DOI: 10.20514/2226-6704-2026-16-3-175-186
УДК 616.8-009.7:616.831.191-085.847
EDN: EYZPVH

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НЕИНВАЗИВНАЯ ВАГУСНАЯ НЕЙРОСТИМУЛЯЦИЯ (НВНС): ОБЗОР ИССЛЕДОВАНИЙ ПРИ ГОЛОВНОЙ БОЛИ, ТИННИТУСЕ, НАРУШЕНИЯХ СНА И ТРЕВОГЕ

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Noninvasive Vagus Nerve Stimulation (NVNS): A Review of Research on Headache, Tinnitus, Sleep Disorders and Anxiety

Резюме

Неинвазивная вагусная нейростимуляция (нВНС) — перспективный метод лечения, который изучается и показывает положительные результаты при большом спектре заболеваний. Стимуляция осуществляется через поверхностные электроды в проекции шейной части или ушной (аурикулярной) ветви блуждающего нерва. Возрастающий интерес к нВНС обусловлен простотой, доступностью, безопасностью и хорошей переносимостью, однако до настоящего времени в России данный метод не нашел широкого применения. В данном обзоре представлены основные параметры, используемые для стимуляции аурикулярной ветви и шейной части блуждающего нерва, а также результаты клинических исследований по использованию нВНС при головной боли, тиннитусе, нарушениях сна и тревоге. Обсуждены рекомендации FDA по применению стимулятора шейного отдела блуждающего нерва при головной боли, а также вопросы, необходимые для повышения уровня доказательной базы нВНС при различных нозологиях. Обозначена востребованность и перспективность разработки отечественного устройства для стимуляции периферической ветви вагуса, с целью более широкого внедрения методики в практику и накопления опыта его амбулаторного применения.

Ключевые слова: *неинвазивная стимуляция блуждающего нерва, вагус, головная боль, мигрень, тиннитус, бессонница*

Конфликт интересов

Соавтор статьи Супонева Н.А. является членом редакционной коллегии журнала «Архивъ внутренней медицины». Статья прошла принятую в журнале процедуру рецензирования. Супонева Н.А. не участвовала в принятии решения о публикации этой статьи. Об иных конфликтах интересов авторы не заявляли

Источники финансирования

Авторы заявляют об отсутствии финансирования при проведении исследования

Статья получена 26.09.2025 г.
Одобрена рецензентом 13.01.2026 г.
Принята к публикации 15.02.2026 г.

Для цитирования: Супонева Н.А., Грозова Д.А., Кириченко О.А. и др. НЕИНВАЗИВНАЯ ВАГУСНАЯ НЕЙРОСТИМУЛЯЦИЯ (НВНС): ОБЗОР ИССЛЕДОВАНИЙ ПРИ ГОЛОВНОЙ БОЛИ, ТИННИТУСЕ, НАРУШЕНИЯХ СНА И ТРЕВОГЕ. Архивъ внутренней медицины. 2026; 16(3): 175-186. DOI: 10.20514/2226-6704-2026-16-3-175-186. EDN: EYZPVH

Abstract

Non-invasive vagus nerve stimulation (nVNS) is a promising treatment showing positive results for a wide range of diseases and is currently under active investigation. Surface electrodes are used to stimulate the cervical or auricular branch of the vagus nerve. The growing interest in nVNS is driven by its simplicity, accessibility, safety, and good tolerability. However, to date, this method has not been widely adopted in Russia. This review covers the main stimulation parameters for auricular and cervical vagus nerve targets and the clinical evidence supporting nVNS use in managing headache, tinnitus, sleep disorders, and anxiety. We discuss FDA guidance on cervical VNS for headache and the research gaps that need to be filled to advance the evidence for nVNS in various conditions. We emphasize the necessity and prospects for a domestic (Russian) peripheral vagus nerve stimulation device, which would promote wider clinical integration and data collection on outpatient use.

Key words: *noninvasive vagus nerve stimulation, vagus, headache, migraine, tinnitus, insomnia*

Conflict of interests

Co-author of the article Suponeva N.A. is a member of the editorial board of the journal «The Russian Archives of Internal Medicine». The article passed the journal's peer review procedure. Suponeva N.A. was not involved in the decision to publish this article. The authors did not declare any other conflicts of interest

Sources of funding

The authors declare no funding for this study

Article received on 26.09.2025
Reviewer approved 13.01.2026
Accepted for publication on 15.02.2026

For citation: Suponeva N.A., Grozova D.A., Kirichenko O.A. et al Noninvasive Vagus Nerve Stimulation (NVNS): A Review of Research on Headache, Tinnitus, Sleep Disorders and Anxiety. The Russian Archives of Internal Medicine. 2026; 16(3): 175-186. DOI: 10.20514/2226-6704-2026-16-3-175-186. EDN: EYZPVH

CBT — cognitive behavioural therapy, nVNS — non-invasive vagus nerve stimulation, PSQI — Pittsburgh Sleep Quality Index, FDA — Food and Drug Administration

Introduction

Over the past several decades, neuromodulation techniques have been increasingly employed in the treatment of neurological disorders. One such approach is invasive vagus nerve stimulation (VNS), which has been approved by the U.S. Food and Drug Administration (FDA) for the treatment of epilepsy and depression in patients older than 12 years of age [1]. Despite being considered minimally invasive, the procedure is associated with a risk of implantation-related complications, including bradyarrhythmias, peritracheal hematoma due to the close anatomical relationship between the vagus nerve and the carotid artery, and respiratory complications such as vocal cord dysfunction and dyspnoea [2]. Rare cases of late-onset bradyarrhythmias and severe asystole have also been reported in patients with implanted devices [3]. These concerns continue to limit the widespread adoption and broader implementation of invasive vagus nerve stimulation.

A promising alternative that avoids the limitations associated with invasive stimulation is non-invasive vagus nerve stimulation (nVNS). In nVNS, stimulation is delivered through surface electrodes placed over the cervical portion of the vagus nerve or the auricular branch of the vagus nerve [2, 4]. The neurophysiological mechanisms underlying this technique have been extensively investigated at the preclinical level. Briefly, vagus nerve stimulation transmits afferent signals to the nucleus tractus solitarius, which in turn activates the locus coeruleus and promotes the release of norepinephrine. Increased norepinephrine levels subsequently stimulate the dorsal raphe nucleus, leading to enhanced serotonin release, a process associated with increased synaptic plasticity and neurogenesis. In addition, vagus nerve stimulation activates the basal nucleus, thereby modulating the cholinergic system, which plays a crucial role in neuroplasticity, including through mechanisms of long-term potentiation [5].

The therapeutic potential of nVNS extends beyond the treatment of depression and epilepsy. This approach is currently being investigated in a wide range of neurological disorders, including headache, tinnitus, insomnia, pain syndromes, restless legs syndrome, Parkinson's disease, and others [4, 5]. Adverse effects associated with nVNS are generally mild and include skin irritation at the stimulation site; less commonly, patients report headache, dizziness, nausea, nasopharyngitis, and other symptoms [6]. To date, non-invasive vagus nerve stimulation has not been widely adopted in Russia.

The aim of this review is to summarise and systematise the available evidence regarding the use of nVNS in the treatment of headaches, tinnitus, sleep disturbances, and anxiety.

A literature search was conducted using the PubMed (including MEDLINE) and Web of Science databases, as well as the Russian scientific electronic libraries CyberLeninka and eLibrary.Ru. The following keywords were used: "non-invasive vagus nerve stimulation", "vagus", "headache", "migraine", "tinnitus", and "insomnia".

Use of nVNS in headache, tinnitus, sleep disturbances, and anxiety

A brief overview of studies investigating the efficacy of nVNS is presented in Table 1.

Table 1. *Brief description of studies of the effectiveness of nVNS in headache, tinnitus, sleep disorders and anxiety*

Author, year, reference	**Nosology (number of patients)**	**Stimulation site (side)**	**Stimulation parameters:** 1. pulse width 2. intensity 3. frequency	**Treatment regimen**	**Result**
P.J. Goadsby et al, 2014 [8]	episodic migraine (30)	neck (R)	1. NS 2. NS 3. NS	– 2 x 90s doses (15 min apart) after the onset of the headache – follow-up period — 6 weeks	2 hours after onset of headache: – with moderate and severe attack — no pain in 21 % (first attack)/22 % (all attacks) – with mild attack — 63 % pain free (first attack)/38 % pain free (all attacks)
P. Barbanti et al, 2015 [9]	chronic migraine (50)	neck (R)	1. NS 2. NS 3. NS	– 2 x 120s doses (3 min apart) within 20 min of the onset of mild or moderate headache – follow-up period — 2 weeks	48 patients: – after 1 hour: ≥ 50 % reduction in VAS in 56,3 % of patients, VAS = 0 in 35,4 % of patients – after 2 hours: ≥ 50 % reduction in VAS in 64,6 % of patients, VAS = 0 in 39,6 % of patients 131 migraine attacks: – after 1 hour: ≥ 50 % reduction in VAS in 38,2 % of attacks, VAS = 0 in 17,6 % of attacks – after 2 hours: ≥ 50 % reduction in VAS in 51,1 % of attacks, VAS = 0 in 22,9 % of attacks
T.M. Kinfe et al., 2015 [10]	treatment-refractory migraine and sleep disturbance (20)	neck (L, R)	1. 1 ms 2. up to 24 V 3. 25 Hz	– for treatment — 120s on each side – for prevention — 120s on each side, 2 times a day, 3 months	– decreased frequency (p <0,01), intensity (p <0,0001) and duration (p <0,002) of migraine attacks – improvement in performance, sleep quality and depressive symptoms (p <0,05)
L. Grazzi et al., 2016 [11]	menstrual /menstrually related migraine (51)	neck (L, R)	1. 0,2 ms 2. up to 60 mA 3. 25 Hz	– 120s on each side, 3 times a day – from –3 days before estimated onset of menstruation through +3 days after the end of menstruation during each cycle of the 12-week treatment period	reduction in the number of menstrual migraine/ menstrually related migraine days and analgesic use (p <0,001)
C. Tassorelli et al, 2018 [12]	episodic migraine (120)	neck (L, R)	1. 0,2 ms 2. 60 mA 3. 25 Hz	120s on each side within 20 min of the onset of headache	nVNS is superior to placebo for pain freedom at 30 minutes and 60 minutes after the onset of the attack (p <0,01), increases the probability of having mild pain or being pain-free 2 hours poststimulation
S.D. Silberstein et al, 2016 [13]	chronic migraine (59)	neck (R)	1. NS 2. up to 60 mA 3. NS	– 2 x 120s doses (5-10 min apart), 3 times a day – follow-up period — 8 months	reduction in the number of headache days compared to baseline (p <0,01)
C. Gaul et al., 2016 [14]	chronic cluster headache (45)	neck (R)	1. NS 2. 60 mA 3. 25 Hz	3 x 120s doses, 2 times a day	a greater reduction in the number of headache attacks per week compared with the control group (p = 0,02)

Table 1. (Continued)

Author, year, reference	Nosology (number of patients)	Stimulation site (side)	Stimulation parameters: 1. pulse width 2. intensity 3. frequency	Treatment regimen	Result
S.D. Silberstein et al, 2016 [15]	episodic and chronic cluster headache (150)	neck (R)	1. 0,2 ms 2. up to 60 mA 3. 25 Hz	3 x 120s doses (1 min apart)	in the nVNS group, more patients with episodic cluster headache responded to treatment (VAS = 0 or 1 after 15 minutes) (p =0,008)
P.J. Goadsby et al, 2018 [16]	episodic and chronic cluster headache (48)	neck (on the attack side)	1. 0,2 ms 2. up to 24 V 3. 5 kHz	3 x 120s doses	in the nVNS group, a higher proportion of episodic cluster headache attacks achieved pain-free status within 15 minutes (p <0,01)
A. Straube et al, 2015 [19]	chronic migraine (46)	ear, concha (L)	1. 0,25 ms 2. below pain threshold 3. 1 Hz or 25 Hz	4h a day, 12 weeks	stimulation with a frequency of 1 Hz leads to a greater reduction in headache days over a 28-day period compared to stimulation with a frequency of 25 Hz (p =0,035)
J. Lehtimäki et al, 2013 [26]	tinnitus (10)	ear, tragus (L)	1. NS 2. above sensory threshold (about 0,8 mA) 3. 25 Hz	7 sessions x 45/60 min	decreased severity of tinnitus symptoms (THI and mini-TQ questionnaires), improved mood (WHO-5 questionnaire); no statistical verification was performed
P.M. Kreuzer et al, 2014 [31]	tinnitus (50)	NS	1. NS 2. 0,1-10 mA 3. 25 Hz	– phase I: 6h a day – phase II: 4h a day – follow-up period — 24 weeks	– phase I (terminated prematurely due to two cardiac events) — decreased TQ scores (p =0,036) – phase II — insignificant decrease in TQ scores (p =0,146)
Z. Mei et al, 2014 [27]	tinnitus (32)	ear, concha (NS)	1. 1 ms 2. 1 mA 3. 20 Hz	– 20 min, 2 times a day – daily for 8 weeks	higher efficacy (THI and TDI questionnaires) in the main group (nVNS + sound therapy) compared with the control group after 8 weeks (p <0,05)
H.J. Shim et al, 2015 [28]	tinnitus (30)	ear, concha (L)	1. 0,2 ms 2. 1-10 mA (below pain threshold) 3. 25 Hz	10 sessions x 30 min	– insignificant decrease in THI scores (p =0,339) – decrease in tinnitus loudness (p =0,005) and tinnitus awareness (p =0,020)
W.C. Suk et al, 2018 [29]	tinnitus (24)	ear (cavum, cymba and tragus) (NS)	1. 0,2 ms 2. below pain threshold 3. 30 Hz	4 sessions x 12 min (each site for 4 min) for 2 weeks (day 1-3-8-10)	1 month after the end of the sessions: – reduction of tinnitus characteristics (loudness, awareness, annoyance and effect on life) (p <0,05) – decrease in THI scores (p <0,001) – decrease in BDI scores (p =0,004)
T.Yu. Vladimirova et al, 2023 [30]	tinnitus (25)	ear, cymba (L)	1. NS 2. 10 mA 3. 1-30 Hz	14 sessions x 10 min	patients of the main group (nVNS + medications) were 60 % more likely to have a positive effect from treatment in the following indicators: the assessment of the strength of subjective ear noise, the tone of the autonomic nervous system, the results of the THI questionnaire, the qualitative hearing characteristics

Table 1. (The end)

Author, year, reference	Nosology (number of patients)	Stimulation site (side)	Stimulation parameters: 1. pulse width 2. intensity 3. frequency	Treatment regimen	Result
M. Luo et al, 2017 [40]	primary insomnia (35)	no data	no data	– 30 min, 2 times a day – 5 days a week, for 4 weeks	– decrease in PSQI scores at the end of the 2nd week (p <0,05) – decrease in HAMD and HAMA scores at the end of weeks 4 and 6 (p <0,05)
Y. Jiao et al, 2020 [41]	insomnia (31)	ear, concha (on both sides)	1. NS 2. adjusted by participants 3. 20 Hz — 10 s, 4 Hz — 5 s	– 30 min, 2 times a day – 5 consecutive days a week, for 4 weeks	significant decrease in PSQI score in the main group (nVNS) at week 4, with no significant difference compared to the control group (sham nVNS)
Y. Wu et al, 2022 [42]	insomnia (15)	ear, concha (on both sides)	1. 0,2 ms 2. 1 mA 3. 20 Hz	– 20 min, 2 times a day – 1 month	a more significant decrease in PSQI scores in the main group (nVNS) compared with the control group (sham nVNS) (p =0,027)
L. Zhang et al, 2023 [43]	altitude insomnia (33)	ear, tragus (L)	1. 0,5 ms 2. NS 3. 25 Hz	– 45 min x once a day – 5 consecutive days a week, for 4 weeks	– significant decrease in PSQI, ISI and GAD-7 scores in the main group (nVNS) and the CBT group – the effectiveness of nVNS at 4 and 8 weeks after treatment is higher than that of CBT
S. Zhang et al, 2024 [45]	insomnia (36)	ear, cymba and cavum (on both sides)	1. 0,2 ms ±30 % 2. 0,8-1,5 mA (below pain threshold) 3. 20 Hz — 10 s, 4 Hz — 5 s	– 30 min, 2 times a day – 5 consecutive days a week, for 8 weeks – follow-up period — 20 weeks	– a more significant decrease in PSQI, ISI, HAMD, HAMA and FFS scores after 8 weeks in the main group (nVNS) compared with the control group (sham nVNS) (p <0,001) – the advantage of nVNS persisted during the 20-week follow-up period
J.W. Yeom et al, 2025 [44]	insomnia (no data)	no data	no data	30 min daily for 6 weeks	– a more significant decrease in PSQI (p =0,009) and ISI (p = 0,023) scores in the main group (nVNS) compared with the control group (sham nVNS) – increased total sleep time (p =0,019) and improved quality of life in the nVNS group (p =0,047)
V. Srinivasan et al, 2024 [46]	anxiety (no data)	no data	no data	– 30 min – 4 days a week, for 4 weeks	a more significant decrease in anxiety symptoms (GAD-7 questionnaire) and salivary cortisol levels in the main group (nVNS) compared with the control group (Jacobson's PMR)
V. Srinivasan et al, 2024 [47]	anxiety and sleep disturbances (no data)	no data	no data	– 30 min – 3 days a week, for 4 weeks	significant improvement in sleep quality and anxiety reduction at 4 weeks (p = 0,001)

Note. BDI — Beck Depression Inventory; CBT — Cognitive behavioral therapy; FFS — Flinders Fatigue Scale; GAD-7 — Generalized Anxiety Disorder-7; HAMA — Hamilton Anxiety Rating Scale; HAMD — Hamilton Rating Scale for Depression; ISI — Insomnia Severity Index; L — left; NS — not stated; nVNS — noninvasive Vagus Nerve Stimulation; PMR — Progressive Muscle Relaxation; PSQI — Pittsburgh Sleep Quality Index; R — right; TDI — Tinnitus Dysphoria Inventory; THI — Tinnitus Handicap Inventory; TQ — Tinnitus Questionnaire; VAS — Visual Analogue Scale; WHO-5 — World Health Organization-Five Well-Being Index

Table 2. Treatment recommendations for using the gammaCore Sapphire stimulator [Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf21/K211856.pdf (accessed date on 03.08.2025)]

Indication	Treatment recommendations
The preventive treatment of migraine headache in adolescent (aged 12 and older) and adult patients	120-second stimulation cycle, 2 consecutive stimulations on either side of the neck as follows: • First daily treatment: within 1 hour of waking • Second daily treatment: 4-6 hours after the first daily treatment • Third daily treatment: within 1 hour before going to sleep
The acute treatment of pain associated with migraine headache in adolescents (aged 12 and older) and adult patients	120-second stimulation cycle, 2 bilateral stimulations up to 3 times a day
Adjunctive use for the preventive treatment of cluster headache in adult patients	120-second stimulation cycle, 3 consecutive stimulations on either side of the neck as follows: • First daily treatment: within 1 hour of waking • Second daily treatment: 7-10 hours after the first daily treatment
The acute treatment of pain associated with episodic cluster headache in adult patients	120-second stimulation cycle, 3 consecutive stimulations up to 8 times a day
Treatment of hemicrania continua in adults in adolescents (aged 12 and older) and adult patients	120-second stimulation cycle, 2 stimulations ipsilateral to the side of pain up to 3 times a day
Treatment of paroxysmal hemicrania in in adolescents (aged 12 and older) and adult patients	120-second stimulation cycle, 2 stimulations ipsilateral to the side of pain up to 3 times a day

nVNS and headache management

Electrical neuromodulation techniques, including nVNS, occupy a distinct niche among non-pharmacological approaches to the management of primary headache disorders [7].

The first device designed for cervical vagus nerve stimulation was the gammaCore system (electroCore, Inc., USA). Results of the pilot study by P.J. Goadsby et al., published in 2014, demonstrated the efficacy and favourable tolerability of cervical nVNS for the acute treatment of episodic migraine attacks [8]. Subsequent studies confirmed these findings, showing that nVNS significantly reduced the frequency, intensity, and duration of migraine attacks, decreased analgesic consumption, and alleviated associated functional impairment, sleep disturbances, and depressive symptoms [9–12]. According to the results of the double-blind, randomised, controlled PRESTO trial, the efficacy of nVNS for the acute treatment of episodic migraine corresponds to a level of evidence of 1b [12]. In addition, the preventive effect of nVNS in chronic migraine, manifested by a reduction in the number of headache days, was demonstrated in a study by S.D. Silberstein et al., published in 2016, with a level of evidence of 2b [13]. In addition to migraine, nVNS may alleviate pain attacks in patients with trigeminal autonomic cephalalgias [14–17], with the most compelling evidence (level of evidence 1b) reported for episodic cluster headache [15, 16]. The gammaCore Sapphire cervical vagus nerve stimulator has received FDA approval for the treatment of several headache disorders, including migraine, cluster headache, hemicrania continua, and paroxysmal hemicrania [18] (Table 2).

The NEMOS device (Cerbomed, Germany) is designed to stimulate the auricular branch of the vagus nerve. In a study by A. Straube et al., 46 patients with migraine underwent stimulation with the NEMOS device for 4 hours daily over a period of three months. The results demonstrated the safety of nVNS and showed that stimulation at a frequency of 1 Hz was more effective than stimulation at 25 Hz for the prevention of chronic migraine. In the 1 Hz stimulation group, approximately one-third of patients experienced a reduction of more than 50 % in the number of headache days (level of evidence 2b) [19]. Currently, functional MRI is being used to investigate the pathophysiological mechanisms underlying the effects of electrical stimulation [20, 21], as well as to identify predictors of [22] response to auricular nVNS in patients with migraine.

nVNS and tinnitus management

Subjective tinnitus represents a significant medical and social problem, as it can substantially impair quality of life by affecting both social interactions and work performance. Episodic tinnitus is experienced by 30–45 % of the adult population, approximately 8 % of individuals perceive it constantly, and in about 1 % of cases it has a considerable impact on daily functioning [23]. Individuals of working age, particularly those between 40 and 60 years old, are most commonly affected. The development of tinnitus is associated with a variety of factors, including overweight and obesity, comorbid conditions such as hypertension and diabetes mellitus, the use of certain medications (aminoglycosides, furosemide, cisplatin, and some nonsteroidal anti-inflammatory drugs or antidepressants), as well as otologic disorders resulting in hearing loss. In addition, an important role is attributed to an individual's premorbid psychological status, particularly the level of anxiety [24].

Because the development of tinnitus is often unrelated to structural abnormalities of the auditory conduction system, objective registration of the symptom is generally not possible. As all currently available assessment methods are subjective, the patient's own description of the tinnitus characteristics plays a pivotal role in the diagnostic process [24].

Current treatment approaches aimed at alleviating tinnitus are diverse and include psychotherapy, tinnitus maskers and sound therapy, biofeedback, pharmacological treatment, various neuromodulation techniques (such as transcranial magnetic stimulation, deep brain stimulation, and different forms of peripheral nerve stimulation), as well as acupuncture. These approaches differ considerably in terms of availability, efficacy, cost, and degree of invasiveness [25].

The results of a pilot study evaluating nVNS combined with sound therapy in 10 patients with tinnitus were published in 2013. The sound therapy consisted of specially selected classical music from which one octave corresponding to each patient's tinnitus frequency had been removed. After seven sessions of left tragus stimulation, most participants reported improvements in mood, as assessed by the WHO-5 questionnaire, as well as a reduction in tinnitus severity, reflected by decreases in scores on the Tinnitus Handicap Inventory (THI) and the Mini-Tinnitus Questionnaire (mini-TQ). One patient experienced no change in tinnitus characteristics, while another reported only minimal symptom improvement [26]. The beneficial effects of nVNS, both in combination with sound therapy and as a standalone intervention, have also been demonstrated in other studies [27–30]. However, the second phase of the study conducted by P.M. Kreuzer et al. failed to show a significant reduction in the total Tinnitus Questionnaire (TQ) score after 24 weeks of nVNS treatment [31]. It should be noted that the vast majority of published studies have been characterised by low or very low methodological quality [26, 28–31]. Moderate evidence supporting the efficacy of combined therapy (nVNS plus tinnitus sound masking), corresponding to a level of evidence of 2b, was provided only by the study of Z. Mei et al. published in 2014 [27].

In a systematic review published in 2021, the authors analysed studies investigating both invasive and non-invasive vagus nerve stimulation and concluded that, due to methodological limitations and the poor reporting quality of the included studies, the effects of these interventions on tinnitus remain uncertain [32]. Therefore, the efficacy of nVNS for the treatment of tinnitus, including its use as a standalone intervention without concomitant sound therapy, requires confirmation in larger and methodologically rigorous studies [33].

nVNS and sleep disturbances and anxiety

Insomnia is a common sleep disorder characterised by persistent difficulties with sleep initiation and/or sleep maintenance, resulting in insufficient sleep duration [34]. Currently, insomnia is classified as acute (symptoms lasting less than 3 months), chronic (symptoms occurring at least three times per week for at least 3 months), or unspecified [35].

Epidemiological studies have shown that insomnia affects up to 10 % of adults worldwide [36] and up to 50 % of patients seeking primary care [34], with a higher prevalence observed among women [37]. Insomnia has a substantial negative impact on quality of life and work productivity and is recognised as an important risk factor for cardiovascular disease, type 2 diabetes mellitus, cognitive impairment, and psychiatric disorders [35].

Cognitive behavioural therapy (CBT) is considered the cornerstone of treatment for chronic insomnia; however, a shortage of qualified specialists limits the widespread implementation of this therapeutic approach [35]. Although pharmacotherapy demonstrates efficacy comparable to CBT in the management of acute sleep disturbances, its effectiveness in chronic insomnia is reduced because of a substantial decline in the durability of the therapeutic effect [38]. Consequently, alternative treatment strategies, particularly non-invasive vagus nerve stimulation, have attracted growing interest. Owing to its targeted modulation of the auricular branches of the vagus nerve, nVNS is generally well tolerated [39]. In addition, the user-friendly interface of stimulation devices makes them suitable for self-administration in the outpatient setting.

In an analysis of the nVNS effects in 35 patients with insomnia and affective disorders, M. Luo et al. [40]

observed a significant reduction in Pittsburgh Sleep Quality Index (PSQI) scores by the end of the second week of treatment ($p < 0.05$), as well as significant decreases in Hamilton Depression Rating Scale (HAMD) and Hamilton Anxiety Rating Scale (HAMA) scores by the fourth and sixth weeks of therapy ($p < 0.05$). Based on these findings, the authors concluded that nVNS may improve sleep quality and alleviate symptoms of anxiety and depression. However, the absence of a control group in this study limits the interpretation of the results.

Subsequently, studies with a higher level of evidence (1b) were conducted. For instance, Y. Jiao et al. [41] reported a significant reduction in PSQI scores after four weeks of treatment in both the active nVNS group and the sham stimulation group, with no statistically significant difference between them. However, superior efficacy of nVNS compared with sham stimulation in the treatment of insomnia was demonstrated in several other studies [42–44]. Moreover, in a study by L. Zhang et al. [43], which analysed the effects of stimulation in 100 men living at high altitude, nVNS not only showed efficacy comparable to that of CBT, but also outperformed CBT with respect to several outcome measures.

In a recent randomised clinical trial [45], the duration of nVNS therapy was extended to eight weeks for the first time. Patients in the active treatment group demonstrated a significant reduction in PSQI scores, indicating the clinical efficacy of nVNS in chronic insomnia, with superiority over sham stimulation persisting for up to 20 weeks. In addition, vagus nerve stimulation exerted significantly greater effects on reducing symptoms of depression and anxiety, as well as daytime fatigue, in patients with insomnia.

The effects of nVNS on anxiety symptoms during and after the COVID-19 pandemic were investigated by V. Srinivasan et al. [46, 47]. These studies demonstrated significant reductions in Generalised Anxiety Disorder-7 (GAD-7) scores and salivary cortisol levels after four weeks of nVNS. Furthermore, nVNS was shown to be superior to Jacobson's progressive muscle relaxation technique [46] and was associated with significant improvements in sleep quality [47].

The findings of a recent systematic review and meta-analysis suggest that nVNS represents a promising, safe, and non-invasive therapeutic option for insomnia [48]. The simultaneous improvement in sleep quality and anxiety symptoms is particularly relevant for patients with comorbid disorders. To enhance the reproducibility of findings and optimise the application of this approach across broader populations, standardisation of nVNS protocols is required.

Devices based on nVNS technology are not yet available on the Russian market, creating opportunities for the development of domestic systems. A key priority in this process is the identification of optimal stimulation parameters for both the auricular branch and the cervical portion of the vagus nerve.

Stimulation parameters of the auricular branch of the vagus nerve

In 2024, a review of 109 studies investigating auricular nVNS was published, including an analysis of the stimulation parameters used across studies [5]. The authors noted that only three studies provided a complete description.

Stimulation *intensity* ranged from 0.5 to 50 mA; however, in 77 % of the studies reporting this parameter, the average intensity did not exceed 6 mA. In 68 % of the studies, the intensity of auricular nVNS was individually adjusted to a level between the participant's sensory and pain thresholds. Pulse *frequency* was specified in most studies, with frequencies of 20 or 25 Hz being used in 74 % of cases. Three studies reported the use of a combination of two frequencies, namely 4 and 20 Hz. In the vast majority of studies, the *wavelength* ranged from 0.05 to 1.0 ms, with values of 0.20 or 0.25 ms being employed in 51 % of the reports. The *side* of stimulation was specified in 84 studies; among these, left-sided stimulation was used most frequently (62 %). Bilateral stimulation was applied in 27 % of studies, whereas right-sided stimulation was employed in 11 %. The stimulation *site* was largely determined by electrode geometry, with electrodes most commonly attached to the cymba conchae (31 studies), the concha (27 studies), or the tragus (21 studies) of the auricle. Information regarding the *duty cycle (the ratio between stimulation and pause periods)* was reported in only 32 studies (29 %), with a 30 s on/30 s off pattern being used in 14 of them. The *duration and number of stimulation sessions* varied considerably both within studies investigating the same condition and across different indications. Therefore, the optimal parameters for transcutaneous stimulation of the auricular branch of the vagus nerve have yet to be established [5].

Stimulation parameters of the cervical vagus nerve

The vast majority of studies employing cervical vagus nerve stimulation have been conducted in patients with headache disorders [2]. In addition, a case report published in 2011 described the resolution of intractable hiccups following transcutaneous stimulation of the phrenic nerve and the cervical vagus nerve [49], while a study published in 2016 evaluated the effects of cervical nVNS on inflammatory cytokine levels in healthy volunteers [50].

The stimulating surface of the nVNS device is positioned over the sternocleidomastoid muscle on either the right or left side of the neck, or sequentially on both sides. Stimulation *intensity* is individually adjusted, with maximum values reaching 24 V and 60 mA. In the majority of studies, a pulse *frequency* of 25 Hz was used, whereas one study [49] employed a frequency of 1 Hz. *Wavelength* was set at either 0.2 ms or 1 ms. The *duration* of individual stimulation cycles ranged from 30 to 120 seconds [2]. Treatment can be safely administered several times per day. The FDA recommendations regarding the use of the gammaCore Sapphire cervical stimulator for headache disorders are summarised in Table 2.

Conclusion

The growing interest in nVNS is driven by the simplicity, accessibility, safety, and favourable tolerability of this approach. The development of a domestic device implementing nVNS techniques therefore represents an important and timely objective. The number of studies investigating nVNS continues to increase, accompanied by a broadening range of clinical conditions in which its efficacy is being evaluated. The results obtained with the gammaCore cervical vagus nerve stimulator formed the basis for the FDA approval of its use for the preventive and acute treatment of cluster headache and for the acute treatment of episodic migraine. Subsequently, the indications were expanded to include migraine prevention, as well as the treatment of cluster headache and hemicrania continua. With regard to non-invasive stimulation of the auricular branch of the vagus nerve, despite encouraging results in headache disorders, tinnitus, insomnia, and anxiety, further high-quality studies are required to strengthen the evidence base. Such studies should include larger sample sizes, standardised stimulation protocols or detailed descriptions thereof, and appropriate randomisation and blinding procedures.

Вклад авторов:

Все авторы внесли существенный вклад в подготовку работы, прочли и одобрили финальную версию статьи перед публикацией

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Author Contribution:

All the authors contributed significantly to the study and the article, read and approved the final version of the article before publication

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