

Effect of Vagal Nerve Stimulation on Anxiety and Sleep Disturbances among Geriatric Population: A Pilot Study

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Abstract

Background: Anxiety during the COVID-19 pandemic has been a significant concern for people of all age groups, including geriatric individuals. The elderly population has faced unique challenges during this time, which can contribute to increased anxiety levels. The uncertainty and fear surrounding the pandemic can lead to increased anxiety and stress, which can negatively impact sleep quality and duration.

Purpose: The aim of this study is to find out the effect of vagal nerve stimulation on anxiety and sleep disturbances among geriatric population.

Methodology: Using the Purposive Sampling method, a total of 20 individuals were chosen based on the inclusion and exclusion criteria. The participants were divided into two groups using the closed envelope method, and they took part in therapy sessions lasting 30 minutes, three times per week for a period of four weeks. The control group received Jacobson's progressive relaxation technique, whereas the experimental group received non-invasive Transcutaneous auricular vagal nerve stimulation.

Result: With a p value of 0.001, transcutaneous auricular vagal nerve activation significantly improved sleep quality and reduced anxiety after 4 weeks.

Conclusion: Study showed that transcutaneous vagal nerve stimulation was effective in reducing Anxiety and improving sleep quality in geriatric population.

Key Words: Anxiety, insomnia, geriatrics, covid-19

Introduction

Anxiety during the COVID-19 pandemic is a very common and understandable response to the challenging and uncertain circumstances that many people have been facing. The pandemic has brought significant changes to daily life, including concerns

about health, economic hardships, social isolation, and disruptions to routines. Psychopathology could be brought on by immune system disruption brought on by an infection, and psychiatric aftereffects have been noted following prior coronavirus outbreaks. High-burden non-communicable illnesses including PTSD,

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major anxiety, and mood disorders are all linked to years of living with a disability. We recommend in light of the troubling effects experienced by COVID-19 survivors, there is a growing focus on advancing research related to inflammatory biomarkers. This research aims to aid in the diagnosis and treatment of emerging psychiatric conditions that may arise as a consequence of the virus. Assessing the psychological disorder of COVID-19 infection on psychological wellness, current insights on irritation in mental health care, and the current observation that worse inflammation results in worse depression¹.

The aged are a group of people who are vulnerable to all three: physical, emotional, social, and financial difficulties. Therefore, staying inside and avoiding social interaction for several months straight is one of the world's recommended treatments for them. Loneliness is a real risk factor for health and wellbeing².

The first group to leave interactions in our country as a technological step within the context of isolation measures was people over the age of 65 and those with chronic diseases, who were seen as being at high risk of mortality due to "immunosenescence," which is known as immunodeficient status developing due to aging³.

The elderly may be one of the most vulnerable groups of people during the lockdown. Older people typically display many changes in their sleep patterns as a result of the physiological process of aging. During the pandemic emergency, stress levels rose, and people's symptoms of anxiety and depression were exacerbated. According to several research, younger people experience higher levels of anxiety, depression, and stressful situations⁴.

Elderly people frequently experience chronic sleep issues. For a restful sleep, an individual must get enough total sleep time and sleep that is in harmony with their circadian cycle. More than half of senior individuals encounter at least one recurring sleep problem. In primary healthcare settings, chronic sleep issues such as insomnia and excessive daytime sleepiness are commonly observed⁵.

For the elderly, loneliness is a big risk factor that can compound their issues. For the elderly, things got harder when COVID-19 began. More harm is looming

in their future as a result of the COVID-19 epidemic, the ambiguity around the disease's dimensions, and the biological effects of aging⁶.

During this pandemic, sleep issues like insomnia, diminished sleep, and poor sleep quality have been a common complaint. It is crucial to comprehend if these issues grew worse throughout the pandemic because sleep disorders and complaints related to sleep affect the elderly frequently in a range of twenty percent to fifty percent around the world⁷.

Different methods and strategies are used in anxiety management to deal with and lessen anxious sensations. Due to safety and tolerability concerns, tricyclic antidepressants are typically used as second-line treatments for anxiety disorders despite having adequate efficacy data. These medications have the benefit of acting quickly. Sleep management are there was some advice for all. The Academy advised managing anxiety and stress through journaling and talks and post emotional content on social media, Practice good habits, such as frequent exercise. Health care professionals were advised to let their coworkers or supervisor know if they needed a little nap after a long shift. The Academy recommended CBT as the initial therapy option for a sleeping disorder with considerable daytime functioning due to its proven efficacy and lack of side effects⁸.

This study mainly concentrates on vagus nerve, through its input and efferent channels, the vagus nerve, a significant part of the nervous system that controls emotions, regulates metabolic balance and is crucial for the neuro-endocrine-immune axis, which helps to maintain homeostasis⁹. Many studies have been done through invasive method. Hence, the study aim is to find out the effect of vagal nerve stimulation on anxiety and sleep disturbances among geriatric population.

Aim

To determine the effect of vagal nerve stimulation on anxiety and sleep disturbances among geriatric population.

Material and Methods

The research project was designed as a pilot study with the primary aim of exploring the effectiveness

of transcutaneous auricular vagal nerve stimulation (a non-invasive procedure) in reducing anxiety and enhancing sleep quality among geriatric participants. This pilot study was conducted in a private hospital in Chennai. Before commencing the research, the study was ethically approved by a Scientific Study Board and followed all necessary regulations and ethical guidelines a rigorous review by the Scientific Study Board of a private college. The study was assigned the approval number 01/026/2022/ISRB/PGSR/SCPT.

Before enrolling in the study, each participant's informed consent was obtained, and the study employed a double-blind design to enhance the validity of its findings. The study was conducted from January 2023 To February 2023 .

Inclusion criteria

- Participants with both geriatric genders.
- Age group: 60 and above years.
- Participants with a pre-test of anxiety who scores more than 17 in generalized anxiety scale 7.
- Participants with a pre-test of anxiety who scores more than 17 in insomnia severity scale.

Exclusion criteria

- History of various neurological and psychological disorders.
- Lack of interest in participating.

Outcome measure: The GAD-7 total score, derived from the seven items, falls within the range of 0 to 21. Scores between 0 and 4 are indicative of minimal anxiety, scores between 5 and 9 suggest mild anxiety, scores between 10 and 14 suggest moderate anxiety, and scores between 15 and 21 indicate severe anxiety¹⁰. The ISI has been used in numerous research investigations and has been found to be a valid and reliable indicator of the severity of insomnia. Seven things make up the ISI, and each one is evaluated from 0 to 4 on a scale. Higher scores indicate more severe insomnia, with a total score that runs from 0 to 28¹¹

Procedure

In this study, the participants were divided into 2 groups, referred to as Group A and Group B, using the closed envelope method. Both groups underwent

a 4-week intervention involving 30-minute therapy sessions, conducted three days a week. The experimental group received a transcutaneous auricular vagal nerve stimulation. Stimulation is applied to the vagal nerve in the Cymba concha of the left ear by using clip electrodes and lasted for approximately 20 minutes during each session. The stimulation followed an ON-OFF pattern, with 30 seconds of stimulation followed by 5 minutes rest. The frequency was set at 25 Hz, the amplitude at 1 mA, and the pulse width at 330 seconds.

The control group received Jacobson relaxation technique for 20 minutes. At the end of the four-week treatment period, a post-test analysis was conducted to evaluate the effects of the interventions on the participants. The evaluation was performed using two scales: the GAD scale and the ISS scale.

Data analysis

Statistical analysis was performed to evaluate the efficacy of a treatment on anxiety and sleep disorders. The study gathered pre- and post-test data for two outcome measures: Generalized Anxiety Disorder (GAD) and Insomnia Severity Index (ISI). The data was analyzed using 2 non-parametric tests: the Wilcoxon Signed Rank Test for within-group comparisons and the Mann-Whitney U Test for between-group differences.

Table 1: Baseline characteristics of included population.

Characteristics	Group A	Group B
Age (mean \pm SD)	61.7 \pm 1.9	61.4 \pm 1.5
Gender	6	4
No of male		
No of female	5	5
GAD scale	14.1 \pm 1.8	14.1 \pm 1.8
ISS	14.6 \pm 1.5	14.6 \pm 1.5

Table 2: Comparison of intervention group pre and post-test analysis, which were obtained using GAD

Outcome	Pre test	Post test	Z Value	P Value
	Mean and SD	Mean and SD		
GAD	12 \pm 16	8 \pm 10.0	-2.82	<0.001

Table 3: Comparison of control group pre and post-test analysis, which were obtained using GAD

Outcome	Pre- test	Post- test	Z Value	P Value
	Mean and SD	Mean and SD		
GAD	12±16	11±14.0	--2.91	<0.001

Group B (control group), also showed a considerable improvement in reducing anxiety symptoms, revealing a Z value of -2.913 and W= -55

Table 4: Comparison of intervention group pre and post-test analysis, which were obtained using ISS

Outcome	Pre- test	Post- test	Z Value	P Value
	Mean and SD	Mean and SD		
ISS	13±16	8±10	-2.82	<0.001

Table 5: Comparison of control group pre and post-test analysis, which were obtained using ISS

Outcome	Pre- test	Post- test	Z Value	P Value
	Mean and SD	Mean and SD		
ISS	13±16	11±14	-2.85	<0.001

Table 6: Post test analysis of both the group, indicating the difference in improvement of reducing anxiety

Outcome	Group A	Group B	t Value	P Value
	Mean and SD	Mean and SD		
ISS	8.0±10	11±14.0	63	<0.001

Table 7: Post test analysis of both the group, indicating the difference in improvement of sleep quality

Outcome	Group A	Group B	t Value	P Value
	Mean and SD	Mean and SD		
ISS	8.0±10	11±14	56	<0.001

Results

The study involved 2 groups, Group A (intervention group) and Group B (control group), each comprised of 10 members. Group A received transcutaneous auricular vagal nerve stimulation, while Group B received Jacobson relaxation technique. The study was conducted over a period of four weeks, starting from February 2023.

Data collection began in January 2023, and all participants remained in their respective groups until the end of the research. To assess the outcomes, the researchers used two scales, these scales were administered as pre-tests to both groups before the therapy began to establish baseline characteristics. After the four-week treatment period, the same scales were used as post-tests to evaluate the changes in anxiety and sleep event impact in both groups. The statistical analysis of the study revealed significant results. For Group A, which received transcutaneous auricular vagal nerve stimulation, the p-value was less than 0.004. This indicates that the combination of treatments had a significant effect on the participants' anxiety levels and improved sleep quality. For Group B, which received only conventional treatment, the statistical analysis also showed a significant p-value of 0.018.

Discussion

The study aims to explore a novel and non-invasive approach for vagus nerve stimulation (VNS) to alleviate nervousness and sleep problems among the geriatric population. Vagus nerve stimulation is a therapeutic technique that involves the application of electrical impulses to the vagus nerve, a major nerve in the body responsible for various physiological functions, including mood regulation and sleep-wake cycles. During the COVID-19 pandemic, anxiety and sleep problems have been particularly prevalent among geriatric populations. A lack of structured activities may also affect sleep patterns and quality.

In 2021, Subash das, et al., conducted a study anxiety and depression among elder individuals during pandemic, He stated that seventy-five of the participants in the study were in the 60-70 age range, and the majority were men who were married and belonged to nuclear families¹².

In 2022, Umran varli et al., conducted a research on health anxiety in elderly patients and the author concluded that the earlier study that examined data from China found that the hospitalization rate after receiving a COVID-19 diagnosis rose with age, reaching 18 percent for people over the age of 80. The fear of dying and losing something causes older people to worry more about their health and see illnesses as being more serious¹³.

In 2021, Qian-qian zhang et al., conducted a study on prevalence of sleep disorders and he concluded that during the epidemic, nearly one in four older Chinese adults experienced symptoms of sleeplessness, routine evaluations of sleeplessness symptoms, and, as needed, psychiatric evaluation and treatment¹⁴.

In 2022, Yating wu et al., conducted a research on vagus nerve stimulation for sleep problems and the author concluded that anxiety and despair are frequently present alongside sleeplessness, and they can also make it worse. It has been demonstrated that emotional improvement can enhance both the quality and quantity of sleep and also he stated that with good safety and great compliance with daily stimulation, the t-VNS treatment also considerably reduced the level of depressive symptoms and anxiety as measured by the HAMD and HAMA scores¹⁵. The study's limitation and recommendation is that, since it was self-funded, no quantitative analysis, such as a parametric test, was performed. Instead, scales were used to assess the data, and geriatrics were included in the study's population. This paper highlights the significant effects of the COVID-19 on geriatrics. In the future, the population will be examined in greater detail in order to establish the prevalence of anxiety and sleep disorders in the general population.

Conclusion

In conclusion, our study provides information on how vagal nerve stimulation (VNS) may be utilized as a non-invasive therapeutic method for senior populations during the pandemic to reduce anxiety and improve sleep quality. In conclusion, transcutaneous auricular vagal nerve stimulation for 4 weeks significantly improved the vagal nerve, which plays a vital role in lowering anxiety and sleep disorders.

Ethical clearance: An institution and private hospital in Chennai obtained approval from the ISRB committee to undertake human research in accordance with all relevant institutional and national laws. Application01/026/2022/ISRB/PGSR/SCPT.

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