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ORIGINAL ARTICLE

OPEN LABEL SINGLE CENTRIC CLINICAL EXPLORATORY OF EFFICACY STUDY ON NATUROVITA CAPSULE, AN AYURVEDIC PROPRIETARY FORMULATION

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ABSTRACT

Introduction: Respiratory disorders such as Kaasa (productive cough), Swaasa (expiratory wheezing), and Swara bheda (hoarseness of voice) significantly impact quality of life, often leading to discomfort and reduced lung function. Conventional treatments, including bronchodilators and corticosteroids, provide symptomatic relief but may have long-term side effects. Ayurvedic medicine offers a natural and holistic approach to respiratory health. The present study clinically validates Naturovita Capsule, a proprietary Ayurvedic formulation, for its efficacy in managing respiratory conditions and enhancing immunity. **Objective:** The primary objective of this Phase-II-A, single-center, open-label, therapeutic exploratory clinical trial was to evaluate the effectiveness of Naturovita Capsule in alleviating respiratory symptoms and promoting lung health. **Methods:** A total of 20 patients with respiratory ailments were enrolled following ethical clearance. Each patient received 1-2 capsules twice daily with lukewarm water for 30 days. Clinical and laboratory assessments were conducted on Day 1 (Baseline) and Day 30 (End of Trial) by qualified AYUSH doctors. Symptoms such as difficulty in breathing, shortness of breath, loss of appetite, and nausea were monitored throughout the study. **Results:** After 30 days of treatment, 75% (15 patients) exhibited very good improvement, 15% (3 patients) showed moderate improvement, and 10% (2 patients) had mild improvement. No severe adverse effects were reported, indicating Naturovita Capsule is effective and safe for respiratory health. **Conclusion:** This study confirms that Naturovita Capsule is a potent Ayurvedic intervention for respiratory disorders, significantly reducing symptoms and enhancing lung function and immunity. Further large-scale trials are recommended for broader validation.

Keywords: Respiratory disorders, Swaasa, Swara bheda, Naturovita Capsule

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INTRODUCTION

Respiratory disorders such as Kaasa (productive cough), Swaasa (expiratory wheezing), and Swara bheda (hoarseness of voice) are among the most common health concerns affecting individuals worldwide. These conditions are often caused by viral or bacterial infections, environmental pollutants, allergens, smoking, and weakened immunity[1]. Chronic respiratory conditions like asthma, chronic bronchitis, and COPD lead to difficulty in breathing, persistent cough, and reduced lung function, significantly impacting quality of life[2]. Conventional treatments, including bronchodilators, corticosteroids, and antihistamines, provide symptomatic relief but may lead to side effects such as immune suppression, dependency, and metabolic disorders[3]. As a result, there is a growing interest in natural and holistic approaches, particularly Ayurvedic medicine, for managing respiratory ailments effectively and safely[4].

Ayurvedic Perspective on Respiratory Disorders

Ayurveda, the ancient Indian system of medicine, categorizes respiratory disorders under PranavahaSrotasVikara (diseases affecting the respiratory system). According to Ayurvedic principles, Kaasa (cough) and Swaasa (breathing difficulty) occur due to an imbalance in Vata and Kapha doshas, leading to excess mucus production, airway inflammation, and bronchial congestion[5]. Ayurvedic treatment focuses on restoring this balance through herbal formulations, dietary modifications, detoxification therapies (Panchakarma), and lifestyle changes[6]. Traditional Ayurvedic remedies incorporate mucolytic, bronchodilator, and immune-boosting herbs that help alleviate symptoms and improve lung function[7].

One such formulation is Naturovita Capsule, a proprietary Ayurvedic medicine designed to support respiratory health and immunity. It contains a blend of herbs known for their anti-inflammatory, antimicrobial, expectorant, and adaptogenic properties. Key ingredients like Vasaka (Adhatoda vasica), Tulsi (Ocimum sanctum), Pippali (Piper longum), Yashtimadhu (Glycyrrhiza glabra), and Haridra (Curcuma longa) have been extensively studied for their therapeutic effects on the respiratory system[8]. These herbs work synergistically to clear mucus, reduce airway inflammation, relieve cough, and enhance immune function[9].

Scientific Basis for Ayurvedic Herbs in Respiratory Health

Scientific research has confirmed the efficacy of several Ayurvedic herbs in treating respiratory disorders. Vasaka (Adhatoda vasica), for instance, is a well-known bronchodilator and expectorant that helps clear the airways and relieve cough[10]. Studies show that vasicine alkaloids present in Vasaka improve mucociliary clearance, reduce bronchial inflammation, and suppress excessive mucus secretion[11].

Similarly, Tulsi (Ocimum sanctum) has been recognized for its anti-allergic, antimicrobial, and adaptogenic properties, making it beneficial in treating asthma, bronchitis, and respiratory infections[12]. Research suggests that Tulsi can modulate immune responses, reduce airway hyperreactivity, and inhibit pro-inflammatory cytokines, thereby preventing recurrent respiratory infections[13].

Pippali (Piper longum) is another potent Ayurvedic herb known for its expectorant and immune-enhancing properties. It contains bioactive compounds that stimulate respiratory secretions, alleviate congestion, and enhance oxygen uptake in the lungs[14]. Yashtimadhu (Licorice) has a well-documented role in soothing inflamed airways, suppressing cough reflexes, and reducing throat irritation[15]. Studies indicate that glycyrrhizin, the active compound in licorice, has antiviral and anti-

inflammatory effects, making it useful in managing viral respiratory infections[16].

Furthermore, Haridra (Turmeric, Curcuma longa) is a powerful anti-inflammatory and antioxidant agent that protects lung tissues from oxidative stress and inflammation[17]. Curcumin, the principal bioactive compound in turmeric, has been shown to reduce airway inflammation, modulate immune responses, and prevent fibrosis in chronic respiratory conditions[18].

Importance of Herbal Medicine in Respiratory Care

Given the increasing prevalence of respiratory disorders and emerging antibiotic resistance, there is a growing need for safe and effective plant-based therapeutics[19]. Ayurveda offers a holistic approach by addressing the root cause of respiratory ailments, enhancing immune defense, and improving lung function without harmful side effects[20]. Clinical trials and modern pharmacological studies have validated the efficacy of Ayurvedic formulations in managing respiratory distress, reducing inflammation, and preventing recurrent infections[21].

The present study aims to clinically validate the efficacy of Naturovita Capsule through a Phase-II-A, single-center, open-label, therapeutic exploratory clinical trial. The study focuses on assessing symptomatic relief in patients with Kaasa (cough), Swaasa (breathing difficulty), and Swara bheda (hoarseness of voice) over a 30-day treatment period. Patients were evaluated based on respiratory function, symptom relief, and immune enhancement through clinical and laboratory assessments[22].

Respiratory ailments significantly impact quality of life, necessitating safe and effective treatment alternatives. Naturovita Capsule harnesses the power of Ayurvedic herbs to provide symptomatic relief, reduce inflammation, and improve lung function naturally. This clinical validation study will help establish scientific evidence supporting the use of Ayurvedic medicine in respiratory health and promote its integration into modern therapeutic practices[23].

METHOD AND MATERIALS

Description of the population to be studied

The population of Salem city is more than 10,00,000, and the estimated prevalence rates of patients with “Kaasa (Productive cough), Swaasa (Expiratory Wheezing), Swara bheda(Hoarseness of voice), with symptoms like Difficulty in breathing, Shortness of breath, Loss of appetite, Nausea,” etc. shall be more than 30 % in the area. To recruit the participants, we had advertised in the Social media (friend's groups, Local groups, Private Siddha/Ayurveda doctor groups, and on the Facebook pages of Siddha/Ayurveda hospitals and creating awareness inpublic exhibitions.

Responsibility of potential risks and benefits, if any, to human subjects.

As per Siddha/Ayurveda textual references found in First schedule (section 3a) of Drugs and cosmetic act 1940, and scientific research studies done anywhere regarding the herbal ingredients found in the formula supplied by the manufacturing unit, an Undertaking has been obtained from the Manufacturer of the product that the Sample supplied for clinical trials contains only the herbal ingredients mentioned in the references found in first schedule Siddha/Ayurveda classical texts.

The Clinical research center has recruited the patients willing for the study after obtaining their written consent and provided the medicine in the prescribed dosage indicated in

the package under the supervision of qualified Siddha/Ayurveda physician.

It has been clarified to the manufacturer that any Metals if included in the formula shouldconduct Toxicity studies and Pre-clinical animal studies before conducting clinical trials, and it was also clarified that the Manufacturer of the product is solely responsible for potential risk - if any, to human subjects undergoing this clinical study.

Quality control and quality assurance

The Manufacturing Unit of the drug is responsible for the hygienic packaging of the dose of the herbal product to be dispensed to the participant. The label should necessarily contain the word “For Clinical studies only”.

Description of and justification for, the route of administration, dosage, dosage regimen, and treatment period.

Route of Administration Dosage - Oral usage

Dosage - 1-2 capsules bds with 100 ml lukewarm water.

Dosage regimen - Morning and night, after food.

Treatment period - 30 days.

Trial study center

The centre of study is, Outpatient department. CRO - Ashram Siddha research institute, Swarnapuri, Salem city, Salem district.

IEC clearance

The prospective Phase-II-A, Single center, Open label, Therapeutic exploratory clinical trials is duly approved by the INSTITUTIONAL ETHICAL COMMITTEE FOR CLINICAL RESEARCH OF THECRO, Ashram Siddha Research Institute, constituted under Rule-7 and registered under Rule-8 of The Central Drugs Standard Control Organization (CDSCO) under Directorate General of Health Services, Ministry of Health and Family welfare, Govt. of India as per Ethical guidelines for Biomedical Research on Human subjects 2006 issued by AYUSH-ICMR guidelines. All patients were obtained with written informed consent.

Sample size and Period of study

Enrollment: 20 patients

Study Start Date: 29.11.2024

Study Completion Date: 31.12.2024

Screening of Patients for study: In the present study, patients suffering from symptoms like “Kaasa (Productive cough, Swaasa (Expiratory wheezing), Swara bheda (Hoarseness of voice), with symptoms like Difficulty in breathing, Shortness of breath, Loss of appetite, Nausea,” etc. was taken for study. The Inclusion and exclusion were made by recording their past history and through clinical examination. After recruitment, all follow-up visits were performed at the same hospital by qualified Siddha/Ayurveda graduate investigators in keeping with the protocol.

Obtaining patient consent: Whenever a patient is included in the study a consent form in his mother tongue (enclosed) detailing the procedures with side effects if any, benefits from the treatment, was explained and details of the follow up visit was also explained. The

procedure for referral clause, withdrawal, and adverse effects was explained thoroughly.

Criteria for Inclusion: Patients above 20 years and below 60 years, suffering from clinical symptoms "Kaasa (Productive cough), Swaasa (Expiratory Wheezing), Swara bheda (Hoarseness of voice), with symptoms like Difficulty in breathing, Shortness of breath, Loss of appetite, Nausea," etc. was taken for study.

Criteria for Exclusion: Participants will be excluded if they are above 65 years, experiencing or have a history of the following: Osteo arthritis, history of drug/alcohol abuse, night/shift-work employment, Diabetic complications, Psoriatic arthritis and any endocrine disorders.

Criteria for withdrawal: During the course of the trial, if any serious conditions develop (or) the symptoms aggravate which requires urgent treatment, such subjects may be withdrawn from the trial.

Outcome measure: Routine Examination and assessment as per Indian Medicine Physiology

The complete History and physical examination of the patients along with Envagaithaervu, tridoshanaadi, saptha dhatu thaervu etc. were recorded in a case sheet on first day. The second Clinical assessment were done on 30th day of treatment.

Blood test: Blood samples were obtained the same day when each session was initiated. Participants reported to the hospital between 09:00 am and 10:00 am, after overnight fasting, for blood withdrawal from the antecubital vein. Samples were analy2ed using routine automatic techniques in the prescribed laboratory. All follow-up visits scheduled for this trial were performed at the referral hospital by the registered investigators.

Intervention: The patients were provided with Proprietary Ayurvedic Medicine- NATUROVITA CAPSULE and advised to take 1-2 capsules, Morning and evening.

As Lifestyle management with diet and exercise can improve the condition and patient self- management life style changes were advised.

Success indicators: Reduction of minimum 10 percent in symptoms at baseline and at the completion of treatment in the words of the patient, and measured as per the physician's conscience, can be taken as Success indicator.

Laboratory Investigations and discussion:

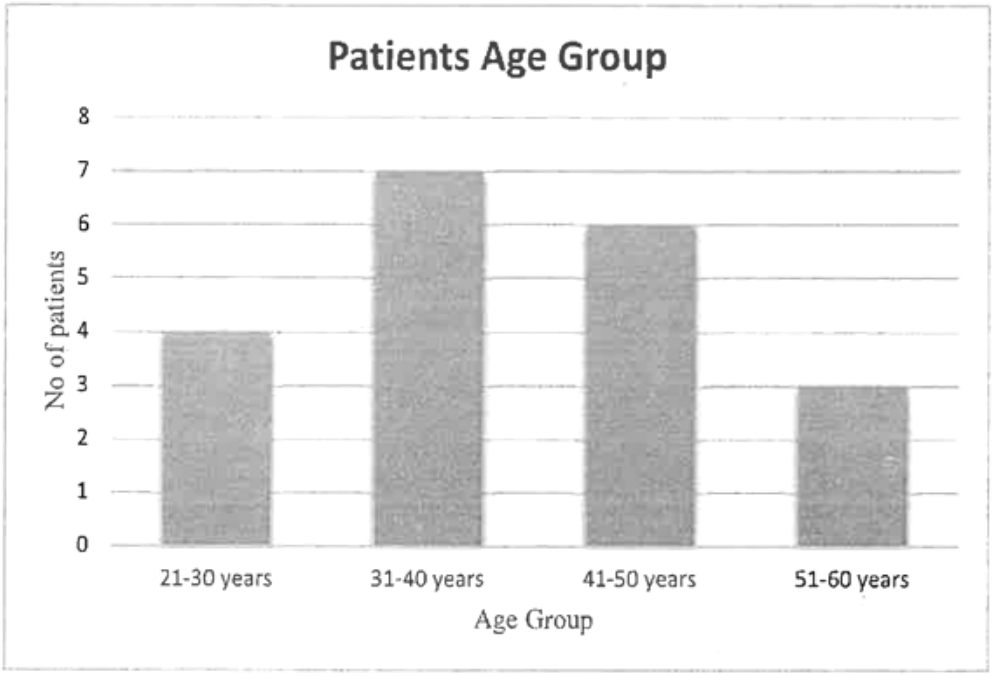
Blood samples were obtained the same day when each session was initiated. Participants reported to the hospital between 09:00 am and 10:00 am, after overnight fasting, for blood withdrawal from the antecubital vein. Samples were analyzed using routine automatic techniques in the prescribed laboratory. All follow-up visits scheduled for this trial were performed at the referral hospital by the registered investigators reported to the hospital between 09:00 am and 10:00 am, after overnight fasting, for blood withdrawal from the antecubital vein. Samples were analyzed using routine automatic techniques in the prescribed laboratory. All follow-up visits scheduled for this trial were performed at the referral hospital by the registered investigators

SPECIMEN	TEST NAME	METHOD	VALUE	UNITS	REF.RANGE
CLINICAL CHEMISTRY					
Serum/Plasma	Glucose(Fasting)	GOD-POD		mg/dl	70-110
Serum/Plasma	Glucose(PP)	GOD-POD		mg/dl	100-140
Serum/Plasma	Creatinine	Kinetic		mg/dl	0.6-1.4
Blood	Differential count(DC)	VESMATIC			
	Neutrophils			%	40-80
	Lymphocytes			%	20-40
	Eosinophils			%	01-06
	ESR			mm/hr	0-10
Serum	HbA1c	Sysmex XS 8 i		%	Normal ;Below 6.0 Prediabetic ;6.0-6.4 Diabetic ;6.5 and above
CLINICAL PATHOLOGY					
URINE COMPLETE	Glucose	Comber(Roche)			
	Protein				
	Ketone				

Discussion, Statistical Analysis & Interpretation of the Results Obtained

TABLE -A; Age group of Patients (20)

Age group	Total	%
21–30	8	40%
31–40	6	30%
41 - 50	5	25%
51 - 60	1	5%

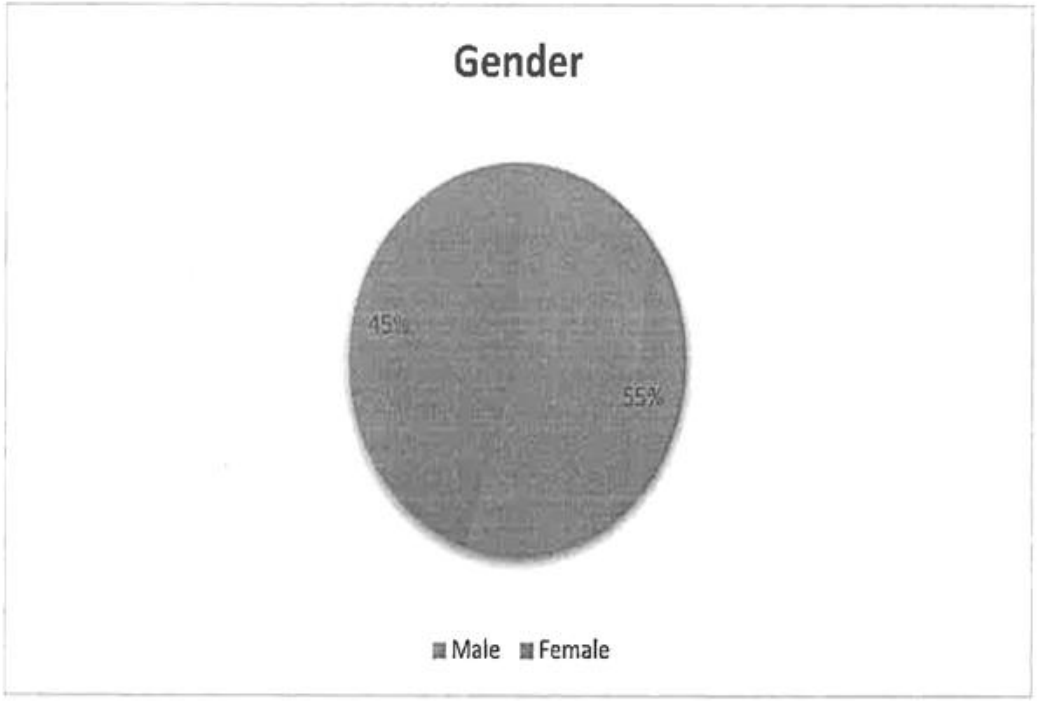


Interpretation

From the above chart, the sample size of the study is 20, out of which 8 patients belong to age group 21-30 years, 6 patients belong to age group 31-40 years, 5 patients belong to age group 41-50 years and 1 patient belong to age group 51-60 years.

TABLE – B ; Gender of the Patients (20)

Sex	Total	%
Male	12	55%
Female	8	45%



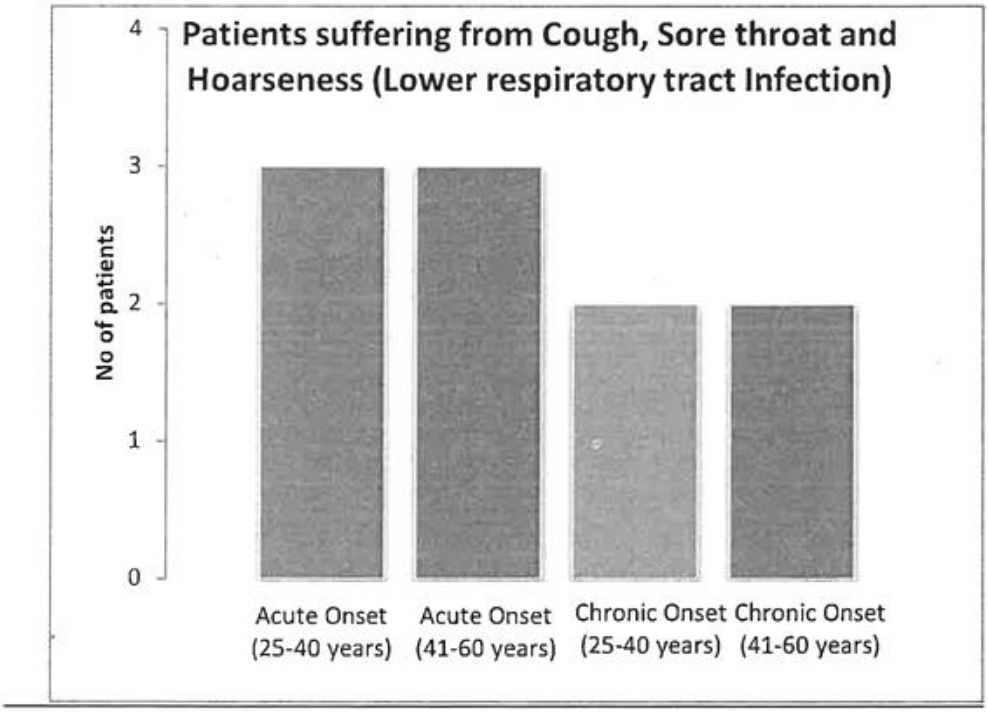
Interpretation

From the above chart, the sample size of the study is 20, out of which, there are about 55% male and 45% female patients

Table-C, Patients suffering from Cough, Sore throat and Hoarseness (20)

(Lower respiratory tract Infection)

Onset	Age group	Total
Acute onset (within 1 week)	25-40 years	7
	41-60 years	4
Chronic onset (more than 1 week)	25-40 years	7
	41-60 years	2

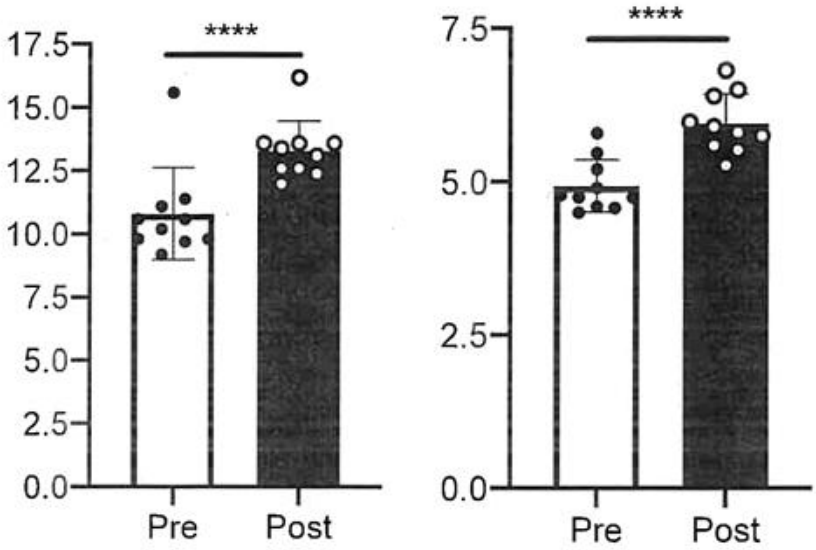


Interpretation

In Group-1, 7 patients belonging to age group 25-40 years and 4 patients belonging to age group 41-60 years respectively who had been taken for study had the LRTI symptoms of Cough, Sore throat and Hoarseness within one week and more than one week.

IMPROVEMENT IN LABORATORY FINDINGS

PRE TREATMENT-POST TREATMENT PLOTTING DOCUMENTATION FOR STATISTICAL ANALYSIS



IMPROVEMENT IN LABORATORY FINDINGS

PRE TREATMENT-POST TREATMENT PLOTTING DOCUMENTATION FOR STATISTICAL ANALYSIS

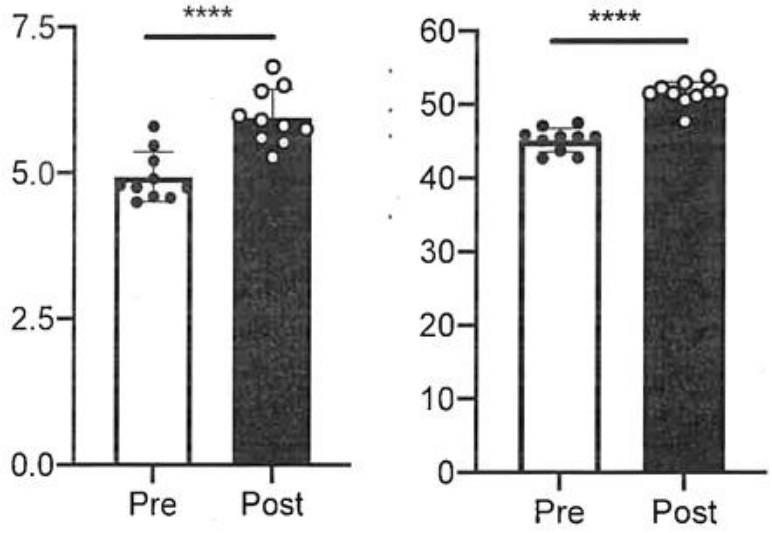
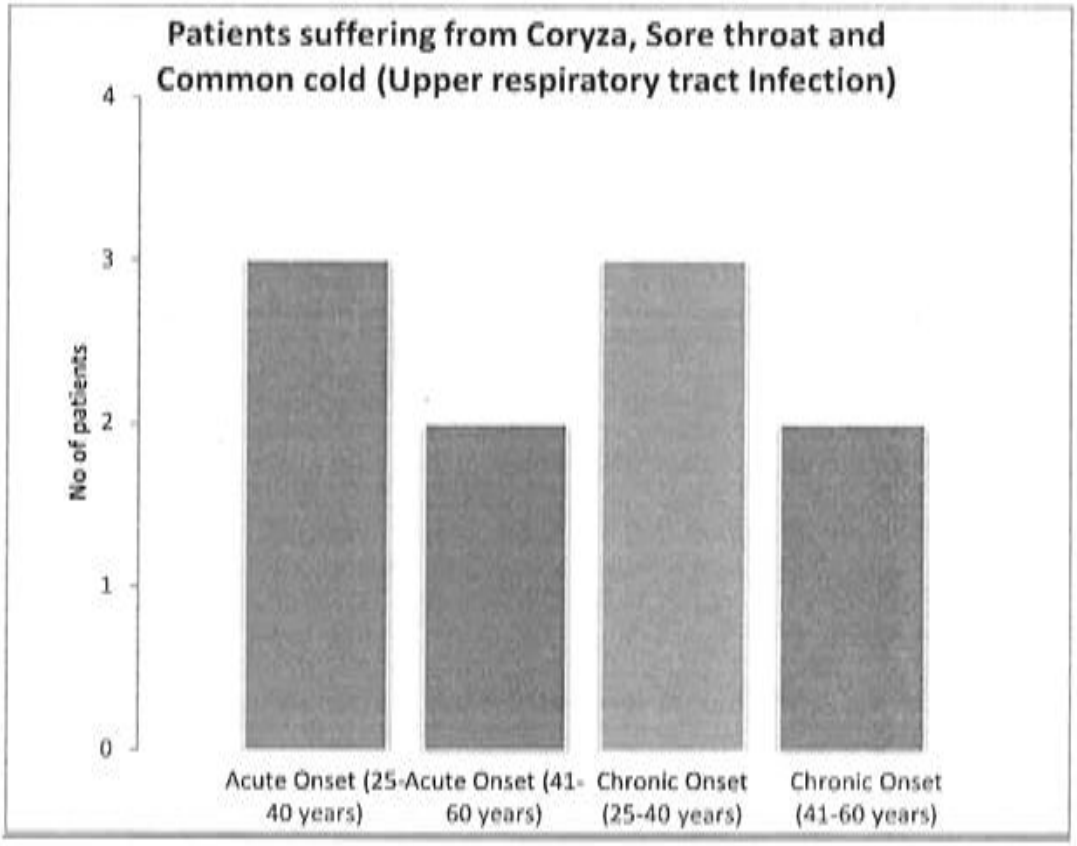


TABLE – D; Patients suffering from Coryza, Sore throat and Common cold (20)

(Upper respiratory tract Infection)

Onset	Age group	Total
Acute onset (within 1 week)	25-40 years	6
	41-60 years	5
Chronic onset (more than 1 week)	25-40 years	7
	41-60 years	2

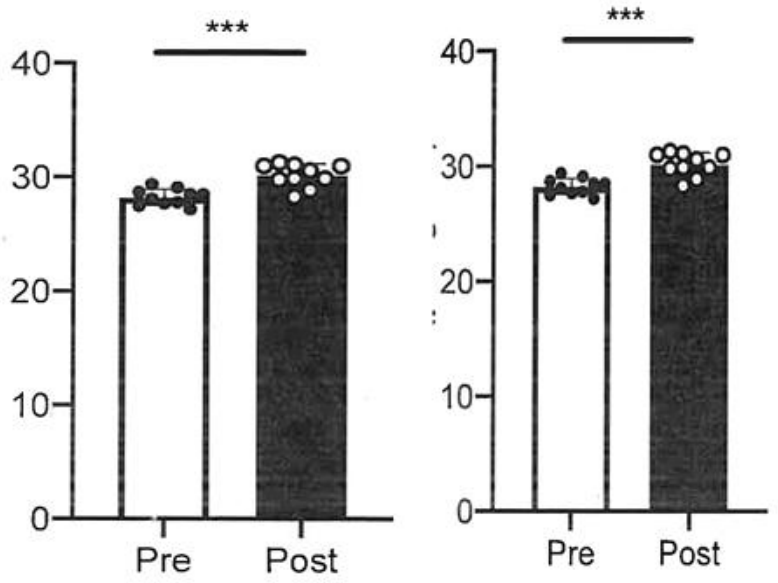


Interpretation

In Group-2, 6 patients belonging to age group 25-40 years and 5 patients belonging to age group 41-60 years respectively who had been taken for study had the URTI symptoms of Coryza, Sore throat and Common cold within one week and more than one week.

IMPROVEMENT IN LABORATORY FINDINGS

PRE TREATMENT-POST TREATMENT PLOTTING DOCUMENTATION FOR STATISTICAL ANALYSIS



IMPROVEMENT IN LABORATORY FINDINGS

PRE TREATMENT-POST TREATMENT PLOTTING DOCUMENTATION FOR STATISTICAL ANALYSIS

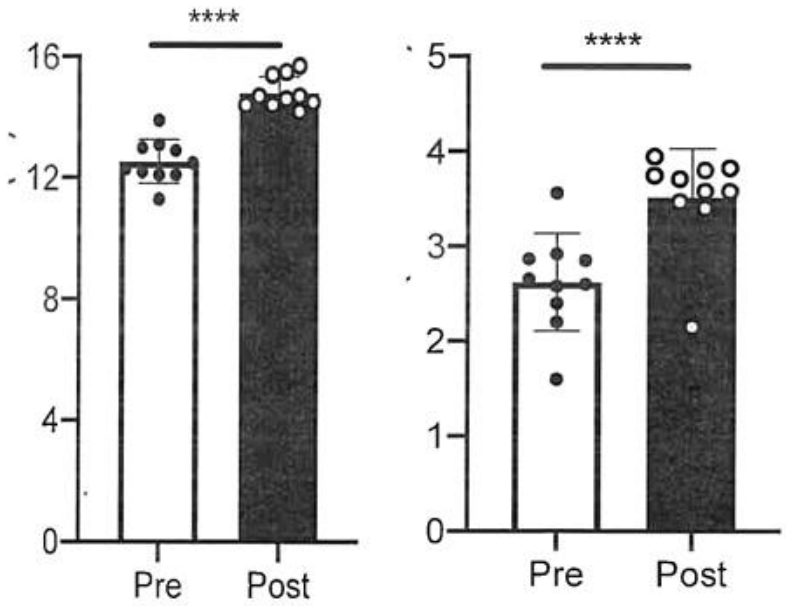
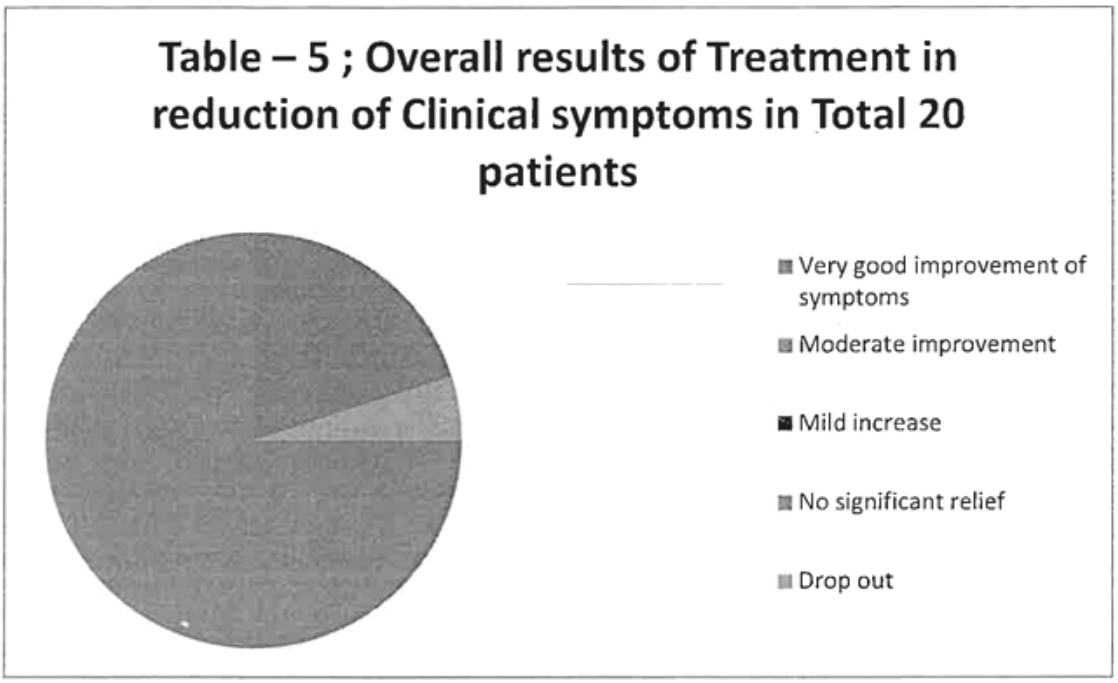


Table – 6; Overall results of Treatment in reduction of Clinical symptoms in patients treated (Total 20 patients)

Results	No. of patients	Percentage
Very good improvement (all 4 symptoms)	15	75 %
Moderate improvement (2-3 symptoms)	03	15 %
Mild improvement (less than 2 symptoms)	02	10%
No significant relief	0	0 %
Drop out	0	0 %



Interpretation

After the treatment of 30 days, 15 patients (75%) had very good improvement of symptoms, 3 patients (15%) had moderate improvement, 2 patients (10%) had mild improvement from the study.

Direct access to source data/documents: We hereby agree that the investigator(s)/ institution will permit trial-related monitoring, audits, institutional review board/independent ethics committee review, and regulatory inspection(s), by the Research Council/ Department of AYUSH providing direct access to source data/documents.

Quality control and quality assurance: The Manufacturing Unit of the drug is responsible for the hygienic packaging of the dose of the herbal product to be dispensed to the participant. The label should necessarily contain the word "For Clinical studies only".

Compensation to the Participant: As per GCP guidelines the subjects were compensated for the inconvenience and time present in connection with their participation in this clinical trial by signing a Voucher after payment of compensation.

Participant protections and ethics: To protect human participants, the protocol was written according to general ethical guidelines, such as the Declaration of Helsinki and Good Clinical Practice and was approved by the institutional ethical committee of the organization. The study participant consent process includes information about potential risks, benefits, alternatives, and responsibilities during the trial.

Before participants agree to participate in this trial, researchers will explain this information in detail in person.

Data and safety monitoring: Regular monitoring that will be clarified in a standard operating procedure will be conducted to ensure good data quality. Monitors from IEC will evaluate whether the case report forms are properly written and whether the recruiting and treatment procedures are adequately performed according to the protocol. Investigators will be contacted to discuss whether it is necessary to revise the study protocol or inclusion criteria and other important issues. The investigators and independent researchers will assess the progress of the clinical trial and severe adverse events and determine whether they are acceptable and whether it will be necessary for the trial to be modified or stopped.

Case Sheets prepared for each patient and all the records and vouchers will be retained with the treatment centre for Three years.

CONCLUSION

Phase-II-A, Single center, Open label, Therapeutic exploratory clinical trials; The current Phase-II-A, Single center, Open label, Therapeutic exploratory clinical trials is designed to evaluate the efficacy of Proprietary Ayurvedic Medicine– NATUROVITACAPSULE, Manufactured by VIJAYANI NUTRACEUTICALS PVT LTD, No.2B/1,2B/2, 6th street, 3rd Main road, Ambattur Industrial estate South, Ambattur, Chennai-600058. Tamil Nadu on patients suffering from clinical symptoms of "Kaasa (Productive cough, Swaasa (Expiratory Wheezing), Swara bheda (Hoarseness of voice), with symptoms like Difficulty in breathing, Shortness of breath, Loss of appetite, Nausea," etc.

By consolidating the results obtained in the clinical investigations and laboratory investigations, it is hereby concluded that the Proprietary Ayurvedic Medicine- NATUROVITA CAPSULE is highly effective in controlling Clinical symptoms of "Kaasa (Productive cough), Swaasa (Expiratory Wheezing, Swara bheda (Hoarseness of voice, with symptoms like Difficulty in breathing, Shortness of breath, Loss of appetite, Nausea," etc It also contributed Enhanced Immunity and promoted Lung health at baseline and at the completion of treatment, in the recruited patients.

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