Synergistic Effects of Intra-Nasal Low-Level Laser Therapy and Bhramari Pranayama on Sino-nasal Symptoms and Sleep Quality in Chronic Rhinosinusitis: A Randomized Controlled Trial

Sandy Hany Michel Gad ElRab*[1], Nesreen Ghareeb Mohamed El-Nahas[1], Hazem Othman Ibrahim[2], Hend Abd El-Monaem Abd El-Monaem[1]

[1]Department of Physical Therapy for Cardiovascular/Respiratory Disorders and Geriatrics, Faculty of Physical Therapy, Cairo University, Egypt

[2]Department of Otolaryngology, Faculty of Medicine, Cairo University, Egypt

***Corresponding author:** Sandy Hany Michel, **Mobile:** (+20)01278762232, **E-mail:** sandy.gadelrab@hotmail.com

ABSTRACT

Background: Chronic rhinosinusitis (CRS) is a persistent, often debilitating inflammatory disorder of the sinonasal mucosa that not only impairs nasal function but also significantly disrupts sleep quality. Until now, non-pharmacological interventions have remained underexplored.

Objective: This study aimed to evaluate the efficacy of intra-nasal low-level laser therapy (LLLT) combined with Bhramari Pranayama breathing exercises on sino-nasal symptoms and sleep quality in CRS patients.

Methods: 54 patients with chronic rhinosinusitis without nasal polyps (CRSsNP) were randomly allocated into two equal groups (n = 27 each). Group A received intra-nasal LLLT (650 nm, 288J/cm², 3×/week) combined with a daily Bhramari Pranayama breathing exercise regimen for four weeks. Group B practiced the daily Bhramari Pranayama breathing exercise and received sham laser for the same duration. SNOT-22 scores for sino-nasal symptom severity and PSQI scores for sleep quality were assessed both at baseline and post-intervention.

Results: After the intervention, group A experienced a greater reduction in SNOT-22 scores compared to group B (29% vs. 9%, p = 0.001). Both groups showed improvement in PSQI scores (group A: 36%, group B: 20%, p = 0.001), with no significant difference between groups post-treatment (p = 0.125). Group A's intervention resulted in a significant reduction in sinonasal symptoms and a greater improvement in sleep quality compared to breathing exercises alone.

Conclusion: This study indicated that intra-nasal LLLT, as a non-invasive and low-risk intervention, may offer additional therapeutic benefits by enhancing patient-reported outcomes in CRS.

Keywords: Photobiomodulation, Complementary therapy, Breathing techniques, Quality of life, Upper airway inflammation, Sinonasal rehabilitation, Sleep disturbance.

INTRODUCTION

Chronic rhinosinusitis (CRS), defined as inflammation of the nasal cavity and paranasal sinuses persisting for 12 weeks or longer, affects 5–12% of adults worldwide, imposing substantial socioeconomic burdens due to persistent symptoms, reduced productivity, and frequent healthcare utilization [1]. Characterized by nasal obstruction, facial pain, purulent discharge, and hyposmia, CRS significantly diminishes quality of life (QoL), with patients reporting worse scores than those with chronic conditions such as congestive heart failure or chronic obstructive pulmonary disease (COPD) [2].

Additionally, CRS has been strongly linked to poor sleep quality, fatigue, and a general decline in psychosocial well-being [3]. Disrupted sleep in CRS patients is often due to increased upper airway resistance, nocturnal hypoxia, and sleep fragmentation [4]. Beyond its local morbidity, CRS is increasingly recognized as a component of the "unified airway" paradigm, where upper and lower respiratory pathologies coexist due to shared inflammatory pathways [5].

The pathophysiology of CRS involves a complex interplay of mucosal edema, ciliary dysfunction, and microbial dysbiosis, often exacerbated by anatomical obstructions (e.g., deviated septum) or immune dysregulation [6]. Despite advances in medical management—including intranasal corticosteroids, biologics, and endoscopic sinus surgery—20–30% of patients remain refractory to treatment, highlighting the need for innovative, non-pharmacological interventions [7, 8]. Current guidelines emphasize saline irrigation and corticosteroids as first-line therapies. Still, these approaches fail to address the underlying inflammatory cascade or its extrapulmonary sequelae [9].

Low-level laser therapy (LLLT), or photobiomodulation, has emerged as a promising modality for modulating inflammation and enhancing tissue repair. By delivering non-ionizing light (600–1000 nm) to target tissues, LLLT suppresses pro-inflammatory cytokines, reduces oxidative stress, and promotes microcirculation, offering a steroid-sparing alternative for chronic inflammatory conditions [10, 11].

Yogic breathing techniques, such as Bhramari Pranayama, may work to improve respiratory health. This practice involves slow and controlled exhalation combined with humming, which creates vibrations that help dislodge mucus, reduce swelling in the mucous membranes, increases the production of nitric oxide (NO) and a powerful bronchodilator [12]. Nitric oxide also has antimicrobial properties, which further help to lessen the microbial load in the sinonasal region [13].

This study aimed to throw the light on the combined effectiveness of intra-nasal LLLT and Bhramari Pranayama in managing CRS-related sino-nasal

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symptoms and improving of sleep quality. It promotes non-pharmacological strategies for unified airway disease, providing a scalable solution to a global health issue.

PATIENTS AND METHODS

Study design: This double-blind, randomized controlled trial (RCT) was conducted between June/2024 and September/2024 at the Faculty of Physical Therapy, Cairo University, Egypt.

Participants and recruitment: 54 adults aged 20 to 40 years from both genders with CRSsNP, diagnosed according to the European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS 2020) criteria. They were recruited from otolaryngology and physical therapy outpatient clinics.

Inclusion criteria: (1) persistent symptoms (nasal obstruction, facial pain/pressure and hyposmia) for 12 weeks or more, (2) A SNOT-22 score of 20 or higher and (3) Stable medical management for 4 weeks or more.

Exclusion criteria: Asthma, prior sinus surgery, nasal polyps, immunodeficiency and pregnancy, or comorbid respiratory or cardiovascular diseases (Figure 1: CONSORT flow diagram).

Randomization and blinding: Participants were stratified by gender and baseline SNOT-22 scores (moderate: 20–50; severe: ≥51) and randomized in a 1:1 ratio into; **Group A** (LLLT + Pranayama) or **Group B** (Pranayama with an additional sham laser that had an identical appearance and deactivated emitter to maintain blinding) using block randomization (block size = 4) through a computer-generated sequence (www.randomizer.org). The allocation masking was ensured with sealed opaque envelopes. Outcome assessors and statisticians remained blinded to group assignments.

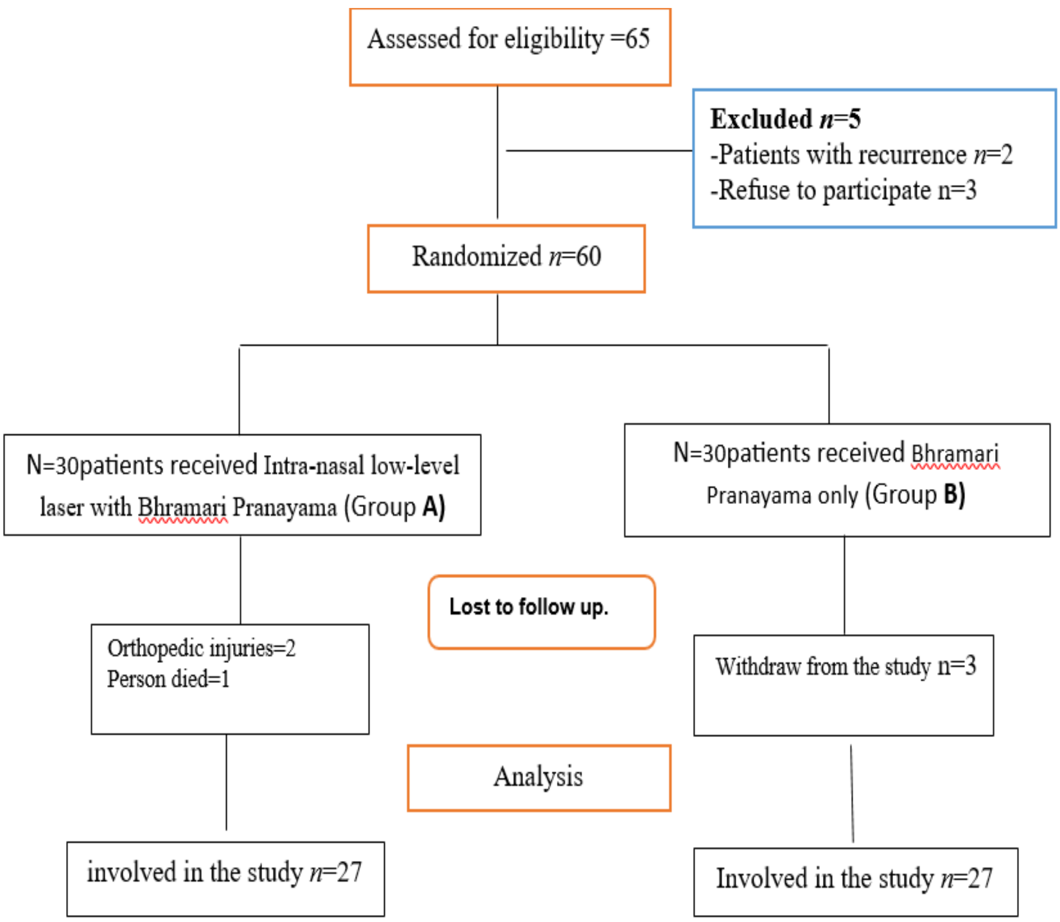

Figure (1): The study's consort diagram.

Procedure: Before starting treatment, each patient underwent an evaluation by an ENT specialist to confirm the diagnosis of chronic rhinosinusitis (CRS). Both groups received medical treatment for chronic sinusitis along with the physical intervention.

Intra-nasal LLLT: A semiconductor diode laser (Model: BS-W11, Hubei Boshi, China) emitted wavelengths (650 nm visible red) with an output power of 5 mW, an energy density of 288 J/cm, and an energy of 8.64. Patients were seated comfortably and instructed to blow their noses before the intra-nasal LLLT application. A single laser probe was sterilized and inserted unilaterally 1 cm into one nostril, three times weekly for four weeks, for 20 minutes per session. Patients were advised to breathe normally through the opposite nostril during the session. Additionally, the session was canceled in the event of nosebleeds or elevation of the body temperature for any reason [14].

Adherence and safety were tracked via session logs and laser device timestamps. No adverse events (e.g., nasal dryness, epistaxis) were noticed during laser application; only slight irritation in the nose was noticed during some sessions.

Bhramari pranayama: Participants engaged in a 20-minute daily session under initial supervision, adopting a comfortably seated posture with their eyes closed. Using their thumb to block the external auditory meatus and their fingers to close their eyelids gently, they inhaled deeply through the nose and exhaled slowly, while producing a humming sound ("Om") that was neither too loud nor too quiet, concentrating their attention on the area between the eyebrows. Each session consisted of five cycles of 2-minute humming with 1-minute rests. **Adherence** to the pranayama technique was ensured through standardized videos and weekly audits [15].

Ethical considerations: The study protocol adhered to CONSORT guidelines and received ethical approval (No: P.T.REC/012/005086) from the Institutional Review Board of Cairo University. All participants provided written informed consent before enrollment. The study adhered to the Helsinki Declaration throughout its execution. The sham laser protocol reduced placebo bias, while ensuring patient safety. Participants received complimentary post-trial access to active LLLT, which was beneficial for 2-3 sessions, addressing ethical concerns about withholding treatment.

Outcome measures:

1. **SNOT-22:** This is a validated questionnaire that patients complete on their own, requiring just a few minutes. It included 22 questions related to CRS, each scored from 0 to 5, resulting in a total possible score between 0 and 110. Higher scores reflect more severe symptoms, as the questionnaire measures the intensity of complaints experienced by patients over the past few weeks due to CRS [16].
2. **Pittsburgh sleep quality index (PSQI):** It consisted of 19 self-reported questions. Participants were asked to report how often they experienced specific sleep problems during the past month and to rate their overall sleep quality. Each question is scored from 0 to 3, where higher scores indicate more severe sleep disturbances [17].

Assessments were conducted at baseline (T0) and post-intervention (T1).

Sample size calculation: The sample size was calculated based on sino-nasal symptoms and sleep quality [18, 19]. We aimed for 80% power with a 5% significance level. The study included two groups and two measurements, with an effect size of 0.39. Using a specific statistical test (MANOVA), we determined that at least 54 participants were required. To account for an estimated 11% dropouts, we included 6 additional participants, resulting in a total of 60 participants, with 30 in each group. The calculation was performed using G*Power software.

Statistical analysis

All analyses were conducted using SPSS version 20. Data were presented as mean ± SD. To compare group characteristics, unpaired t-test was performed, while categorical variables such as sex and smoking status were analyzed using the Chi-square test. The Shapiro-Wilk test assessed whether the data followed a normal distribution. A multivariate analysis of variance (MANOVA) evaluated differences within and between groups for variables including SNOT-22 and PSQI scores. Statistical significance was set at $P \leq 0.05$.

RESULTS

General characteristics of participants: There were no statistically significant differences between group A and group B in terms of age, weight, or height (p = 0.252, 0.194, and 0.684, respectively). Similarly, no significant differences were observed in sex distribution (p = 0.698) and smoking status (p = 0.660) between the two groups (Table 1).

Table (1): Baseline characteristics of participants in both groups

Characteristics	Experimental group A (n=27)	Control group B (n=27)	t-value	p-value
Age (years)	30.1±4.45	31.4±3.84	-1.16	0.252
Weight (kg)	73.21±14.82	78.59±15.47	-1.32	0.194
Height (cm)	167.93±8.52	168.89±8.86	-0.41	0.684
Sex				
Males	13 (48%)	15 (56%)	Chi-square 0.15	0.698
Females	14 (52%)	12 (44%)		
Smoking				
Non-smoker	17 (63%)	16 (59%)	Chi-square 0.19	0.660
Smoker	10 (37%)	11 (41%)		

Sino-nasal symptoms: Between-group analysis revealed no statistically significant difference in baseline SNOT-22 scores (p = 0.896). However, a significant difference was observed in post-intervention **(p = 0.001),** favoring group A. Within-group comparisons showed a significant reduction in SNOT-22 scores in both groups: a 29% decrease in group A (p = 0.001) and a 9% decrease in group B (p = 0.001) (Table 2).

Table (2): Comparison of SNOT-22 scores pre- and post-intervention in both groups

SNOT-22	Group A Mean ±SD	Group B Mean ±SD	Mean difference (95% CI)	P-value[1]	η^2
Pre-study score	50.21 ± 8.95	49.85 ± 11.32	0.36 (-5.1, 5.87)	0.896	0.01
Post-study score	35.71 ± 4.16	45.33 ± 11.05	-9.62 (-14.1, -5.13)	0.001*	0.26
MD (95% CI)	14.5 (12.54, 16.46)	4.52 (2.52,6.52)			
% of change	29%	9%			
P-value	0.001*	0.001*			

SD: standard deviation, **CI:** Confidence interval, **p-value:** level of significance within the group, ***:** significant, **η^2:** partial eta square.

Sleep quality: Between-group analysis showed no statistically significant difference in baseline PSQI scores (p = 0.314) or post-intervention scores (p = 0.125). However, within-group analysis revealed a significant reduction in PSQI scores in both groups: a 36% decrease in group A (p = 0.001) and a 20% decrease in group B (p = 0.001) (Table 3).

Table (3): Comparison of Mean ±SD of PSQI pre- and post-intervention of both groups

PSQI	Group A Mean ±SD	Group B Mean ±SD	Mean difference (95% CI)	P-value	η^2
Pre-study score	10.36 ± 2.96	9.59 ± 2.6	0.77 (-0.75, 2.27)	0.314	0.01
Post-study score	6.64 ± 2.47	7.7 ± 2.58	-1.06 (-2.43, 0.31)	0.125	0.21
MD (95% CI)	3.71 (3.35, 4.08)	1.89 (1.52,2.26)			
% of change	36%	20%			
P-value	0.001*	0.001*			

SD: standard deviation, **CI:** Confidence interval, **p-value:** level of significance within the group, ***:** significant, **η^2:** partial eta square.

DISCUSSION

This study complements showed increasing evidence that chronic rhinosinusitis is a systemic disorder with broad effects including major impact on sleep. After LLLT, better SNOT-22 and PSQI results point to a non-invasive method able to handle CRS's physical symptoms and QoL issues. Our results match those of earlier research showing that nasal tube inflammation might cause problems with nocturnal breathing and disturbance of sleep continuity [3, 4, 20].

In CRS, intranasal LLLT showed effectiveness in reducing mucosal edema, enhancing nasal airflow, and decreasing relapse rates by improving lymphatic drainage and phagocytic activity [14, 21].

Abdulrashid *et al.* [10] reported a 40% reduction in mucosal thickness in pediatric CRS patients after LLLT, which correlated with improved symptom scores.

The therapeutic effects of LLLT are achieved through mechanisms such as inhibiting pro-inflammatory cytokines (e.g., IL-6, TNF-alpha), activating mitochondrial function, and enhancing tissue oxygenation [22, 23]. The etiology of sleep dysfunction in CRS remains unclear, but it is likely multifactorial, with immune modulation, symptom burden, and concurrent disorders potentially serving as significant contributors [24]. Patients with CRS experience sleep disturbances at a much higher rate (60 to 75%) compared to the general population (8–18%) [25]. When nasal obstruction is alleviated and mucosal health is restored, sleep naturally improves, highlighting the close connection between airway patency and sleep regulation.

Kumar and Venkatesh [26] observed 33% reduction in PSQI ratings among adolescents who engaged in six weeks of Bhramari Pranayama practice, confirming its direct influence on sleep quality. Previous LLLT studies have mostly concentrated on symptom relief; this is shown by a 40% drop in mucosal thickness as recorded by **Abdulrashid *et al.*** [10]. Such changes are probably going to improve nocturnal airflow and help to lower sleep disruptions. Our findings are one of the first to test the synergistic effect of LLLT and Bhramari Pranayama on sleep in CRS patients and indicated a complimentary mechanism. While, LLLT improved mucosal function and lowers inflammation, therefore promoting improved sleep patterns, Pranayama changes autonomic balance and increases nitric oxide generation.

Bakshi *et al.* [15] found that combining Bhramari Pranayama with standard CRS care significantly improved QoL and decreased nasal congestion when compared to medical therapy alone. Despite these advantages, no research has examined at how LLLT and Pranayama used together affect symptoms and sleep problems in CRS patients.

Furthermore, as previous studies in respiratory treatment supports, the incorporation of Bhramari Pranayama breathing exercises may have enhanced results by lowering sympathetic activity and raising vagal tone [27]. But the more significant effect in group A in our study pointed to LLLT as the main agent causing clinical changes.

Clinically, this study had transformative potential. CRS patients frequently had little alternatives other than corticosteroids or surgery, which both pose risks of mucosal atrophy, antibiotic resistance, and recurrence [28, 29]. A non-invasive, home-based regimen combining LLLT and Pranayama might lower healthcare expenditures, improve adherence, and lessen systemic adverse effects, especially in comorbid groups (e.g., diabetics and steroid-resistant patients).

CLINICAL IMPLICATIONS

This regimen provided a steroid-sparing alternative for CRS patients with additional respiratory conditions. The 29% reduction in SNOT-22 scores emphasized its potential to enhance QoL.

LIMITATIONS

The short follow-up period (4 weeks) and the lack of inflammatory biomarkers limit mechanistic insights. Future trials should evaluate long-term outcomes and include cytokine profiling. Additionally, the use of single-wavelength LLLT could be substituted with a dual-wavelength (650 nm + 980 nm) approach, which ensures optimal tissue penetration and energy delivery.

CONCLUSION

Intra-nasal LLLT combined with Bhramari Pranayama significantly enhanced sino-nasal symptoms and sleep quality in CRS patients, confirming its role in unified airway management. This synergistic, non-invasive approach deserves integration into multidisciplinary respiratory care.

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Conflict of Interest: Nil.

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