bias

In line with Egger et al. [28], we determined that evaluating publication bias using Egger's test for funnel plot asymmetry was not applicable in this review, given that fewer than ten studies were included.

Results

Study selection

Our search strategy in the databases initially retrieved 141 results. 33 duplicates were removed using automated tools. Only three RCTs were included in our review for analysis based on the eligibility criteria. The Selection process is outlined in (Fig. 1).

Studies characteristics

The three included studies showed similar patterns in the use of vestibular nerve stimulation (VeNS) intervention and Sham devices, in terms of electrical current, frequency, duration, and number of sessions. Two studies had participants use the devices at home after initial training at the start of the study [26, 29], while in the third study, participants were supervised in the medical department by researchers during sessions [25]. All studies included participants with an ISI score of 15 or higher at baseline, indicating moderate to severe insomnia, and excluded individuals with ear problems, sleep medications, neurological issues, or skin conditions that could interfere with vestibular stimulation. Cheung et al. [29] and Curry et al. [26] involved similar age groups, whereas Goothy et al. [25] recruited younger patients aged 18–24 years. The characteristics of the studies are detailed in [Table 1] and [Table 2].

Risk of bias assessment

Two studies were judged to have a low overall risk of bias [25, 26], while Cheung et al. [29] had a high risk overall due to several concerns. The study had an approximately 25% attrition rate, attributed to early dropout and discontinuation, but without sufficient explanation of the underlying reasons. This raises concerns about whether the missing outcome data were not at random but could be dependent on the true outcome's value, as withdrawals may have occurred in patients with improved or worsening insomnia. Additionally, although the authors mentioned analysing the data on an intention-to-treat basis, the data reported in the study were all based on case-only analysis, which is inappropriate for assessing the assignment to intervention. Collectively, these issues raise concerns about the deviation from intervention, missing outcome, and selective reporting domains (Fig. 2).

Outcomes

Insomnia severity index (ISI)

Meta-analysis Our primary outcome was the pooled mean difference (MD) in changes in ISI scores from baseline to post-treatment at four weeks between the VeNS and Sham groups. Our meta-analysis demonstrated a statistically significant reduction in insomnia severity in the VeNS group compared to the sham group (mean difference, 95% CI: -3.65 [-6.84, -0.46]). However, heterogeneity was notably high ($I^2 = 95\%$) (Fig. 3).

A leave-one-out sensitivity analysis identified the study by Goothy et al. [25] as the primary contributor to between-study variability; its exclusion eliminated heterogeneity ($I^2 = 0\%$) while maintaining statistical significance (mean difference, 95% CI: -2.23 [-3.44, -1.03], $P = 0.0003$). (Supplementary Table 1).

Qualitative synthesis Cheung et al. [29] also assessed the ISI scale at one- and three-month follow-ups. At one-month follow-up, they found a between-group difference in mean change from baseline that favored the VeNS group. The VeNS group improved by an average of $\beta = 2.19$ points and an effect size of d = -0.32; however, the

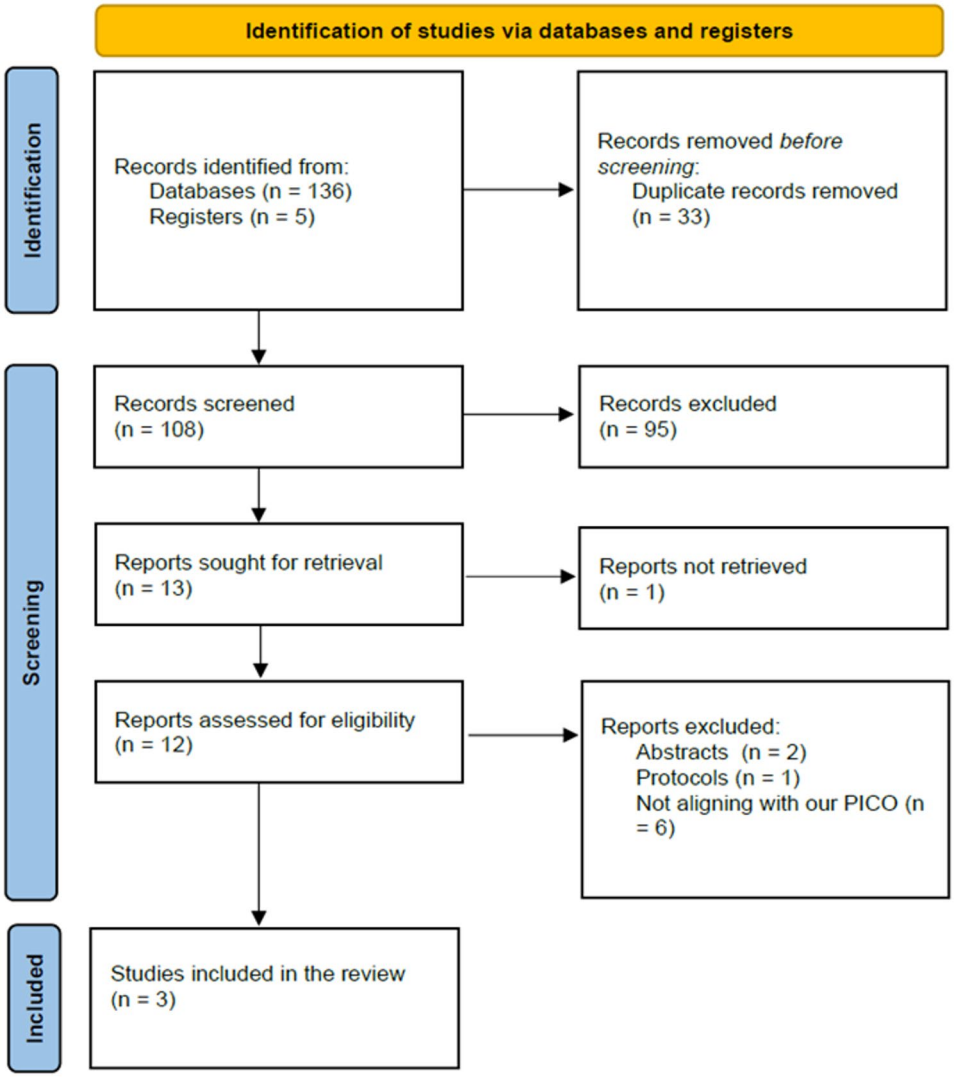

Fig. 1 PRISMA flowchart of the final included studies

difference was not statistically significant ($P = 0.06$). On the other hand, at three-month follow-up, the improvement in the VeNS group was statistically significant compared to sham controls [β (95% CI): 2.62 (0.40, 4.84), $P = 0.02$]. Curry et al. [26] also assessed the ISI at one- and three-month follow-ups, but due to high missing outcome data, the exploratory analysis was not performed. Additionally, they found that 50% of the participants in the VeNS group (31/61 PP cohort) experienced a clinically significant improvement in insomnia severity on the ISI scale. These participants tended to have higher baseline ISI scores compared to those who did not achieve a clinically significant reduction (21.4 ± 3.90 vs. 18.0 ± 3.49, respectively; t [59] = -3.50, $P = 0.001$). However, there was no significant difference between groups regarding the number of participants who achieved a clinically significant improvement ($p = 0.164$). Goothy et al. [25] showed a group-by-time interaction effect on changes in ISI scores from baseline to four weeks ($F_{3, 248} = 295.56$; $P < 0.001$). The mean ISI scores in the treatment group significantly decreased over days (7, 14, 21, and 28; $p < 0.001$). Conversely, the control group only experienced significant reductions in ISI scores after 21 days of use and continued to decrease until the end of the study duration ($P < 0.001$).

Pittsburgh sleep quality index (PSQI)

Meta-analysis Only two out of the three studies included assessed sleep quality using the PSQI scale [26, 29]. Our meta-analysis demonstrated that VeNS intervention ($n = 113$) had a significant effect in improving overall sleep quality compared to the sham group ($n = 117$) (mean dif-

Table 1 Studies' characteristics 1

Study/ Year	Country	Design	Sample Size (*N*)	Study Duration (weeks)	VeNS Intervention	VeNS Sham
Cheung et al., 2025	China (Hong Kong)	Randomized Sham-controlled trial	83 ITT	4 weeks / post-treatment follow-up for 3 months	Received 30-minute at-home sessions of electrical vestibular stimulation adjusted from 0–10 (max. 1 mA at 100 Hz) *via* a mobile app. The headset was placed over the mastoid processes (20 sessions over 4 weeks).	Identical procedure and device with an initial stimulation for 30 s. The group experienced a sham vestibular stimulation at a frequency of 0.8 Hz, followed by a decrease to 0 mA over 20 s before switching off.
Curry et al., 2024	UK & China (Hong Kong)	Randomized Sham-controlled multicenter trial	147 ITT 126 PP	4 weeks at both sites/ post-treatment follow-up for 3 months in Hong Kong	Received 30-minute at-home sessions (0.1–1.0 mA, 0.25 Hz) via the Modius Sleep device with electrode pads over the mastoid processes, 5 days/ week (Hong Kong) for 4 weeks and 28 consecutive days (UK)	Identical procedure and device with a stimulation frequency of 0.8 Hz; Length of stimulation 50 s: 30 s at selected current, ↓ to 0 mA over the next 20 s before switching off
Goothy et al., 2023	India	Randomized Sham-controlled trial	80 ITT	4 weeks/ no follow-up	Received 30-minute supervised sessions (1.0 mA, 0.25 Hz) via mastoid electrodes, 5 days/week for 4 weeks	Identical procedure and device delivered a small electrical current to the skin, initially over the mastoid processes, which slowly decreased to 0 mA over several minutes, before switching off

ITT: Intention-to-treat, PP: Per-protocol, N: Number

Table 2 Studies' characteristics 2

Study/ Year	Age mean (SD)		Sex (M/F) *N* (%)		Outcomes
	VeNS	Sham	VeNS	Sham	
Cheung et al., 2025	39.6 (12.06)	41.8 (12.48)	12 (30%) /28 (70%)	12 (28%) / 31(72%)	ISI / PSQI / (SF-36)
Curry et al., 2024	39.6 (13.9) ITT 40.5 (13.1) PP	42.0 (13.0) ITT 41.9 (12.8) PP	25 (34.2%) / 48 (65.8%) ITT 21 (34.4%) / 40 (65.6%) PP	24 (32.4%) / 50 (67.6%) ITT 21 (32.3%) / 44 (67.7%) PP	ISI / PSQI / (SF-36)
Goothy et al., 2023	21.02 (1.76)	20.30 (1.85)	22 (55%)/ 18 (45%)	20 (50%) / 20 (50%)	ISI / (DASS-21 and WHOQOL-BREF)

SD: Standard deviation, M/F: Male/Female, ITT: Intention-to-treat, PP: Per-protocol, ISI: Insomnia Severity Index, PSQI: Pittsburgh Sleep quality index, SF-36: the RAND 36-Item Short Form Health Survey, DASS-21: Depression, Anxiety and Stress Scale-21 Item, and WHOQOL-BREF: World Health Organization's Quality of Life Questionnaire-26 Item

ference [95% CI] = -0.98 [-1.88, -0.08], I2 = 0%, overall effect; $P = 0.03$). [Fig. 4].

Qualitative synthesis Authors of Cheung's study [29] found that ISI and PSQI have a significant positive correlation at baseline and after four weeks of treatment, indicating that worse insomnia severity was associated with poorer sleep quality in both the VeNS group ($r = 0.424$–0.620, $P < 0.01$) and the sham group ($r = 0.508$–0.685, $P < 0.01$). Nine participants in the intervention group and 10 in the sham group transitioned from poor sleep at baseline to good sleep after four weeks, as reported in the Curry study [26].

Quality of life

The Rand SF-36 scale was used to assess quality of life in Cheung et al. [29]. Only one component (the role limitations due to physical health) showed a statistically significant improvement in the intervention group compared to the control group at four weeks [β (95% CI): −18.79 (−34.71, −2.86), $P = 0.02$, d = 0.26]; however, this significance was not maintained during follow-up at one month ($P = 0.67$) and three months ($P = 0.60$). In contrast, many components of the SF-36 scale demonstrated a significant improvement in the Curry et al. study [26]. In the VeNS within-group difference, all components except for pain and physical functioning showed a significant improvement from baseline to four weeks ($P < 0.01$). Meanwhile, the sham within-group analysis showed improvements in physical and social functioning, energy/fatigue, pain, and general health ($P \leq 0.005$). After Bonferroni correction, the fatigue/energy component remained significantly different between the intervention and control cohorts (ITT; $P = 0.006$, PP; $P = 0.004$).

Goothy et al. [25] also assessed quality of life, but using the WHOQOL-BREF scale along with the DASS-21 score, which measured participants' emotional states. The between-group difference demonstrated a significant improvement in the intervention group compared to the sham group in depression (mean change, 95%; 9.15 [0.56, 8.03]), anxiety (mean change, 95%; 8.20 [6.94, 9.46]),

Fig. 2 Risk of bias assessment of included RCTs using ROB 2.0

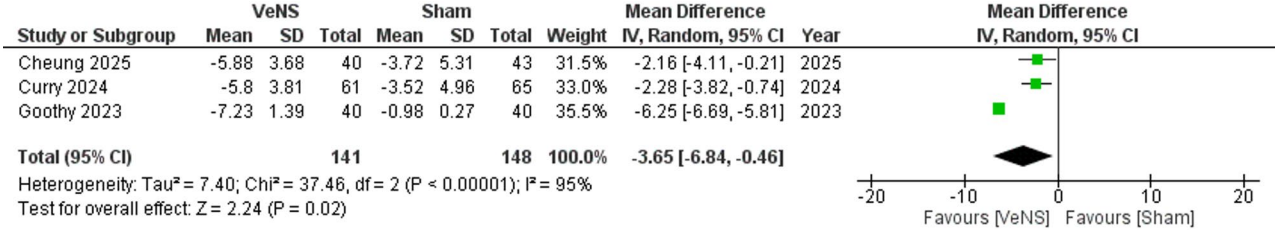

Fig. 3 Forest plot of the effect of VeNS Intervention vs. Sham on Insomnia Severity Index (ISI)

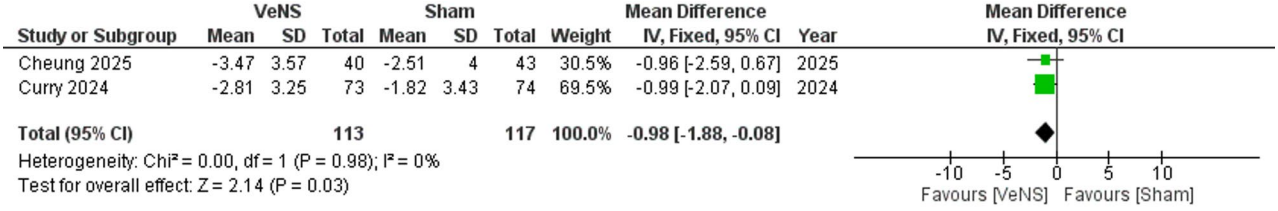

Fig. 4 Forest plot of the effect of VeNS Intervention vs. Sham on Total PSQI Scale

and stress (mean change, 95%; 6.59 [5.60, 8.30]). Additionally, the four components (physical, psychological, environmental, and social health) exhibited a significant increase in the VeNS group compared to the sham cohort ($P < 0.001$).

Discussion

The current study provides a comprehensive systematic review and meta-analysis of electrical vestibular nerve stimulation (VeNS) for insomnia treatment in adults. Our pooled analysis of three RCTs involving 289 participants demonstrates that VeNS produces a statistically significant reduction in insomnia severity compared to sham stimulation, with a mean difference of -3.65 points (95% CI: -6.84 to -0.46) on the Insomnia Severity Index.

Additionally, VeNS showed favorable effects on sleep quality and quality of life domains, particularly energy/fatigue.

The magnitude of effect observed in our meta-analysis (3.65-point ISI reduction) represents a therapeutic benefit that warrants careful interpretation. While falling short of the 4-point frequently used minimal clinically important difference (MCID) threshold [30], this finding aligns with effect sizes reported for other non-pharmacological interventions for insomnia. For comparison, a large meta-analysis of digital CBT-I interventions reported ISI reduction with a mean difference of 5 points [31], suggesting that VeNS produces effects somewhat close to those of established behavioral interventions. Importantly, when excluding the Goothy et al. study [25] that caused heterogeneity, and considering the remaining two studies [26, 29], the effect size remains robust at a 2.23-point mean difference with no statistical heterogeneity, indicating a consistent, albeit modest, therapeutic effect. This, nonetheless, represents a meaningful signal of efficacy that merits serious consideration, particularly given the dearth of novel non-pharmacological interventions demonstrating even modest benefits in rigorously controlled trials. In addition, it is important to note that while our findings demonstrate statistical significance, this does not automatically imply clinical significance; the observed effect remains modest and should be weighed alongside clinical context and patient preferences.

The mechanisms underlying VeNS efficacy appear to involve various interconnected neurophysiological pathways that converge on sleep-regulating brain networks. The vestibular system's influence on sleep architecture is supported by robust physiological evidence showing its capacity to modulate REM sleep [32–34], with labyrinthine inputs influencing the pontine reticular formation neurons involved in mediating the switching between sleep states [35]. Additionally, neural projections from the medial vestibular nucleus extend to arousal-mediating regions, with certain sleep-related processes receiving orexinergic inputs from the lateral hypothalamus [36]. Moreover, vestibular stimulation appears to modulate sleep through dual mechanisms: inhibiting both the hypothalamic-pituitary-adrenal (HPA) axis and the sympathetic-adreno-medullary (SAM) axis, thereby decreasing stress, while simultaneously exciting sleep-inducing areas such as the nucleus tractus solitarius and the serotonergic dorsal raphe nucleus [29]. Furthermore, the characteristic rocking sensation generated by electrical vestibular stimulation contributes to sleep promotion [12], with the input from the vestibular system to sleep-regulating nuclei, facilitating the synchronization of the body's internal state with tranquillizing movements, promoting a state of relaxation and drowsiness conducive to sleep [37].

The substantial statistical heterogeneity observed in our primary analysis (I^2 = 95%) demands careful methodological scrutiny. Our sensitivity analysis identified the Goothy et al. study [25] as an outlier, contributing disproportionately to between-study variance. Several methodological factors likely account for this deviation. First, the exclusive recruitment of young adults (18–24 years) may have selected for a population with distinct insomnia phenotypes, potentially characterized by delayed sleep phase tendencies or technology-related sleep disruption [38–40]. Second, the supervised, clinical setting-based administration model employed by Goothy et al. [25] contrasts sharply with the ecological validity afforded by home-based protocols in the other trials. Given the limited number of included trials and the marked sensitivity of the pooled effect estimate to the removal of a single study, the observed treatment effect should be considered preliminary and interpreted cautiously pending replication in larger, independent samples.

Nevertheless, the clinical relevance of our findings extends beyond statistical significance. First, VeNS offers a unique therapeutic niche as a device-based intervention that requires minimal behavioral modification or cognitive engagement, potentially benefiting patients who cannot access or adequately engage with CBT-I. Second, the intervention's effects on quality of life domains, particularly energy/fatigue improvements, suggest broader benefits beyond sleep parameters alone. These multidimensional improvements may be particularly valuable given the well-documented associations between insomnia, fatigue, quality of life, and functional impairment [41–45].

Regarding safety and adverse events, Goothy et al. study [25] reported the most optimal safety profile with zero adverse events among participants and a 100% study completion rate, while Curry et al. (2024) documented 22 mild adverse events, predominantly consisting of infrequent headaches/migraines ($n = 7$; 6 treatment, 1 sham), eye disorders ($n = 4$; all treatment group, including peripheral vision flashes, shadows, and eye tingling), and ear-related symptoms ($n = 5$; primarily in sham group, including ear pain, tinnitus, and itching), with only one participant withdrawing due to device-related nausea and headaches. One serious adverse event (minor cerebral vascular accident) was reported but determined to be unrelated to the device, with the treatment group achieving an 80.8% completion rate. On the other hand, in Cheung et al. (2025) study [29], while the authors stated that "the full intervention procedures and safety issues are described elsewhere (See Supplemental material)", no supplementary materials were attached to or accessible with the published article, however, they mentioned in the paper that some participants discontinued

the intervention due to "sickness, technical phobia, or fear of adverse effects".

Furthermore, an important consideration for the clinical application of VeNS relates to contraindications. The included trials [25, 26, 29] excluded participants with some conditions that may interfere with vestibular stimulation. Common exclusion criteria across studies included: (a) ear disorders or vestibular dysfunction (which could be exacerbated by vestibular stimulation); (b) implanted electronic devices such as pacemakers or cochlear implants (due to potential electromagnetic interference); (c) skin conditions affecting electrode placement sites; (d) neurological disorders including seizure disorders; and (e) pregnancy (due to insufficient safety data in this population). However, it must be acknowledged that formal contraindications cannot be definitively established based on the current limited evidence. Thus, future research should incorporate systematic safety assessments using standardized reporting frameworks and specifically investigate safety in diverse populations to establish evidence-based contraindication guidelines.

Strengths and limitations

Our review has several notable strengths, including its comprehensive search strategy, adherence to PRISMA guidelines [16], prospective PROSPERO registration, rigorous statistical methodology, incorporation of sensitivity analysis, and assessment of multiple sleep-related outcomes.

However, several limitations merit consideration. The inclusion of only three randomized controlled trials represents an important limitation affecting multiple aspects. Statistical power is substantially constrained, increasing risk of imprecise effect estimates (reflected in wide confidence intervals) and limiting detection of true treatment effects. Generalizability is restricted by the narrow evidence base across populations and settings. Heterogeneity estimates have well-documented limited reliability in meta-analyses with fewer than ten studies and should be interpreted with caution. The small study number also precludes meaningful sensitivity analyses, subgroup analyses, or publication bias assessment. Additionally, one included study had a high risk of bias due to attrition and reporting concerns, and for another study, data extraction from graphical presentations may introduce measurement variability.

An additional limitation is the exclusive reliance on subjective self-report instruments. While validated and widely used, these instruments capture patient perception rather than objective physiological parameters. None of the included studies incorporated polysomnography, actigraphy, or electroencephalography. This limits our ability to determine whether reported improvements reflect actual changes in sleep architecture. Additionally, adverse event reporting across the included trials was non-standardized and inconsistent, with one study providing no accessible safety data, limiting our ability to draw firm conclusions about the safety profile of VeNS interventions. Furthermore, the short intervention duration and limited follow-up periods prevent conclusions about long-term efficacy. Finally, the absence of active comparator trials prevents definitive positioning of VeNS within the insomnia treatment hierarchy relative to established interventions such as cognitive behavioral therapy or pharmacological treatments.

Future research directions

Several research priorities emerge from our analysis. First, larger, adequately powered RCTs with extended treatment periods and longer follow-ups are needed to establish optimal treatment parameters and the durability of effects of VeNS. These studies, if possible, should also incorporate objective sleep measures to validate subjective improvements and elucidate effects on sleep architecture. Moreover, comparative trials against established treatments (CBT-I or pharmacotherapy) would clarify VeNS's relative efficacy and identify optimal treatment strategies. Furthermore, investigation of optimal stimulation parameters could enhance efficacy, while cost-effectiveness analyses are essential for informing healthcare policy decisions. Beyond these, future trials should also explore VeNS efficacy in various insomnia phenotypes, comorbid populations, as well as its potential as an augmentation to existing treatments. Most importantly, and while addressing the aforementioned research questions, future studies must implement standardized safety reporting protocols to properly determine the safety profile of VeNS interventions.

Conclusions

The VeNS intervention demonstrated statistically significant improvements in insomnia severity and sleep quality compared to sham stimulation. However, the current evidence base, limited to three small trials (total $n = 289$) with short follow-up periods, exclusive reliance on subjective outcome measures, considerable heterogeneity, and minimal safety reporting, render it insufficient to support clinical implementation at this stage. Until larger, well-designed trials with objective sleep measures, active comparators, longer follow-up periods, and comprehensive safety assessments are available, VeNS intervention should be considered experimental requiring further investigation to confirm its effects.

Abbreviations

CBT-I	Cognitive behavioral therapy for insomnia
CI	Confidence interval
DASS-21	Depression, Anxiety and Stress Scale-21 Item

DSM-5	Diagnostic and Statistical Manual of Mental Disorders, 5th Edition
GVS	Galvanic vestibular stimulation
HPA	Hypothalamic-pituitary-adrenal (axis)
IGL	Intergeniculate leaflet
ISI	Insomnia Severity Index
ITT	Intention-to-treat
LC	Locus coeruleus
PP	Per-protocol
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PSQI	Pittsburgh Sleep Quality Index
RCT	Randomized controlled trial
RoB	Risk of Bias
SAM	Sympathetic-adreno-medullary (axis)
SD	Standard deviation
SF-36	RAND 36-Item Short Form Health Survey
VeNS	Vestibular nerve stimulation
VGL	Ventral lateral geniculate nucleus
WHOQOL-BREF	World Health Organization Quality of Life Questionnaire (Brief version)

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12888-026-07922-4.

Supplementary Material 1

Supplementary Material 2

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A.Z: Conceptualization, Methodology, Data Curation, Writing – original draft, Writing - Review & Editing, Project Administration. R.A: Methodology, Formal analysis, Investigation, Data Curation, Writing – original draft, Writing - Review & Editing, Project Administration. M.M.E: Methodology, Investigation, Data Curation, Writing – original draft, Writing - Review & Editing, Project Administration. M.A.T.M: Investigation, Data Curation, Writing – original draft, Writing - Review & Editing. M.M: Data Curation, Investigation, Writing - Review & Editing. E.G: Data Curation, Investigation, Writing - Review & Editing. Y.A: Data Curation, Investigation, Writing - Review & Editing. J.M: Investigation, Writing - Review & Editing, and Supervision.

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Data availability
All data generated or analysed during this study are included in this published article [and its supplementary information files].

Declarations

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Consent for publication
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Competing interests
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