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EFFECTIVENESS OF THRESHOLD-LEVEL VAGUS NERVE STIMULATION IN MODULATING PSYCHOEMOTIONAL STATES

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Abstract

Introduction. Vagus nerve stimulation (VNS), both invasive and non-invasive, has demonstrated significant effects on emotional states in various psychiatric and neurological disorders, with evidence supporting its role in improving mood, reducing anxiety, and enhancing overall quality of life. Despite demonstrated effectiveness, non-invasive vagus nerve stimulation has a set of shortcomings and unsolved technical problems.
Aim. We aimed to examine an individual threshold of vagus nerve stimulation for minimizing the negative impact of everyday job-related stress.
Materials and methods. A total of 14 volunteers, 40 ± 13.75 years, were recruited for the study. We used a combination of pleasant meditative classical music and a slow bi-polar wave of non-invasive transcutaneous electrical stimulation of the auricular area (BrainPatch platform for non-invasive stimulation). The set of 7 neuromodulation sessions was performed during staff work hours. Psychological testing included State and Trait Anxiety (STAI), psychological stress level (PSM-25), severity of emotional burnout (MBI), depressive symptomatology (IDS), generalized anxiety (GAD-7), and experienced positive and negative emotions (PANAS).
Results. VNS leads to significant decreases in depression, generalized anxiety, and State Anxiety scores. Due to the large variability of the data and a generally fairly low level of burnout in the sample, the detected changes were not statistically significant. Our data indicate that the first signs of improvement in psychoemotional state (decrease in Negative Affect scores and the increase in Positive Affect) are observed after three sessions of threshold stimulation, with improvements maintained at follow-up for the final day.
Conclusions. The proposed approach to selecting an effective stimulation regimen proves its validity. An individual threshold has demonstrated significant therapeutic effects of taVNS on emotion regulation, depression, and anxiety. BrainPatch non-invasive stimulation technology demonstrates potential for reducing depression symptoms, anxiety, and improving mood, making it a promising intervention for individuals experiencing stress and burnout.

Keywords: **vagus nerve stimulation, emotional burnout, depression, anxiety, emotions**

INTRODUCTION

Large proportions of populations in various countries report high levels of stress, anxiety, and depression, with rates reaching up to 26.4% for depression of US adults [1], 19.2% for depression, 16.5% for anxiety, and 11.2% for stress in the elderly population globally [2]. Notably, stress prevalence in the United States is 75%, the United Kingdom 74%, and Brazil 70%, with substantial regional and demographic differences observed within countries [3, 4, 5]. A substantial proportion of individuals with depression remain untreated, with significant variation across populations and countries. Treatment coverage for major depressive disorder (MDD) is low globally, with only 20-51% of individuals receiving treatment across 84 countries [6, 7]. In high-income countries, the rate of untreated major depressive disorder among diagnosed patients ranges from 21% to 32%, while in the UK, studies including undiagnosed individuals report rates as high as 62-77%. In Italy, 29% of MDD patients are untreated, and in Hungary, the rate is 55-60% [8]. Moreover, even for those who get treated, studies report that up to 30%-40% of patients with major depression do not respond to typical antidepressant medications and are considered treatment-resistant [9, 10].

Solving the problem of treatment-resistant mental disorders requires new approaches. Vagus nerve stimulation (VNS), including both invasive and non-invasive (transcutaneous auricular VNS, taVNS) approaches, has been increasingly used as a treatment for mental and mood disorders, particularly major depressive disorder and treatment-resistant depression, with some studies reporting increasing response rates over time [11, 12]. Transcutaneous vagus nerve stimulation (tVNS), when combined with medication, leads to significant reductions in anxiety scores in patients with generalized anxiety disorder (GAD) [13]. VNS can produce acute and sustained improvements in anxiety symptoms in treatment-resistant cases of obsessive-compulsive disorder (OCD), panic disorder, and post-traumatic stress disorder (PTSD) [14, 15]. Studies reported that taVNS significantly reduces anxiety scores and physiological markers (e.g., salivary cortisol) in the elderly, university students, and healthcare workers [16, 17].

The efficacy of VNS is highly dependent on the adjustment of stimulation parameters such as current intensity, frequency, and duration. Moderate intensity and frequency often yield optimal results, with both lower and higher intensities being less effective due to an inverted-U relationship between stimulation intensity and neuromodulatory activation. The temporal dynamics of pulse delivery (e.g., continuous vs. burst) also significantly affect outcomes, with continuous or precisely paired stimulation enhancing efficacy [12, 18, 19]. At a given frequency, taVNS has shown changes in brain connectivity relevant to depression, while threshold-level stimulation is associated with autonomic and affective improvements [20, 21, 22]. Further research is needed to identify the influence of stimulation parameters and find optimal and standardized treatment protocols while considering medical history for mental and stress-related disorders.

AIM

In summary, the aforementioned evidence demonstrates

- a consistently high prevalence of stress, anxiety, and depression across countries and populations, with rates further elevated by crises and among vulnerable groups,
- depending on the definitions and criteria used, the rate of treatment-resistant depression (TRD) in patients is converging around 20-40% of patients with depression,
- taVNS is a promising, non-invasive alternative with growing evidence for efficacy in major depressive disorder (MDD) and TRD,
- the efficacy of VNS is linked to stimulation parameters.

Considering all of the above, we aimed to explore the influence of the adjustment of stimulation parameters for optimizing therapeutic outcomes and minimizing side effects.

MATERIALS AND METHODS

Sample

A total of 14 participants, employees of the Rehabilitation Center «Meirrim» (Almaty, Kazakhstan, https://rcmeirim.kz/) were recruited in the study (13 female and 1 man, mean age = 40 ± 13.75 years); however, the final sample included 12 participants owing to the exclusion of data from 2 individuals due to incomplete psychological testing. All participants were active clinic staff who continued their regular work routine throughout the study. The sample represented a single experimental group (a within-subject design with repeated measures, without a control group).

Participants provided written informed consent before the study, following the Declaration of Helsinki, with explicit communication about the investigational nature of the study and adherence to institutional and state guidelines. The exclusion criteria were individuals with major psychiatric disorders requiring daily medication, manifestations of cognitive impairment, and those taking psychoactive medication, drugs, or alcohol.

Procedure

The study was conducted according to a protocol involving 7 neuromodulation sessions delivered once per day, in the morning hours, for seven consecutive working days for 3 minutes and 20 seconds using the BrainPatch device. Psychological testing was carried out on the first («0») and last («7+1») days of the study. The experienced emotions (PANAS) were measured throughout, on each day of stimulation as well as the first and the last days of the study to track daily emotional dynamics.

Stimulation Procedure

The BrainPatch® e-Meditation® device was used (Fig. 1, https://www.brainpatch.ai/). A mobile neuro-headset combines simultaneous acoustic (sound) and current stimulation with electrodes placed behind the ears, all controlled via a mobile application. The stimulation zone included the mastoid area involving the auricular branch of the vagus nerve (ABVN) at the tympanomastoid fissure. Electrical stimulation parameters were individually adjusted for each participant within a safe range of 0.2-1.6 mA to just above their sensitivity level («Personalization» protocol on BrainPatch® App for iOS). A series of waveforms with personalized maximum zero-to-peak amplitude and a wave frequency of 0.1-0.5 Hz were delivered over 3 minutes and 20 seconds as the intervention («e-Meditation» protocol). Participants were instructed to close their eyes, relax and the stimulation was accompanied by relaxing piano music delivered through the same headset.

Figure 1. BrainPatch™ device.

PSYCHOLOGICAL TESTING

Symptoms of Burnout

In order to diagnose occupational burnout, we used the 22-item Maslach Burnout Inventory (MBI). The MBI comprises three core components: emotional exhaustion, feelings of being emotionally overextended and depleted (EE, the 9-item scale), depersonalization, detachment or impersonal response toward work and others (DP, the 5-item scale), and reduced personal accomplishment, feelings of incompetence and lack of achievement at work (PA, the 8-item scale). Personal accomplishment and job-related outcomes are closely linked, with multiple factors such as achievement motivation, job attributes, feedback, social support, and professional identity playing significant roles. Emotional exhaustion is significantly associated with factors such as job demands, work-life conflict, lack of workplace support, and coping strategies. Higher scores in emotional exhaustion and depersonalization, and lower scores in personal accomplishment, indicate greater burnout.

Personality and mental health variables

The Lemur-Tessier-Fillion Psychological Stress Measure (PSM-25) (adapted by N.E. Vodopyanova) was used to evaluate subjective stress and perceived tension on an 8-point Likert scale ranging from 25 to 200 points. PSM-25 measures 3 levels of stress: Low stress (<14), Moderate stress (14-26), and High stress (>27).

The 30-item Inventory of Depressive Symptomatology (IDS) assesses the severity and dimensions of depressive symptoms. IDS measures the severity of depression, ranging from none (0-13), mild (14-25), moderate (26-38), severe (39-48), to very severe (49-84).

The Generalized Anxiety Disorder-7 (GAD-7) is a seven-item self-report questionnaire assessing anxiety symptoms over the past two weeks. GAD-7 measures 5 levels of anxiety ranging from minimal (0-4), mild (5-9), moderate (10-14), to severe anxiety (15-21) as a persistent and pervasive disorder characterized by unfocused worry and anxiety across various settings without connection with recent stressful events.

The State-Trait Anxiety Inventory (STAI, adapted by Yu. Hanin) assesses the level of anxiety on the basis of the 4-point Likert self-assessment scale (high, medium, low anxiety). The STAI consists of two subscales: State Anxiety (reflecting temporary, situational anxiety) and Trait Anxiety (reflecting a stable predisposition to anxiety). These theoretically independent subscales include items covering behavioral, cognitive, emotional, and physiological aspects. Scores for State and Trait Anxiety range from 20 to 80 each, with higher scores indicating higher levels of Anxiety: Low Anxiety (20-37), Moderate Anxiety (38-44), and High Anxiety (45-80).

The 20-item Positive and Negative Affect Schedule (PANAS) was used to measure two primary dimensions of affect: positive and negative, experienced emotions during a specified timespan. The PANAS consists of 20 items, with 10 items each for Positive Affect (PA) and Negative Affect (NA). Respondents rate each item on a 5-point Likert scale (from 1 = very slightly or not at all to 5 = extremely), with total scores for each subscale ranging from 10 to 50.

All questionnaires were standardized and validated. Written instructions were provided before testing, and completion time was not limited (approximately 10-15 minutes per form).

Statistical data analysis

The processing of the statistical data was performed using IBM SPSS Statistics for Windows (version 15.0). Comparisons of paired samples from the same population were performed using the nonparametric Wilcoxon signed-rank test. We used the significance level ($p < 0.05$) to determine whether a result is statistically significant.

RESULTS

Side effects and sensations

Stimulation parameters for non-invasive VNS were set at just above the individual's perceptual threshold – the threshold of sensation, based on participant ratings of subjective perception. This approach aims to maximize comfort and minimize discomfort during stimulation. The reported sensations of light-headedness and slight dizziness due to the vestibular component of the stimulation are generally perceived as pleasant and are not reported as adverse side effects. The taVNS is generally rated as safe and well-tolerated; no serious adverse events were reported in this study, nor in the literature to the best of our knowledge.

Psychoemotional State

Burnout and Stress symptoms

The distinctive features of this study were its targeted sample (or rather, its approach to selecting study participants) and its location. Participants were healthcare facility staff with experience in emotionally charged personal interactions with patients. The results of pre-modulation psychological testing served as the basis for further analysis of Vagus Nerve Stimulation (VNS) effects and also made it possible to assess the impact of job conditions on the mental well-being of employees.

Before neuromodulation sessions, the emotional exhaustion and depersonalization were under development in 41.67% (n = 5) of the participants. The reduction of personal achievements was formed in 16.67% (n = 2) of the participants, and in 25% (n = 3) of the participants was under development. The testing that followed the stimulation has revealed a trend towards improvement. Both emotional exhaustion and depersonalisation scores in affected individuals were reduced by 31.56% and 68.57% respectively, so that almost all of them no longer met the criteria. The personal accomplishment score was reduced by 6.4% on average, which is a trend towards improvement, and the integral burnout index average was lower (9.68%). However, due to large variability of the data and a generally fairly low level of burnout in this sample or due to the high variations in the baseline, the observed trends were not statistically significant at $p< 0.05$ threshold.

Depressive Symptomatology

VNS led to significant decreases in depression scores. IDS scores were reduced by 65.16% on average (p = 0.0186) (Table 1). The depression scores were reduced in 83% of participants, and moreover were significantly reduced by more than 5 points in 5 participants.

Anxiety and Mood

Our data suggest that the threshold vagus nerve stimulation reduces generalized Anxiety (GAD-7) scores (–52.22%, p = 0.0128) (Table 1). The generalized anxiety was reduced in 75% of participants. Mean State Anxiety scores dropped from 30.25 at baseline to 26.67 at one week in our study (–11.84%, p = 0.0186). Reduction in State Anxiety (STAI) was observed in 83% of participants, the Trait Anxiety approached statistical significance with a reduction observed in 75% of participants (Table 1).

Table 1

The Cumulative Effect of VNS on Psychoemotional State

Psychological testing		Protocol testing		Significance level (p)
Questionnaires	Scale, subscale	first (“0”) day of the study	last (“7+1”) day of the study	
Maslach Burnout Inventory (MBI)	emotional exhaustion	13.33±6.33	11.91±5.79	0.540
	depersonalization	4.5±3.58	3.08±2.19	0.209
	reduction of personal achievements	37.5±7.94	39.92±6.13	0.308
	integral index	0.62±0.16	0.56±0.12	0.209
Psychological Stress Measure (PSM-25)	subjective stress and perceived tension	66±21.6	59.83±18.57	0.308
Inventory of Depressive Symptomatology (IDS)	severity and dimensions of depressive symptoms	14.58±8.33	9.5±6.21	0.019
Generalized Anxiety Disorder-7 (GAD-7)	anxiety	3.83±4.13	1.83±2.24	0.013
State-Trait Anxiety Inventory (STAI)	State Anxiety	30.25±6.42	26.67±5.12	0.0376
	Trait Anxiety	37.17±7.84	33.5±6.80	0.099

Our data on the VNS-induced mood changes is consistent with the results of other groups [23, 24] – VNS treatments led to substantial decreases in Negative Affect (NA) scores (–56.31%, p = 0.0033) and a significant increase in Positive Affect (PA) (PANAS) on the third day after the stimulation (+105.14%, p = 0.0117), with improvements maintained until follow-up for the final day (Fig. 2).

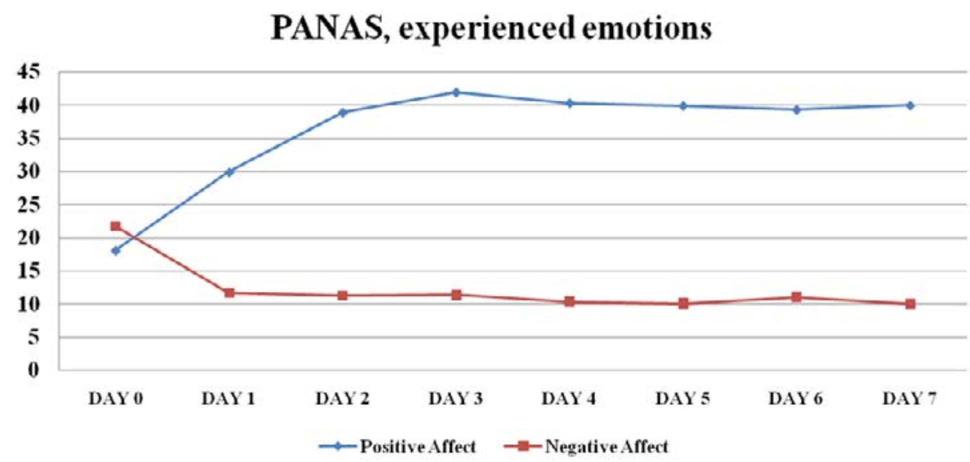

Figure 2. The cumulative effect of VNS on experienced emotions.

DISCUSSION

Transcutaneous auricular vagus nerve stimulation (taVNS) is shown to be effective in reducing stress, and in this pilot study, we aimed to investigate the role of the optimal stimulation parameters in the efficacy of the intervention.

To some extent, our obtained data coincide with previously conducted studies. The normalizing effect of VNS on the psychoemotional state was manifested in the improving mood and reducing job-related stress, emotional burnout and their components of emotional burnout, such as depersonalization and reduction of personal achievements, as measured by the Maslach Burnout Inventory [25, 26]. Emotional exhaustion is linked to reduced vagal function and heart rate variability (HRV) [27]. Prolonged positive effect on burnout symptoms [25] is thought to be mediated by shifting the sympatho-vagal balance toward functional optimum and increasing vagus-mediated heart rate variability [26].

The observed statistically and biologically significant reduction in depression scores is consistent with data from previous studies [28, 29, 30], where the depression scores were significantly reduced in some participants, but not others, reflecting the complexity and heterogeneity of depression.

Current scientific evidence indicates that VNS, including transcutaneous and invasive approaches, can produce sustained reductions in anxiety levels over the long term, particularly in individuals with treatment-resistant anxiety disorders, trauma-related conditions and Generalised Anxiety Disorder [13, 14]. In our case, the use of an individual threshold shows the effectiveness of VNS.

Previous studies have established that vagus nerve stimulation (VNS), particularly through non-invasive methods like transcutaneous auricular stimulation (taVNS/tVNS), modulates various aspects of emotional processing, recognition, regulation, and mood. taVNS enhances cognitive emotion regulation, including the use of cognitive reappraisal, and modulates activity in brain regions critical for emotion regulation, such as the anterior cingulate and medial prefrontal cortex [31, 32]. taVNS has been shown to boost positive mood after effortful tasks and may facilitate mood recovery, potentially by modulating interoceptive feedback and reducing stress responses [23, 24]. Our data are consistent with the literature showing the beneficial and maintained effects of taVNS on both – the positive affect and the negative affect.

Taking into account all of the above, our approach to selecting an effective stimulation regimen proves its validity. An individual threshold has demonstrated significant therapeutic effects of taVNS on emotion regulation, depression, and anxiety.

CONCLUSIONS

BrainPatch non-invasive stimulation technology demonstrates potential for reducing depression symptoms, anxiety, and improving mood, making it a promising intervention for individuals experiencing burnout. Such interventions tailored to individual thresholds are safe, well-tolerated, and provide a non-pharmacological alternative for mental and stress-related disorders.

Perspectives for further research. The efficacy of taVNS stimulation is strongly linked to stimulation parameters. Both invasive VNS and taVNS require parameter tuning for maximal efficacy and tolerability. Future research should focus on optimization and personalization of VNS/taVNS stimulation parameters, including adaptive protocols and biomarker-guided approaches. Our future plans include longitudinal studies tracking mental health trajectories across VNS stimulation. The development of closed-loop systems and real-time monitoring for individualized therapy is the next step.

FUNDING AND CONFLICT OF INTEREST

N.V. holds a majority ownership in BrainPatch Ltd., Y.G. and S.T. are working for BrainPatch Ltd. Y.G., N.V., A.Z., Y.K., J.F., P.B., and S.T. declare no other competing interests. The article was funded at the authors' own expense.

COMPLIANCE WITH ETHICAL REQUIREMENTS

In this study, the authors adhered to the Ethical Principles for Medical Research Involving Human Subjects, as outlined in the World Medical Association's Declaration of Helsinki (WMA, 1964), and current Kazakhstan regulations. The al-Farabi Kazakh National University Local Ethics Committee (IRB00010790 al-Farabi Kazakh National University IRB#1, protocol No. IRB-A1872, 2025) has approved the study. No animals were used in the study. Artificial intelligence was not used in this study.

AUTHOR CONTRIBUTIONS

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Резюме

ЕФЕКТИВНІСТЬ ПОРОГОВОЇ СТИМУЛЯЦІЇ БЛУКАЮЧОГО НЕРВА В МОДУЛЯЦІЇ ПСИХОЕМОЦІЙНИХ СТАНІВ

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Вступ. Стимуляція блукаючого нерва (ВНС), як інвазивна, так і неінвазивна, продемонструвала значний вплив на емоційні стани при різних психічних та неврологічних розладах, з доказами, що підтверджують її роль у покращенні настрою, зменшенні тривожності та підвищенні загальної якості життя. Незважаючи на продемонстровану ефективність, неінвазивна стимуляція блукаючого нерва має низку недоліків та невирішених технічних проблем.
Мета. Ми мали на меті дослідити індивідуальний поріг стимуляції блукаючого нерва для мінімізації негативного впливу щоденного стресу, пов'язаного з роботою.
Матеріали та методи. Для дослідження було залучено 14 добровольців віком 40 ± 13,75 років. Ми використовували комбінацію приємної медитативної класичної музики та повільної біполярної хвилі електричної неінвазивної транскутанної стимуляції вушної області (платформа BrainPatch для неінвазивної стимуляції). Набір із 7 сеансів нейромодуляції проводився під час робочих годин персоналу. Психологічне тестування включало тривожність, пов'язану зі станом та рисами характеру, STAI; рівень психологічного стресу, PSM-25; тяжкість емоційного вигорання, MBI; депресивну симптоматику, IDS, генералізовану тривожність, GAD-7, та пережиті позитивні та негативні емоції, PANAS.
Результати. Через велику варіабельність даних та загалом досить низький рівень вигорання у вибірці, виявлені зміни не були статистично значущими. ВНС призводить до значного зниження показників депресії, генералізованої тривожності та тривожності через стан. Наші дані свідчать про те, що перші ознаки покращення психоемоційного стану (зниження показників негативного афекту та збільшення позитивного афекту) спостерігаються після трьох сеансів порогової стимуляції, причому покращення зберігаються протягом останнього дня спостереження.
Висновки. Запропонований підхід до вибору ефективного режиму стимуляції доводить свою обґрунтованість. Індивідуальний поріг продемонстрував значний терапевтичний вплив taVNS на регуляцію емоцій, депресію та тривожність. Технологія неінвазивної стимуляції BrainPatch демонструє потенціал для зменшення симптомів депресії, тривожності та покращення настрою, що робить її перспективним втручанням для людей, які відчувають стрес та вигорання.

Ключові слова: **стимуляція блукаючого нерва, емоційне вигорання, депресія, тривога, емоції**

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