CHAPTER 5: INTERVENTION STUDY

5.1 AIM AND OBJECTIVES

5.1.1 Aim of the Research

- The primary aim of this research is to evaluate the effectiveness of a *Shuddhi Kriya*-based *yoga* program in managing allergic rhinitis.

5.1.2 Objectives of the Research

- *Effect on Allergic Rhinitis Symptoms:* To assess the impact of the *Shuddhi Kriya*-based *yoga* program on the symptoms of allergic rhinitis, quantified using the Total Nasal Symptom Score (TNSS).
- *Quality of Life (QOL) Assessment:* To evaluate the influence of the *yoga* program on the quality of life of patients with allergic rhinitis, measured through the Mini-Rhinoconjunctivitis Quality of Life Questionnaire (mini-RQLQ).
- *Visual Analogue Scale (VAS) Evaluation:* To analyze the effectiveness of the program on patient-reported outcomes, specifically using the VAS score to assess the severity of allergic rhinitis symptoms.
- *Peak Flow Rate Analysis:* To investigate the impact of the *yoga* program on the peak flow rate of patients with allergic rhinitis, utilizing a peak flow meter to measure respiratory function.
- *Nasal Patency Assessment:* To determine the effect of the *yoga* program on nasal patency in patients suffering from allergic rhinitis, using a Peak Nasal Inspiratory Flow (PNIF) meter.

5.2 JUSTIFICATION OF THE STUDY

The study on the effectiveness of the *Shuddhi Kriya Yoga* Program for Allergic Rhinitis is justified by several key considerations. Allergic Rhinitis (AR) is a widespread condition that significantly affects individuals' quality of life, daily functioning, and overall well-being. Despite the availability of conventional treatments, many patients continue to seek complementary therapies due to concerns over side effects, cost, and a desire for a more holistic approach to health. *Yoga,* has been shown to offer various health benefits, including improvement in respiratory functions and immune responses. The *Shuddhi Kriya,* a set of cleansing practices within *yoga*, specifically targets nasal and respiratory pathways, which are directly implicated in AR. However, the scientific understanding of the efficacy of such practices in managing AR is limited, necessitating thorough research.

5.3 RESEARCH QUESTIONS

- Does the *Shuddhi Kriya Yoga* Program significantly reduce the severity of symptoms in patients with Allergic Rhinitis as compared to a control group?
- How does the *Shuddhi Kriya Yoga* Program impact the quality of life of patients with Allergic Rhinitis, as measured by the Mini-Rhinoconjunctivitis Quality of Life Questionnaire (mini-RQLQ), in comparison to a control group?
- Is there a significant difference in the Visual Analogue Scale (VAS) scores for symptom severity between patients with Allergic Rhinitis undergoing the *Shuddhi Kriya Yoga* Program and those in the control group?
- Does participation in the *Shuddhi Kriya Yoga* Program lead to an improvement in peak flow rate and Peak Nasal Inspiratory Flow (PNIF) measurements in Allergic Rhinitis patients compared to those in the control group?

5.4 HYPOTHESIS AND NULL HYPOTHESIS

Hypothesis:

The *Shuddhi Kriya Yoga Program* significantly improves symptoms, quality of life, and respiratory function in patients with Allergic Rhinitis as compared to a control group. This improvement is expected to be reflected in the Total Nasal Symptom Score (TNSS), Mini-Rhinoconjunctivitis Quality of Life Questionnaire (mini-RQLQ), Visual Analogue Scale (VAS) scores, peak flow rate, and Peak Nasal Inspiratory Flow (PNIF) measurements.

Null Hypothesis:

The *Shuddhi Kriya Yoga Program* does not lead to significant improvements in symptoms, quality of life, or respiratory function in patients with Allergic Rhinitis when compared to a control group. No significant differences will be observed in the TNSS, mini-RQLQ, VAS scores, peak flow rate, and PNIF measurements between the group undergoing the *yoga* program and the control group.

5.5. METHODS

5.5.1 Sample Size

In determining the sample size for the *Shuddhi Kriya Yoga Program* study on Allergic Rhinitis, a conservative effect size of 0.5 was chosen, despite higher effect sizes observed in previous pharmacological studies. With an alpha of 0.05 and a power of 0.8, the required sample size for each group was calculated to be 26 subjects. To account for a potential dropout rate of 20%, the study aimed to recruit 30 individuals per group. Therefore, the total sample size for the study, including both the *yoga* program group and the control group, was set at 60 subjects (30 in each group).

5.5.2 Selection and Source of Participants

Participants for the *Shuddhi Kriya Yoga Program* study on Allergic Rhinitis were primarily recruited from the Outpatient Department (O.P.D.) of a Nature Cure Centre in Vadodara, Gujarat, India, as well as from health check-up camps organized in the area. The study focused on individuals aged 18 to 41 years who were experiencing symptoms of persistent allergic rhinitis. Eligibility for participation was determined based on the criteria set by the Allergic Rhinitis and its Impact on Asthma (ARIA) standards, specifically targeting those who had been presenting with symptoms for more than one year. The recruitment process was conducted over a period spanning from October 2017 to February 2018, allowing for the inclusion of a diverse group of patients in line with the study's requirements.

5.5.3 Inclusion Criteria

- The study includes both male and female participants aged between 18 and 41 years.
- Eligibility for participation is specifically determined for patients who have been experiencing symptoms of persistent allergic rhinitis.
- These symptoms must align with the criteria set by the Allergic Rhinitis and its Impact on Asthma (ARIA) standards, with a key requirement being that the symptoms have been present for more than one year.

5.5.4 Exclusion Criteria

- Individuals with nasal polyps or a deviated nasal septum that prevents the entry of a rubber catheter.

- Patients suffering from rhinitis medicamentosa.
- Those currently undergoing treatment with systemic corticosteroids for any disorder.
- Patients who have received immunotherapy within the past two years.
- Subjects with a history of epistaxis or cerebrospinal fluid (CSF) rhinorrhea.
- Individuals with hypertension, heart disease, renal disease, hepatic impairments, cancer, or other active medical problems.
- Pregnant women.
- Those deemed clinically unfit to perform the prescribed *yoga* interventions.

5.5.5 Ethical Approval and Consent

Ethical approval for this study was obtained from the Institutional Ethical Committee of S-VYASA, Bangalore. In adherence to ethical research standards, each participant provided written informed consent. This process involved thoroughly educating participants about the *Shuddhi Kriya Yoga* technique, including its potential advantages and disadvantages, ensuring their informed decision-making regarding participation in the study. Additionally, this study was registered with the Clinical Trials Registry of India (CTRI). The registration number for this trial is CTRI/2017/09/009900.

5.5.6 Design of the Study

This study was designed as a prospective, randomized control trial, encompassing two distinct groups. Participants were recruited from the Outpatient Department (OPD) of a Naturopathy Center in Vadodara, Gujarat, and through health camps organized in the area. Eligible subjects, meeting the selection criteria, were randomly assigned to either the intervention group, receiving the *Shuddhi Kriya-based yoga program*, or the waitlist control group. The intervention spanned a period of 8 weeks, during which the participants underwent the prescribed *yoga* program.

Assessments to gauge the effectiveness of the intervention were conducted at the beginning and the conclusion of the study period. Participants who did not receive the intervention as planned during the course of the study were classified as dropouts. The study selection process is clearly depicted in the flow diagram (Figure. 5.1), illustrating each step of participant recruitment, screening, randomization, and allocation to the respective groups for the *Shuddhi Kriya Yoga Program* for Allergic Rhinitis.

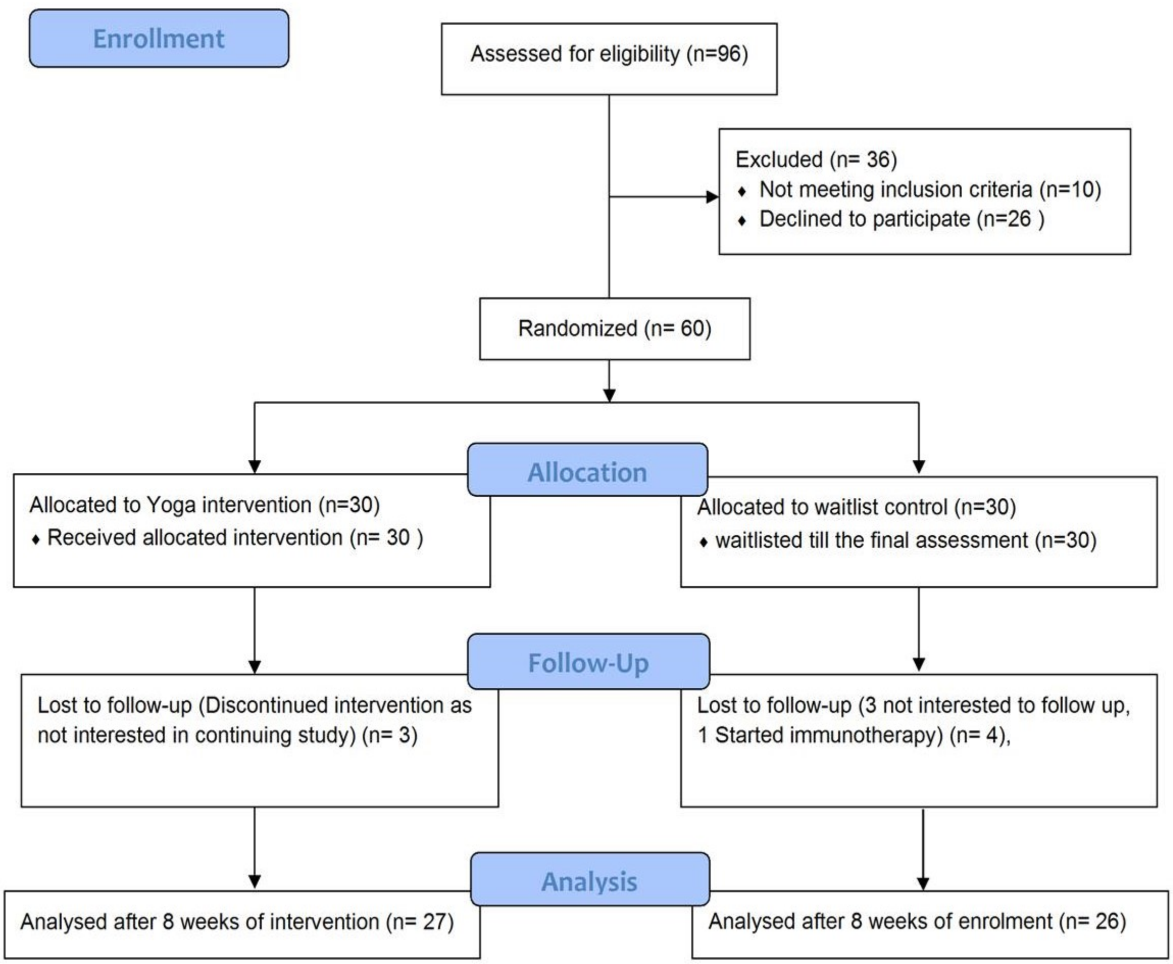

Figure 5.1: Flow diagram for study selection process

5.5.7 Randomization Process

Participants who provided their consent were randomly allocated to either the *Shuddhi Kriya Yoga* Program (SKYP) or the waitlist control group. The randomization process involved the use of opaque envelopes containing group assignments. These envelopes were opened by participants at different sites, ensuring the randomization's integrity. Prior to being randomized, participants were deemed eligible through prescreening and provided their consent, completing all baseline measures. Once randomized, participants proceeded with their respective interventions, either participating in the SKYP or being placed on the waitlist.

5.5.8 Masking and Blinding

Given the nature of the *yoga* intervention, it was not feasible to mask the participants from knowing which group they were in. To mitigate potential investigator bias, the pre and post assessments were conducted by individuals who were not involved in teaching the participants.

5.6 INTERVENTION

5.6.1 *Yoga* Training Protocol Description

The *yoga* training protocol for the study was meticulously designed and supervised by the principal investigators and a qualified *yoga* instructor. Participants in the *Yoga* group engaged in a *Shuddhi Kriya-based yoga* training regimen, which lasted for approximately 60-70 minutes per session. These sessions were conducted four times a week over a period of eight weeks. The comprehensive treatment protocol included a blend of *Yogic Shuddhi Kriyas, asanas (yoga* postures), loosening exercises, breathing exercises, and *pranayama* (yogic breathing techniques). Additionally, the protocol encompassed yogic counseling and educational lectures to enhance participants' understanding and practice of *yoga*. Participants were encouraged to perform

Shuddhi Kriyas, Asanas, and *Pranayamas* in a calm, harmonious, and steady manner, ensuring both safety and effectiveness. For a detailed description of the intervention, including specific exercises and techniques used, refer to Figure 5.2.

5.6.2 Preparation of Solutions for Shuddhi Kriyas

In the implementation of the *Shuddhi Kriyas* as part of the *yoga* intervention, a specific 2% rock salt solution was prepared. This solution was created using filtered water treated with Reverse Osmosis (RO) technology, ensuring a Total Dissolved Solids (TDS) content ranging from 100 to 125 ppm. The temperature of the solution was carefully regulated to be between 99 and 102 °F to ensure comfort and effectiveness. This saline solution was utilized for two specific Shuddhi Kriyas practices: *Vaman* (emetic therapy) and *Jal Neti* (nasal cleansing). In the practice of *Laghu Sankhprakshalana* (short intestinal cleansing), the protocol involved the use of this saline solution as well as simple drinking water. Specifically, the first four glasses provided to the participants were of the 2% saline solution, warmed to a lukewarm temperature (99-102 °F). Subsequent glasses consisted of plain drinking water at room temperature.

5.6.3 *Yogic Shuddhi Kriyas* Practices

The *Yogic Shuddhi Kriyas*, integral to the *yoga* intervention, include the following practices:

Vaman Dhauti: Conducted early in the morning on an empty stomach, this practice involves the participant drinking 4-5 glasses of saline water while in a squatting position. Then, standing up and bending forward, the participant inhales deeply and contracts the abdomen, inducing vomiting by gently rubbing the base of the tongue. This process is designed to cleanse the digestive tract.

Jal Neti: This nasal cleansing technique uses a specialized neti pot with an extended nozzle for the nose. The practitioner stands slightly leaning forward, with the neck bent laterally towards the right. The *neti* pot, held in the left hand, is positioned so its nozzle fits into the left nostril. With the mouth slightly open, breathing is done through the mouth, allowing the water to flow automatically through the right nostril. After using half the water, the *neti* pot is removed, the right nostril is closed, and the participant gently blows from the left nostril to expel the remaining water. The process is then repeated for the other nostril. This technique is aimed at clearing nasal passages and improving respiratory health.

Sutra (Rubber) Neti: In this practice, the subject stands straight and slowly inserts a soft rubber catheter (size 3 number) through the nose until it comes out of the mouth. If the subject experiences any obstruction, the procedure is paused or it may be postponed to the next day. Forceful insertion of the catheter is strictly prohibited to ensure safety.

Laghu Sankha Prakshalana: This yogic method cleanses the entire digestive tract. The practitioner is instructed to drink a total of 12-16 glasses of water to facilitate bowel evacuation. The process begins with consuming 2 glasses of lukewarm saline water, followed by performing a sequence of five *asanas*: *Tadasana, Triyaka Tadasana, Chakrasana, Triyaka Bhujangasana*, and *Uddiyana Bandha*. These *asanas* are repeated after every two glasses of water until there's an urge to evacuate. This procedure continues until clear water is expelled from the anus, ensuring a thorough cleansing of the digestive system.

Kapalbhati: This *yogic kriya* technique, known as *Kapalbhati*, involves forceful exhalations with quick inhalations, mimicking the action of a blacksmith's bellows. As described by Muktibodhananda. (2006), Kapalbhati is renowned for its effectiveness in eliminating mucus-related disorders. It should ideally be practiced on an empty stomach. To perform *Kapalbhati,* one should sit in a comfortable crossed-leg position or in any comfortable posture ensuring the back is straight and hands are resting on the knees. The practice involves contractions of the abdominal muscles paired with forceful exhalations and natural inhalations. Each cycle of exhalation and inhalation constitutes one stroke of *Kapalbhati.*

5.6.4 Deep Relaxation Technique (DRT) Protocol

The Deep Relaxation Technique (DRT), conducted in *Shavasana,* involves a systematic process of relaxing the body and mind, divided into several phases:

Phase 1 (Lower Body Relaxation): The subject starts by becoming aware of their toes, gently moving and relaxing them, and progressively relaxing each part of the lower body from the toes to the waist. During this phase, the subject chants *'A-Kara*,' feeling the vibrations in the lower body.

Phase 2 (Middle Body Relaxation): This phase involves relaxing each part of the middle body, from the waist to the neck, one by one. The subject chants *'U-Kara*,' experiencing vibrations in the middle part of the body.

Phase 3 (Upper Body Relaxation): The subject relaxes each part of the upper body, from the neck to the top of the head, individually. This is accompanied by chanting *'M-Kara'* and feeling vibrations in the upper body.

Phase 4 (Whole Body Relaxation): The subject observes and relaxes the whole body, from toes to head, while chanting *'A-U-M*' in a single breath, feeling resonance throughout the body.

Phase 5 (Body Consciousness Release): In this phase, the subject slowly transitions out of body consciousness, visualizing the body lying on the ground, completely relaxed and collapsed.

Phase 6 (Expansion of Awareness): The subject imagines a vast, beautiful sky, expanding their awareness as vast as the blue sky, becoming one with it, and enjoying the sense of infinite bliss and silence.

Phase 7 (Returning to Body Consciousness): Gradually, the subject returns to body consciousness with deep inhalation, chanting *'Om-kara'* and feeling the resonance through the body.

Phase 8 (Reawakening): The subject gently moves their entire body, feeling lightness, alertness, and energy. After bringing the legs together and placing the hands by the sides, the subject turns to the right or left side and rises when ready.

5.6.5 Quick Relaxation Technique (QRT) Protocol

The Quick Relaxation Technique (QRT) is designed as a shorter relaxation practice and is performed in a supine lying position, consisting of three phases:

Phase 1 - Abdominal Observation: The initial phase involves the participant observing the movements of the abdomen. This observation focuses on the natural rise and fall of the abdomen, promoting awareness of bodily sensations.

Phase 2 - Breathing Association: In this phase, the participant associates these abdominal movements with their breathing pattern. This association enhances the awareness of the breath and its connection to the body.

Phase 3 - Breathing with Feeling: The final phase incorporates feelings into the breathing process.

Inhaling: While inhaling, the participant is encouraged to feel the entire body getting energized and to experience a sense of lightness.

Exhaling: During exhalation, the participant is guided to let the body collapse and sink down comfortably, releasing all tensions completely.

The process involves inhaling deeply and exhaling completely, continuing this pattern for five rounds.

After completing the breathing exercises, the participant is instructed to bring their legs together, place their hands by the sides of the body, and slowly come up to a sitting position with the support of their elbows. This technique provides a quick yet effective method of relaxation.

5.6.6 *OM* Meditation Protocol

OM meditation, an integral part of the *yoga* program, is performed in a cross-legged sitting position. The process begins with breath watching, encouraging participants to relax all their muscles while keeping the spine erect. The practice involves the following steps:

Initial Relaxation: Participants start by focusing on their breath and relaxing each muscle group, which helps in achieving a state of calmness and readiness for meditation.

Chanting 'Aa', 'Uu', and 'Mm':

- The chant '*Aa*' is repeated five times, with the awareness focused on the naval area.
- The chant '*Uu*' is also repeated five times, directing awareness to the heart area.
- Following this, '*Mm*' is chanted five times, with the focus shifting to the forehead area.

Between each chant, there is a brief pause to enhance mindfulness and deepen the meditation experience.

Chanting 'AUM': After the individual chants, participants chant '*AUM*' as a whole for five times, maintaining total awareness and mindfulness throughout the process.

Silent Reflection: Post chanting, participants remain in silence for a few minutes, allowing the resonating effects of the meditation to integrate and settle within.

Concluding with a Prayer: The meditation session concludes with a prayer, marking the end of the practice and the transition back to routine activities.

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 weak	
	Laghu Sankhprakshalana	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	
Sukshmavyayam	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
	ParivrittaTrikoanasana	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-ustrasana	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**

Figure 5.2 **list of yogic practices provided as intervention**

5.7 VARIABLE STUDIED

5.7.1 Nasal Symptom Score Assessment

The Total Nasal Symptom Score (TNSS) questionnaire was employed to evaluate nasal symptoms and associated sleep difficulties both before and after the 8-week study period. Participants in the study were asked to rate the severity of their symptoms, including nasal congestion, runny nose, nasal itching, sneezing, and difficulty in sleeping. Each symptom was scored on a scale ranging from 0 to 3, with 0 indicating the absence of symptoms and 3 denoting severe symptoms significantly interfering with daily activities. The cumulative scores could range from 0, representing no symptoms, to 15, indicating maximum symptom intensity. This scoring system, as outlined by Downie et al. (2004) and Tatar, Sürenoğlu, Özdek, Saylam, & Korkmaz (2013), provided a quantitative measure of symptom severity, allowing for a systematic and standardized assessment of the nasal symptoms experienced by participants throughout the course of the study.

5.7.2 Quality of Life Assessment

The study utilized the Mini-Rhinoconjunctivitis Quality of Life Questionnaire (Mini-RQLQ) to evaluate the quality of life of participants. The Mini-RQLQ is a validated instrument comprising five domains that encompass 14 questions in total. These domains include activity limitations, practical problems, nasal symptoms, eye symptoms, and other symptoms associated with allergic rhinitis. Each question within the questionnaire was rated on a 7-point scale, ranging from 0 to 6. On this scale, a score of 0 signifies no impairment, while a score of 6 indicates severe impairment. Higher scores on the Mini-RQLQ are indicative of a poorer quality of life. This assessment, as developed by Juniper, Thompson, Ferrie, & Roberts (2000), provides a comprehensive measure of the impact of allergic rhinitis on various aspects of daily living, thus offering a nuanced understanding of the condition's effect on individuals' quality of life.

5.7.3 Peak Expiratory Flow Rate (PEFR) Assessment

The Peak Expiratory Flow Rate (PEFR) measurement was utilized to evaluate effort-dependent airflow in participants. Before commencing data collection, each participant was instructed to inhale deeply through the nose and then exhale as forcefully as possible with maximum effort. This was done while securely holding the mouthpiece with their lips to prevent any air leakage. The procedure was conducted with participants seated upright, ensuring the PEFR meter was held parallel to the ground throughout the exercise. To ensure accuracy, PEFR measurements were taken on an empty stomach, typically in the early morning. The best result from three consecutive attempts was recorded as the final measure, in line with the methodologies outlined by Dikshit, Raje, & Agrawal (2005), Leynaert, Neukirch, Demoly, & Bousquet (2000), and Ahmed, Sau, & Kar (2010). This process allowed for a reliable assessment of lung function and respiratory strength in participants, contributing to a comprehensive evaluation of the *Shuddhi Kriya Yoga* Program's impact on respiratory parameters in allergic rhinitis patients.

5.7.4 Visual Analog Scale Assessment

The Visual Analog Scale (VAS) is a simple yet effective tool for assessing the severity of allergic rhinitis (AR). According to the modified Allergic Rhinitis and its Impact on Asthma (ARIA) criteria, VAS cut-off points are set at 4 and 7 to distinguish between three severity categories: mild, moderate, and severe AR (del Cuvillo et al., 2017). In this study, the VAS was employed to evaluate both nasal and ocular symptoms separately, allowing for a comprehensive and nuanced assessment of symptom severity in participants.

5.7.5 Peak Nasal Inspiratory Flow Assessment

The Peak Nasal Inspiratory Flow (PNIF) was measured to determine the rate of nasal air flow and assess nasal obstruction. For this purpose, a PNIF meter (Clement Clark International, UK), known for its reliability and ease of use (Klossek, Lebreton, Delagranda, & Dufour, 2009), was utilized. Participants were instructed to wear a mask covering their nose and mouth, which was connected to the PNIF meter. The device measures the rate of air flow based on the negative pressure created by inhalation, with the diaphragm inside the meter moving along a scale that ranges from 30 to 370 liters per minute. These measurements were taken on an empty stomach for each participant, both before and after the eight-week intervention period. This method provided a quantitative evaluation of nasal airflow, essential for assessing the efficacy of the intervention in reducing nasal obstruction in participants with allergic rhinitis.

5.8 DATA ANALYSIS

R statistical software, version 4.0.2, was used to conduct all of the analyses (R Core Team, 2020). The initial step involved conducting descriptive statistics, supplemented by outlier and missing value analyses. We also assessed baseline matching to ensure the accuracy and reliability of the data. Normality Testing: A normality test was applied to all baseline and post-trial data to determine the distribution of variables. Parametric and Non-Parametric Tests: For variables that followed a normal distribution, an independent sample t-test was employed to ascertain the significance of differences. For data that did not adhere to a normal distribution, the non-parametric Mann-Whitney U test was utilized for analysis. Assessment of Specific Variables: Two variables, namely the Total Nasal Symptom Score (TNSS) 12-hour total and Visual Analog Scale (VAS) for nasal symptoms, did not show baseline matching between the *yoga* and control groups. Therefore, for these variables, the differences in their pre-post scores were specifically taken into consideration for assessment.

5.9 RESULTS

5.9.1 Screening and Participant Retention

The screening process initially identified 96 patients exhibiting symptoms consistent with the study criteria. From this pool, 60 volunteers were successfully recruited and divided into two groups for the study. However, during the course of the study, seven participants dropped out (four from the control group and three from the *yoga* group). Consequently, the final data set comprised information from 53 individuals, as depicted in the trial profile (Figure 5.2).

5.9.2 Baseline Demographics of Participants

At the outset of the study, the baseline demographics of the participants were as follows: the average age in the *yoga* group was 25.44 years (standard deviation [sd] 6.20), while in the control group, it was 29.42 years (sd 7.01). The mean duration of illness reported was 5.37 years (sd 3.24) for the *yoga* group and 5.05 years (sd 2.73) for the control group. Additionally, the mean Body Mass Index (BMI) was 23.19 (sd 4.35) for the *yoga* group, compared to 25.06 (sd 7.08) for the control group, as detailed in Table-5.1.

	Yoga **(n=27)**		**Control (n=26)**	
Variables	**mean**	**sd**	**mean**	**sd**
Age (in years)	25.44	6.20	29.42	7.01
Male (%)	11 (40.7)		8 (30.8)	
Female (%)	16 (59.3)		18 (69.2)	
Duration of sickness	5.37	3.24	5.05	2.73
Height	164.78	9.08	162.96	8.07
Weight	63.33	11.9	66.85	20.8
BMI	23.19	4.35	25.07	7.08
BMI- body mass index, sd- standard deviation				

Table 5.1: General physical characteristics of yoga and control groups in terms of mean and sd.

5.9.3 Total Nasal Symptom Score (TNSS) 12 Hour Morning Assessment

The implementation of the *Shuddhi Kriya-based yoga* intervention yielded a statistically significant improvement in the Total Nasal Symptom Score (TNSS) 12 hour morning rating. Specifically, there was a notable improvement in the score for nasal drainage (z = -2.67, p = 0.007) and the overall total symptom score (z = 3.16, p = 0.002) when compared with the control group. However, no statistically significant differences were observed in other symptom categories. These include nasal blockage (z = -1.43, p = 0.152), nasal itching (z = 0.23, p = 0.816), sneezing (z = -0.31, p = 0.755), and poor sleep (z = -0.65, p = 0.518), as detailed in Table 5.2.

Variable		Mean	sd	median	mad	U	Z	P-value
POST_TNSS_12h Nasal Congestion	*Yoga*(n=27)	1.22	0.801	1	1.48	424.5	-1.43	0.152
	Control(n=26)	1.5	0.583	2	0.00			
POST_TNSS_12h Runny Nose	*Yoga*(n=27)	0.963	0.706	1	0.00	488	-2.67	0.007
	Control(n=26)	1.5	0.762	1.5	0.741			
POST_TNSS_12h Nasal Itching	*Yoga*(n=27)	1.07	0.675	1	0.00	363	0.23	0.816
	Control(n=26)	1.08	0.891	1	1.48			
POST_TNSS_12h Sneezing	*Yoga*(n=27)	1.48	0.753	2	0.00	367	-0.31	0.755
	Control(n=26)	1.62	0.697	1.5	0.741			
POST_TNSS_12h Difficulty in Sleep	*Yoga*(n=27)	0.963	0.854	1	1.48	385	-0.65	0.518
	Control(n=26)	1.077	0.744	1	1.48			
Diff_TNSS_12H Total	*Yoga*(n=27)	2.741	2.94	3	2.97	527	3.16	0.002
	Control(n=26)	0.692	2.09	1	1.48			
P<0.05 shows significant improvement on the respective parameter/variable, TNSS- total nasal symptom score, mad- mean absolute deviation.								

Table 5.2 : the comparison of post intervention nasal symptom score at 12 hour morning and pre-post difference score for total 12 hour morning on different domains between yoga and control groups by using Mann Whitney U Test.

5.9.4 Total Nasal Symptom Score (TNSS) at Two Weeks

In the two-week assessment of the Total Nasal Symptom Score (TNSS), the experimental group, which underwent the *Shuddhi Kriya-based yoga* program, showed significant improvements in all domains of nasal symptoms compared to the control group. Notably, there were marked reductions in nasal congestion (z = -3.43, p = 0.001), nasal drainage (z = -3.39, p = 0.001), nasal itching (z = -3.51, p = 0.001), sneezing (z = -3.89, p = 0.001), and difficulty in sleeping (z = -2.13, p = 0.033). The overall total TNSS also significantly improved (z = -4.71, p = 0.001), as shown in Table 5.3. These results suggest the *yoga* program's efficacy in alleviating various nasal symptoms associated with allergic rhinitis after just two weeks of intervention.

Variable ***Post_TNSS_2w***		**Mean**	**sd**	**median**	**mad**	**U**	**Z**	**P-value**
Nasal Congestion	*Yoga*(n=27)	1.3	0.669	1	0.00	525.5	-3.43	0.001
	Control(n=26)	1.92	0.56	2	0.00			
Runny Nose	*Yoga*(n=27)	1.26	0.526	1	0.00	523	-3.39	0.001
	Control(n=26)	1.88	0.653	2	0			
Nasal Itching	*Yoga*(n=27)	0.852	0.77	1	0.00	532.5	-3.51	0.001
	Control(n=26)	1.615	0.697	1.5	0.741			
Sneezing	*Yoga*(n=27)	1.26	0.764	1	1.48	551	-3.89	0.001
	Control(n=26)	2.08	0.56	2	0			
Difficulty in Sleep	*Yoga*(n=27)	1	0.92	1	1.483	463.5	-2.13	0.033
	Control(n=26)	1.5	0.648	1.5	0.741			
Total	*Yoga*(n=27)	5.67	2.57	5	1.48	614	-4.71	0.001
	Control(n=26)	9	1.41	9	1.48			
P<0.05 shows significant improvement on the respective parameter/variable, TNSS- total nasal symptom score, mad- mean absolute deviation.								

Table 5.3: the comparison of post intervention nasal symptom score for past 2 weeks on different domains between yoga and control groups by using Mann Whitney U Test.

5.9.5 Quality of Life Score Improvement

The participants in the *yoga* group who underwent the *Shuddhi Kriya Yoga Program* (SKYP) experienced a significant reduction in their symptom scores, as measured by the Mini Rhinoconjunctivitis Quality of Life Questionnaire (Mini RQLQ). This improvement was observed across all five domains of the questionnaire. Specifically, there were notable reductions in the areas of activity (z = -4.89, p = 0.001), practical problems (z = -4.18, p = 0.001), and other symptoms (z = -3.21, p = 0.001). Furthermore, there were significant improvements in nose symptoms (t = -4.83, p = 0.001) and eye symptoms (t = -4.83, p = 0.001). The total score also showed considerable enhancement (t = -3.01, p = 0.004), as detailed in Tables 5.4 & 5.5. These findings indicate that the SKYP was effective in enhancing the quality of life for participants suffering from allergic rhinitis, positively impacting various aspects of their daily living.

Mini-RQLQ		Mean	sd	median	mad	U	Z	P-value
Activity	*Yoga*(n=27)	6.22	2.24	6	1.48	624.5	-4.89	0.001
	Control(n=26)	10.08	2.1	10	2.97			
Practical Problems	*Yoga*(n=27)	4.19	2.43	3	1.48	583.5	-4.18	0.001
	Control(n=26)	6.88	1.34	7	1.48			
Other Symptoms	*Yoga*(n=27)	4.37	2.68	4	2.97	530	-3.21	0.001
	Control(n=26)	6.73	1.87	6.5	2.22			

P<0.05 shows significant improvement on the respective parameter/variable
Mini-RQLQ- Mini-rhinoconjuctivitis quality of life

Table 5.4: the comparison of post intervention Mini-RQLQ on domains of Activity, Practical problems and other symptoms between yoga and control groups by using Mann Whitney U Test.

Mini-RQLQ		Mean	SD	SE	t- value	df	p- value
Nasal Symptoms	*Yoga*(n=27)	6.85	2.656	0.511	-4.83	51	0.001
	Control(n=26)	10.54	2.064	0.405			
Eye Symptoms	*Yoga*(n=27)	3.04	1.629	0.313	-4.83	51	0.001
	Control(n=26)	5.50	2.064	0.405			
Total	*Yoga*(n=27)	32.70	9.844	1.895	-3.01	51	0.004
	Control(n=26)	39.73	6.821	1.338			

P<0.05 shows significant improvement on the respective parameter/variable

Table 5.5: the comparison of post intervention Mini-RQLQ score on domains of Nasal symptoms, Eye symptoms and the sum total of all symptoms between yoga and control groups by using Independent sample t – test.

5.9.6 Visual Analog Scale Results

In the study, the Visual Analog Scale (VAS) scores for both ocular and nasal symptoms showed considerable improvement in the *yoga* group compared to the control group. Specifically, the VAS scores for ocular symptoms improved significantly (z = -4.19, p = 0.01), as did the scores for nasal symptoms (z = 4.71, p = 0.01). These results, as detailed in Table 5.6, demonstrate the effectiveness of the *yoga* intervention in reducing the severity of both ocular and nasal symptoms associated with allergic rhinitis, highlighting the beneficial impact of the *Shuddhi Kriya Yoga* Program on the subjective experience of participants.

Variable		Mean	sd	median	mad	U	Z	P-value
POST_VAS_O	*Yoga*(n=27)	1.33	1	1	1.48	578.5	-4.19	0.001
	Control(n=26)	2.65	0.892	3	1.48			
Diff_VAS_N	*Yoga*(n=27)	4.333	2.72	5	2.97	613.5	4.71	0.001
	Control(n=26)	0.346	1.2	0	1.48			

P<0.05 shows significant improvement on the respective parameter/variable, VAS- visual analog scale,

Table 5.6: the comparison of post intervention visual analogue score of ocular problems and pre-post difference score for Nasal problems between yoga and control groups by using Mann Whitney U Test.

5.9.7 PNIF and PEFR Results

In terms of respiratory function, the Peak Nasal Inspiratory Flow (PNIF) exhibited a substantial improvement in the *yoga* group compared to the control group, as indicated by the statistical analysis (z = 2.76, p = 0.006), with the detailed results presented in Table 5.7. On the other hand, the Peak Expiratory Flow Rate (PEFR) did not show a significant improvement (t = 1.95, p =

0.056), as documented in Table 5.8. This contrast in outcomes suggests that while the *yoga* intervention had a notable positive effect on nasal inspiratory flow, its impact on expiratory flow rate was less pronounced. These findings contribute to understanding the specific respiratory benefits of the *Shuddhi Kriya Yoga* Program in individuals with allergic rhinitis.

.Variable		Mean	sd	median	mad	U	Z	P-value
PNIF	*Yoga*(n=27)	88.9	19.5	90	14.8	503.5	2.76	0.006
	Control(n=26)	75.4	12.4	70	14.8			
PNIF-Peak nasal in-flow rate								

Table 5.7: The comparison of post intervention Peak nasal in-flow rate between yoga and control groups by using Mann Whitney U test.

Variable		Mean	SD	SE	t- value	df	p- value
PEFR	*Yoga*(n=27)	377.41	48.722	9.376	1.952	51	0.056
	Control(n=26)	351.15	49.179	9.645			
PEFR- peak expiratory flow rate							

Table 5.8: the comparison of post intervention Peak expiratory flow rate between yoga and control groups by using Independent sample t – test.

5.10 DISCUSSION

5.10.1 Efficacy of the *Shuddhi Kriya Yoga* Program

The primary aim of this study was to evaluate the efficacy of an eight-week *Shuddhi Kriya Yoga* Program (SKYP) in individuals with moderate to severe allergic rhinitis. The findings from the study indicated that participants in the experimental group, who underwent the SKYP, experienced significant improvements in both nasal symptom scores and overall quality of life, compared to the control group. Additionally, an improvement in the Peak Nasal Inspiratory Flow (PNIF) was observed post-intervention, highlighting the program's positive impact on nasal airway function. However, improvements in the Peak Expiratory Flow Rate (PEFR) were not statistically significant.

5.10.2 *Shat Kriyas*: Integral Practices

It is crucial to understand the role of Shat Kriyas, which are central to the practice of *Hatha Yoga.* These six cleansing techniques include *Dhauti* (upper gastrointestinal cleansing), *Basti* (colon cleansing), *Nauli* (abdominal muscle churning), *Neti* (nasal irrigation and cotton thread or rubber catheter technique), *Trataka* (yogic gazing), and *Kapalbhati* (sinus cleansing). The *yoga* protocol in this study aligns with the principles of *Hatha Yoga*, which advocate the practice of *asanas* and *pranayama* after the removal of excess phlegm and bile, using *Shat Kriyas* or *yogic* purification techniques. These techniques are well-documented in classical *Hatha Yoga* literature (Patra, 2017). The study's results underscore the potential of SKYP as an effective adjunct therapy in the treatment of allergic rhinitis, contributing to a greater understanding of integrative health approaches in managing this condition.

5.10.3 Comparative Analysis

The present study incorporates a comprehensive approach to managing allergic rhinitis, integrating *Shat Kriyas* — including *Vaman Dhauti, Jal Neti, Sutra Neti, Shankhaprakshalana, Kapalbhati, and Trataka* — along with *asana, pranayama*, and relaxation techniques. This holistic methodology contrasts with traditional pharmacological management of allergic rhinitis, which typically ranges from topical antihistamines to corticosteroids and immunotherapy (Brożek et al., 2017b; Okubo et al., 2020). In addition to pharmacological treatments, several non-pharmacological approaches like allergen avoidance (Okubo et al., 2020), nasal irrigation (Principi & Esposito, 2017), acupuncture (Choi et al., 2013), and *yoga* (Chellaa et al., 2019b) have been explored in the management of AR. Specifically, studies on the therapeutic efficacy of *Neti* have highlighted its potential in managing conditions of the upper respiratory tract, such as rhinosinusitis, allergic rhinitis, and snoring. The growing body of evidence surrounding *Jal Neti* suggests the necessity of a large, randomized control trial to confirm its therapeutic efficacy (Meera et al., 2020).

5.10.4 Clinical Trials and *Yoga*

Clinical trials on *yoga's* impact on allergic rhinitis have shown promising results. For instance, a study where AR patients practiced *Hatha Yoga* three times per week for eight weeks demonstrated significant improvements in Peak Nasal Inspiratory Flow (PNIF) and Nasal Blood Flow (NBF). These findings indicate that *yoga* not only enhances nasal blood flow but also reduces nasal congestion and inflammation, as evidenced by increased levels of Interleukin-2 (IL-2) in the experimental group compared to the control group (Chanta et al., 2019). Additionally, a three-month *Hatha Yoga* intervention in 51 AR patients resulted in a notable decrease in nasal airflow resistance and an improvement in Forced Vital Capacity (FVC), as measured by rhinomanometry and spirometry, respectively. However, no significant changes were observed in Forced Expiratory Volume in one second or percent residual standard deviation (Chellaa et al., 2019b).

5.10.5 *Shuddhi Kriya Yoga* Program

In our study, the *Shuddhi Kriya Yoga* Program (SKYP) demonstrated a significant reduction in subjective rhinitis symptoms, as evidenced by the Total Nasal Symptom Score (TNSS) at the two-week mark. Furthermore, the quality of life, assessed through the mini-Rhinoconjunctivitis Quality of Life Questionnaire (mini-RQLQ), also showed notable improvement in the experimental group compared to the control group. These outcomes align with the results of pharmacological studies where the combination of Levocetirizine or Montelukast with Mometasone Furoate was used (Tatar et al., 2013), indicating the efficacy of SKYP in parallel with established pharmacological treatments. A key finding from our study was the significant increase in the Peak Nasal Inspiratory Flow (PNIF) rate. The PNIF meter, recognized for its simplicity and reliability, is an effective tool for assessing nasal congestion. The improvement in PNIF rates suggests that SKYP may reduce inflammation of the nasal mucosa, leading to a decrease in nasal congestion. This finding corroborates with two previous Hatha *Yoga* intervention studies conducted in 2019, one utilizing a PNIF meter (Chanta et al., 2019) and the other employing rhinomanometry to measure total nasal resistance (Chellaa et al., 2019b). Both studies reported reductions in nasal blockage.

5.10.6 Role of Psychological Stress

Psychological stress is increasingly recognized as a contributing factor to the persistence of allergic rhinitis. Studies have shown that when stress is managed effectively, symptoms of allergic rhinitis improve, and the quality of life (QOL) of individuals is enhanced (El Hennawi, Ahmed, & Farid, 2016). Our study's findings align with this perspective, particularly noting the beneficial effects of various forms of *yoga* on stress reduction (Wang & Szabo, 2020), which correlate with decreased cortisol levels (Moghadasi & Najafi, 2017). Additionally, *yoga* interventions have been shown to enhance parasympathetic nerve activity and regulate stress hormone levels (Eda, Ito, & Akama, 2020). These factors reduced stress, increased parasympathetic activity, and balanced stress-related hormones are likely mechanisms contributing to the alleviation of allergic rhinitis symptoms and improvements in quality of life. This holistic approach, addressing both the physical and psychological aspects of allergic rhinitis, is crucial in managing the condition effectively. Furthermore, studies have revealed that the activation of the vagus nerve, which occurs not only in the nose but also in the cardiovascular system, plays a role in allergic rhinitis (Yokusoglu et al., 2007). The ability of *yoga*-based interventions to calm the mind and body, thereby regulating hyperactive nerves (Nagarathna, 1985), offers another potential explanation for the observed improvements in allergic rhinitis symptoms and quality of life.