

Effect Of Shuddhi Kriya Based Yoga Program (Skyp) For Allergic Rhinitis: A Randomized Control Study

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ABSTRACT

Background: Allergic rhinitis (AR) is a chronic inflammatory disorder of the nasal mucosa that can have a substantial impact on one's quality of life. The purpose of this two-group randomized, waitlist-controlled trial was to determine the efficacy of a Shuddhi Kriya-based yoga programme (SKYP) in the management of AR.

Methods: The study comprised 60 individuals who had been suffering from moderate to severe chronic allergic rhinitis for more than a year were randomly assigned to either a yoga or a control group. Seven patients were withdrawn from the yoga and control groups, leaving 53 patients (yoga = 27 and control = 26). For eight weeks, the yoga group participated in the SKYP module for around 60 minutes each day, four days a week. The nasal symptom score (TNSS), the Mini-Rhinosinosis quality of life questionnaire (mini-RQLQ), the PEF, and the PNIF were all measured before and after the 8-week treatment period.

Results: SKYP appears to be beneficial in the reduction of nasal symptoms, enhance quality of life, non-nasal symptoms and nasal passage potency on the PNIF meter. Despite considerable reductions in mean symptom scores, SKYP had no effect on the 12-hour morning score for nasal congestion, nasal itching, sneezing, difficulty sleeping, or peak expiratory capacity in individuals with allergic rhinitis.

Conclusion: The results of the present study conclude that Yogic practices seem appropriate in reducing nasal and ocular symptoms furthermore yoga can improve quality of life and nasal potency for individuals with AR.

Keywords: Allergic rhinitis; Shuddhi kriya; Yoga; Neti; sneezing

INTRODUCTION

Allergic rhinitis is one of the common immune mediated inflammatory disorders primarily affecting nasal mucosa, it is characterized by runny nose, sneezing and nasal congestion (Scadding & Scadding, 2016). Further additional

symptoms may be watery eyes, sniffing, impaired olfaction and mouth breathing. Allergic rhinitis is also known by other names, such as nasal allergy and nasal hypersensitivity. Allergic rhinitis is an important public health concern since it may have a considerable impact on one's quality of life, sleep efficiency (Kim et

al., 2017), and work/school performance (James W. Mims, 2012). A recent study observed elevated prevalence and its negative impact on their academic activity (Chauhan, Rajesh, & Chauhan, 2022). Additionally, AR has been linked to lower respiratory disorders such as bronchial asthma (Dixon et al., 2006). Asia, Europe, America, and Africa all indicated a 15-25 percent prevalence of AR, with children and teenagers being the most afflicted age groups (Passali et al., 2018). Early-life antibiotic use, pets in the home, mites, humidity, diet, lifestyle and environment are all common independent risk factors for AR (D.-Y. Wang, 2005 and Tamay et al., 2007). Allergic rhinitis is the most frequent type of non-infectious rhinitis; it is categorised into two types: Intermittent AR and Persistent AR. Intermittent AR refers to symptoms occurring fewer than four days per week or lasting less than four conjugative weeks, whereas persistent AR refers to symptoms occurring more than four days per week or lasting more than four conjugative weeks. AR is further categorized into mild and "moderate to severe" grades based on severity (Bousquet et al., 2008).

Allergic rhinitis is frequently treated with complementary and alternative medicine (CAM), such as acupuncture, homoeopathy, and yoga. Yoga is a collection of self-realization techniques that originated in ancient India. Hatha yoga is one of the yoga schools that focus on yogic physical training, which primarily comprises purifying techniques (Shuddhi kriyas), physical postures (Asana), and breathing techniques (Pranayama). Yoga appears to have favorable impacts on the immune system as well as the respiratory system, according to emerging data (Chellaa et al., 2019). A comprehensive assessment of the usefulness of yoga as therapy for AR came to the conclusion that yoga is not only effective for major symptoms, but it may also alleviate other associated symptoms such as psychological stress and sleep impairment in AR patients by enhancing vagal tone (Chauhan & Rajesh, 2020). There is emerging evidence that yoga plays a multifaceted function in lowering immune-inflammation and consequently reducing AR symptoms. Researchers observed that a yoga intervention increased the anti-

inflammatory cytokine IL10 and reduced the pro-inflammatory cytokine IL-12 (Cahn, et al., 2017). The HPA axis is also involved in boosting the amount of cytokines in acute inflammation associated with AR (Buske-Kirschbaum, Ebrecht, & Hellhammer, 2010). Several studies showing significant changes in Serum cortisol and salivary cortisol levels following yoga based intervention support the idea that yoga regulates the HPA axis (Vedamurthachar et al., 2006; Michalsen et al., 2005 and Raghavendra et al., 2009).

The impact of SKYP, on the other hand, has yet to be examined in depth. Aims of the current study were to assess the effects of SKYP on the symptoms and quality of life associated with AR. In addition, the peak nasal inspiratory flow (PNIF) and peak expiratory flow rate (PEFR) were evaluated.

METHODS

Study Design

The study used a pre-post randomized waitlist control design with two groups. We had to recruit 30 participants in each group to have a total sample size of 60 students. The experimental group did Shuddhi kriya based yoga, whereas the control group kept their daily routine. The total nasal symptom score for the last 12 hours of the morning, the total nasal symptom score for the last two weeks, the rhinoconjunctivitis quality of life, and the visual analogue scale for nasal and ocular symptoms were examined pre and post 8 weeks. Furthermore, the Peak nasal inspiratory flow rate (PNIF) and Peak expiratory flow rate (PEFR) were measured.

Participants

From the O.P.D. of nature cure centre, vadodara, Gujarat, India and the health checkup camps, 60 patients with allergic rhinitis aged 18–41 were invited to participate in this study. Patients who have been presenting with symptoms of persistent allergic rhinitis, as defined by the ARIA standards, for more than one year are eligible. A screening of 96 patients with symptoms resulted in 60 volunteers, who were divided into two groups and seven of them

dropped out in the middle of the study (4 in control and 3 in yoga group). For 53 individuals, the final data was available (**fig.1**). Individuals with high blood pressure, severe asthma, COPD, pulmonary tuberculosis, people with life-threatening diseases, and those who were taking oral and nasal steroids were excluded from the study. Patients were instructed to abstain from taking antihistamine medications for four days

prior to the evaluation. A written informed consent was obtained from each participant after they were educated about the technique and the advantages and disadvantages of participating in it. The protocol for the study was approved by the institutional ethical review board. The study was registered with the Clinical Trials Registry of India (CTRI) (Registration Number–CTRI/2017/09/009900).

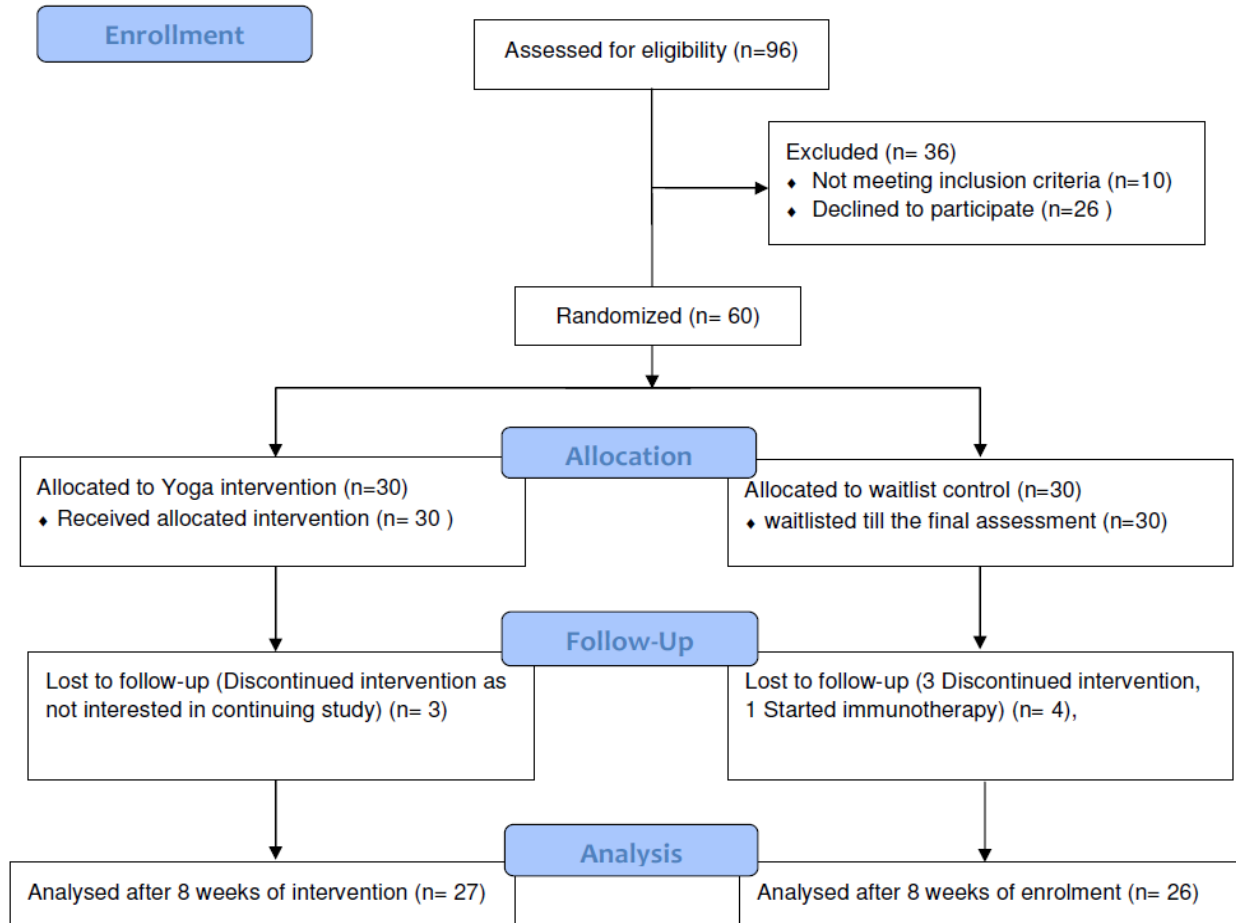


Fig. 1: Flow diagram for trial profile

Yoga Training Protocol

Under the supervision of the principal investigators and a yoga instructor, the YOG group followed a shuddhi kriya based yoga training protocol for 60-70 minutes per session, four times a week for eight weeks. A combination of Yogic Shuddhi Kriyas, asanas,

loosening exercises, breathing exercises, pranayama, as well as yogic counseling and lectures, were incorporated in the treatment protocol. Participants were advised to practice Shuddhi Kriyas, Asanas, and Pranayamas calmly, harmoniously, and steadily. **Fig-2** contains a detailed description of the intervention.

Categories	Yogic Practices	Description	Repetition	Time duration
Suddhi Kriyas	Vaman Dauti	Induced vomiting	3 days a week	
	Jal Neti	Saline nasal irrigation	3 days a week	
	Rubber Neti	Introducing rubber catheter through nose to come out from mouth	Once a week	
	Laghu Sankhprakashana	Alimentary canal washing with saline water	Once in 30 days	
	Trataka	Yogic gazing	Once a week	
	Kapalbhati	Repeated Active exhalation and passive inhalation	60-180 strokes	
Sukshmayayam	Angulishaktivikasika	finger stretch	10	2 min
	Manibandhashaktivikasika	wrist stretching	10	2 min
	Kaponishaktivikasika	elbow banding	10	1 min
	Skandha chakra	shoulder rotation	10 each side	2 min
	Greevasanchalana	neck bend and stretching	5 each side	2 min
	Padangulinaman	toe stretching	10	2 min
	Gulf naman	ankle stretch	10	2 min
	Gulf goornan	ankle rotations	10 each side	2 min
	Janunaman	knee bending	5 each leg	2 min
	Baddhkonasana asana	full butterfly pose	10 rounds	1 min
Asanas				12 min
Standing	Ardhakatichakrasana	Half waist wheel pose	30 sec each side	1 min
	ParivrittaTrikoanasa	Revolve triangle pose	30 sec each side	1 min
Prone	Bhujangasana	Cobra Pose	2	2 min
	Salabhasana	Locust Pose	2	2 min
Supine	Viparita Karni	Inverted Pose		1 min
	Pawanmuktasana	Wind releasing pose	3 times each side	3 min
Sitting	Usttrasana/ardh-usttrasana	Camel pose		1 min
	Paschimottanasana	Forward Stretch		1 min
Pranayama				13 min
	Vibhagiya Pranayama	Sectional Breathing	9 rounds each	5 min
	Nadisuddhi	Alternate nostril breathing	9 rounds each	5 min
	Bhramari	Bee sound	9 rounds	5 min
Relaxation	Relaxation - DRT, QRT	Deep relaxation technique Quick relaxation technique	Twice a week each	5-15 min
Meditation	OM Meditation (OM Dhyana)		Twice a week	10 min

Fig. 2: List of yogic practices provided as intervention.

Assessments

Nasal symptom score

The Total Nasal Symptom Score (TNSS) questionnaire was used to capture nasal symptoms as well as poor sleep. Prior to and after the 8-week study, participants were asked to rate their symptoms of nasal congestion, runny nose, nasal itching, sneezing, and difficulty in sleeping. The severity of their symptoms was scored on a scale from 0 to 3, where 0 indicating no symptom and 3 indicating significant symptom that interfered with everyday activities. Possible scores range from 0 (no symptoms) to 15 (maximum symptom intensity) (Downie et al., 2004 and Tatar et al., 2013)

Quality of Life

Mini-rhinosinusitis quality of life (RQLQ) is used to evaluate quality of life. It is a validated tool that has five domains covering 14 questions. The domains are activity constraints, practical problems, nasal symptoms, eye symptoms and other symptoms. Each question was scored on a scale with 7 points ranging from 0 to 6; 0 stands for no impairment and 6 for severe impairment. High scores indicated a poor quality of life (Juniper et al., 2000).

Peak Nasal Inspiratory Flow

In order to determine nasal air flow rate for nasal obstruction, a PNIF meter (Clement Clark International, UK) was used. This meter is dependable and simple to use (Klossek et al., 2009). Participants were required to wear a mask that covered their nose and mouth and was attached to a meter. The diaphragm inside the device moves in response to negative pressure on a scale ranging from 30-370 lit/min. This has been recorded on an empty stomach for each participant before and after the intervention's eight-week period.

Peak expiratory flow rate

The peak expiratory flow rate (PEFR) was used to determine effort-dependent airflow. This is a simple and effective process that may be performed with a portable instrument to measure airflow. Prior to data collection, each participant

was told to inhale through the nose and then exhale as strongly as possible with maximal effort while tightly holding the mouth piece through the lips to prevent air leakage. This was done in a straight sitting position, with the PEFR meter remained parallel to the ground throughout the procedure. The PEF measures were obtained on an empty stomach in the early morning hours, with the best of three tries being used to determine the results (Dikshit, Raje, & Agrawal, 2005; Leynaert et al., 2000 and Ahmed, Sau, & Kar, 2010).

RESULTS

We transferred the recorded data from the questionnaire sheets to an excel spreadsheet. The following variables were analyzed at different domains: TNSS 12 hour's morning, TNSS 2 weeks, mini-RQLQ, VAS nasal and ocular symptoms, PNIF, and PEFR. R statistical software, version 4.0.2, was used to conduct all of the analyses (R Core Team, 2020). At first, we performed descriptive statistics and used outlier and missing value analyses, as well as a baseline matching assessment, to ensure the accuracy of the data. Sixty persons were randomly divided into two groups: yoga (n=30) and control (n=30). An overall total of seven people dropped out of the study, three from the Experimental group and four from the Control group. As a result, the Experimental and Control groups consisted of 27 participants (11 males and 16 females) and 26 people (8 males and 16 females, respectively, details shown in the **figure 1**. General physical characteristics and baseline data of yoga and control groups in terms of mean and range are presented in **table 1**. The normality test was performed for all the baseline and Post trial data. In this study, baseline scores for six variables (TNSS 2 week total, RQLQ activity, RQLQ practical problems, RQLQ nasal symptoms, VAS nasal score, and PEFR) were normally distributed, and a parametric independent sample t-test was used to determine whether the variables were significant. Due to the fact that the remainders of the variables were not normally distributed, the non-parametric Mann Whitney U test was used to analyze the data. Two variables (TNSS 12 hour total and VAS nasal) showed no baseline

matching between the yoga and control groups; hence the differences in their pre-post scores

were taken for assessment.

Variables	Yoga (n=27)		Control (n=26)	
	mean	Range	mean	range
Age (in years)	25.44	19-39	29.42	19-41
Male (%)	11 (40.7)		8 (30.8)	
Female (%)	16 (59.3)		18 (69.2)	
Duration of sickness	5.370	1.5 -15	5.05	1-12
Height	164.78	143 -180	162.96	150-180
Body weight	63.337	35.6 - 91.2	66.854	43-147
BMI	4.21	14.00- 32.60	25.0673	14.20-46.92
TNSS 12Hour Total	8.44	1-14	7.46	5-12
TNSS 2 week Total	9.74	6-15	9.31	6-13
Mini-RQLQ Total	44.56	28-65	41.65	30-54
VAS Nasal	7.37	5-10	5.77	2-9
VAS Ocular	3.48	1-7	2.85	1-6
PNIF	79.63	50-140	76.92	50-100
PEFR	360.37	270-450	351.92	280-440

Table 1: General physical characteristics and baseline data of yoga and control groups in terms of mean and range.

Total Nasal symptom score (TNSS) 12 hour morning

The use of a yoga intervention based on Shuddhi Kriya led to a statistically significant improvement in the TNSS 12 hour morning score for nasal drainage ($z = -2.67$, $p = .007$) and total symptom score ($z=3.16$, $p = .002$) when compared to control group. There were no statistically significant differences in other categories, such as nasal blockage ($z=-1.43$, $p = .152$), nasal itching ($z = 0.23$, $p = .816$),

sneezing ($z = -0.31$, $p = .755$), and poor sleep ($z = -0.65$, $p = .518$) (Table 2).

Total nasal symptom score (TNSS) two weeks

Compared to the control group, the experimental group experienced significant reductions in nasal symptoms on the 2 week TNSS score for all domains, including nasal congestion ($z = -3.43$, $p=.001$), nasal drainage ($z = -3.39$, $p = .001$), nasal itching ($z = -3.51$, $p=.001$), sneezing ($z = -3.89$, $p=.001$), difficult sleep ($z = -2.13$, $p = .033$) and total ($z = -4.71$, $p = .001$) (Table 2).

Variable	TNSS 12 hour morning					TNSS past 2 weeks				
	Yoga (n=27)		Control (n=26)		P-value	Yoga (n=27)		Control (n=26)		P-value
Median	mad	median	mad	Median		mad	Median	mad		
Nasal congestion	1	1.48	2	0	0.152	1	0	2	0	0.001
Runny nose	1	0	1.5	0.741	0.007	1	0	2	0	0.001
Nasal itching	1	0	1	1.48	0.816	1	0	1.5	0.741	0.001
Sneezing	2	0	1.5	0.741	0.755	1	1.48	2	0	0.001
Difficult sleep	1	1.48	1	1.48	0.518	1	1.483	1.5	0.741	0.033

Total	3	2.97	1	1.48	0.002	5	1.48	9	1.48	0.001
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Table 2: The comparison of nasal symptom score at 12 hour morning and past 2 weeks on different domains between yoga and control groups.

Quality of Life Score

Subjects in the Yoga group who received SKYP had a significant reduction in symptom scores on the mini RQLQ for all five domains, including activity ($z = -4.89$, $p = .001$), practical problems ($z = -4.18$, $p = .001$), other symptoms ($z = -3.21$, $p = .001$), nose symptoms ($t = -4.83$, $p = .001$), eye symptoms ($t = -4.83$, $p = .001$), and total score ($t = -3.01$, $p = .004$) (Table 3&4).

Visual Analog Scale

VAS scores for nasal ($z = -3.16$, $p = .02$) and ocular ($z = -4.19$, $p = .01$) were considerably improved in SKYP patients compared to controls (table 4).

PNIF & PEFR

However, the PEFR did not demonstrate significant improvement ($t = 1.95$, $p = .056$) (table 3) compared to control, whereas the PNIF showed substantial improvement ($z = 2.76$, $p = .006$) (table 4).

Variables	Yoga (n=27)		Control (n=26)		P-value
	Mean	sd	mean	sd	
Mini-RQLQ					
Nasal symptoms	6.85	2.656	10.54	2.064	0.001
Eye Symptoms	3.04	1.629	5.5	2.064	0.001
Total Symptoms	32.7	9.844	39.73	6.821	0.004
PEFR	377.41	48.72	351.15	49.18	0.056

Table 3: The comparison of parametric variables on different domains between yoga and control groups.

Variables	Yoga (n=27)		Control (n=26)		P-value
	Median	mad	median	mad	
Mini-RQLQ					
Activity	6	1.48	10	2.97	0.001
Practical problem	3	1.48	7	1.48	0.001
Other symptoms	4	2.97	6.5	2.22	0.001
VAS nasal	5	2.97	0	1.48	0.002
VAS ocular	1.48	2.65	3	1.48	0.001
PNIF	90	14.8	70	14.8	0.006

Table 4: The comparison of non-parametric variables on different domains between yoga and control groups.

DISCUSSION

The purpose of this study was to determine the efficacy of eight weeks of SKYP on individuals with moderate to severe allergic rhinitis. When

comparing the experimental and control groups, it was shown that the experimental group had significantly lower score for nasal symptom and quality of life. In addition, the experimental

group's PNIF value improved after two months of following the SKYP programme, although the PEFr improvement was not statistically significant. It is essential to understand that six shat kriyas are vital aspect of hatha yoga. They include: Dhauti (upper gastrointestinal cleanser), Basti (colon cleanser), Nauli (churner of abdominal muscles), Neti (both nasal irrigation and cotton thread or a rubber catheter), Trataka (yogic gazing), and Kapalbhata (sinus cleansing). The yoga protocol used in this study is based on the notion of hatha yoga, which states that asanas and pranayama should be practiced after eliminating excess phlegm and bile through the use of shat kriyas, or yogic purification techniques, which are described in the classical hatha yoga literature (Patra, 2017).

Along with asana, pranayama, and relaxation techniques, the present investigation introduces Vaman dhauti, Jalneti, Sutra neti, Shankhprakashana, Kapalbhata, and Trataka as Shat Kriyas.

Allergic rhinitis can be managed pharmacologically in a variety of ways, ranging from tropical antihistamines to corticosteroids and immunotherapy (Brožek et al., 2017 and Okubo et al., 2020). Preventing exposure to allergens (Okubo et al., 2020), nasal irrigation (Principi & Esposito, 2017), acupuncture (Choi et al., 2013) and yoga (Chellaa et al., 2019) are examples of non-pharmacological treatments that are not included in mainstream therapy. Studies regarding therapeutic efficacy of neti has shown influences on a variety of conditions in the upper respiratory tract, including rhinosinusitis, AR, and snoring. According to research, this evidence is strong enough to justify the need for a large, randomised control trial to verify the therapeutic efficacy of jal neti (Meera et al., 2020). A few number of clinical trial studies have been conducted on AR following yoga practice. PNIF (nasal nasal blood flow) and NBF (nasal nasal blood flow) were significantly improved in a randomized control trial in AR patients who received hatha yoga intervention three days per week for eight weeks. Additional research indicates that yoga not only improves nasal blood flow, but it also reduces nasal congestion and inflammation, as seen by a high level of LI-2 in the experimental group compared to the control group (Chanta et

al., 2019). Further, study on 51 AR patients who received a three-month hatha yoga intervention demonstrated a substantial reduction in nasal airflow resistance and an improvement in forced vital capacity FVC on rhinomanometry and spirometer, respectively, when compared to healthy controls. However, the study showed no statistically significant changes in forced expiratory volume in one second or percent residual standard deviation. This study further validates the findings of a prior investigation that included a variety of evaluation techniques (Chellaa et al., 2019).

In our study subjective rhinitis symptoms score on TNSS 2 weeks scale and quality of life score on mini-RQLQ were significantly reduced in the experimental group in comparison to control. The results are consistent with the observations of pharmacological study with adding Levocetirizine or Montelukast to Mometasone Furoate (Tatar et al., 2013). A substantial increase in the PNIF rate was seen in this investigation. The nasal congestion index (PNIF) meter is a straightforward and dependable means of assessing nasal congestion. This implies that the SKYP treatment can help to reduce inflammation of the nasal mucosa, which in turn can help to minimize nasal congested. Our findings are similar with the findings of two previous hatha yoga intervention studies conducted in 2019. One study utilized a PNIF meter (Chanta et al., 2019) while another used rhinometry to determine total nasal resistance (Chellaa et al., 2019). In both investigations, nasal blockage was found to be reduced.

Psychological stress has been shown to be a contributing factor to persistent allergic rhinitis. When stress is addressed by the use of a stress management treatment, allergic rhinitis symptoms improve, and quality of life (QOL) improves (El Hennawi, Ahmed, & Farid, 2016). According to the findings of the study, most varieties of yoga have beneficial benefits on stress reduction (F. Wang & Szabo, 2020), which results in decreased cortisol levels (Moghadasi & Najafi, 2017). Additionally, yoga intervention has been shown to increase parasympathetic nerve activity and stress

hormone levels (Eda, Ito, & Akama, 2020). Reduced stress, increased parasympathetic nerve activity, and enhanced stress-related hormones can all be listed as potential mechanisms for improved allergic rhinitis symptoms and a higher quality of life. Further, study has discovered that the activation of the vagus nerve happens not only in the nose, but also in the cardiovascular system among allergic rhinitis (Yokusoglu et al., 2007). The potential of yoga-based interventions to relax the mind and body, thereby regulating hyperactive nerves (Nagarathna, 1985), gives another probable rationale for enhanced allergic rhinitis symptoms and quality of life.

The current study contains a number of limitations that should be highlighted. The 8-week period of the yoga intervention demonstrated the effect; however a much longer trial would be ideal. The sample sizes of both groups were too small to be able to generalize the findings of the study. Due to the fact that there is no acceptable placebo available for yoga, the subject cannot be blinded during the study. A randomization process was used for assigning people to one of two groups; nevertheless, the selection of patients was not randomized. This study was carried out in a single centre; as a result, it may not be possible to infer the conclusions towards the entire population of the country. Because of the widespread usage of yoga in India, every subject participate in the experiment had a positive opinion about the benefits of yoga. Furthermore, biomarkers for allergic rhinitis such as cytokines, neurotrophins, proinflammatory neuropeptides IgE, and stress hormones are not included in the assessment. The findings of this assessment will enable for a more detailed understanding of the potential mechanism of action of yoga-based interventions for allergic rhinitis. Furthermore, the current study takes a comprehensive approach to yoga, focusing more on shuddhi kriyas, however it does not examine the impact of individual yogic practice.

CONCLUSION

This study demonstrates encouraging outcomes in improving the Nasal Symptom Score, the Quality of Life Score, and the Peak Nasal Inflow

Rate in patients with allergic rhinitis, indicating the potential value of shuddhi kriyas based yoga management as an adjuvant to conventional care. Now a days, Yoga is practiced at large, so inclusion of yogic Suddhi kriyas may be an addition to improve respiratory health. The purpose of this study is to build a framework for the implementation of yogic practices for the treatment of upper respiratory and allergic disorders. Research at a larger scale with longer follow-up periods will most likely be the focus of future endeavors. The importance of shuddhi kriyas, in particular, has to be investigated in greater depth.

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