International
Journal of Medical and Exercise Science
(Multidisciplinary, Peer Reviewed and Indexed Journal)

ORIGINAL ARTICLE

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

Search engine:
www.ijmaes.org

S. Suman[1], P. Karthikeyan[2], S. Moulishankar[3], S. Sridhar [4], G. Raaja[5]*, G.S. Aathithiah[6],M. Vetriselvan[7], Joemon[8], R. Pachiyappan[9], B. Devendran[10]

Authors:

[1]Managing Director, Vijayani Nutraceuticals Pvt Ltd, [2]Director, Vijayani Nutraceuticals Pvt Ltd, [3]Director, Vijayani Nutraceuticals Pvt Lt, [4]Principal Research Investigator, Ashram Siddha Research Institute, [5]Medical Officer, Vijayani Nutraceuticals Pvt Ltd, [6]Medical Officer, Vijayani Nutraceuticals Pvt Ltd, [7]General Manager, Vijayani Nutraceuticals Pvt Ltd, [8]Manufacturing Incharge, Vijayani Nutraceuticals Pvt Ltd, [9]Product Development, Oriens Global Marketing Pvt Ltd, [10]Pharmacologist, Vijayani Nutraceuticals Pvt Ltd.

Corresponding Author:

*Dr. G. Raaja, Medical Officer, Vijayani Nutraceuticals Pvt. Ltd., Chennai, Tamil Nadu, India.

Email ID: raaja.ayurdoctor@gmail.com

ABSTRACT

Introduction: Antioxidant, anti-inflammatory, and immunomodulatory properties. It has been traditionally used in Ayurveda for detoxification, blood purification, and enhancing energy levels. Chronic conditions such as Kasa (chronic cough), Swasa (asthma), Dhathukshaya (muscle wasting), Dourbalya (general weakness), cachexia, and fatigue result from oxidative stress, inflammation, and immune dysfunction. Conventional treatments for these disorders often include steroids, bronchodilators, and synthetic supplements, which may cause long-term side effects. This study clinically validates Wheat Grass Capsule, a proprietary Ayurvedic formulation, for its efficacy in improving respiratory health, boosting immunity, and enhancing overall well-being. The primary objective of this Phase-II-A, single-center, open-label, therapeutic exploratory clinical trial was to evaluate the safety and efficacy of Wheat Grass Capsule in managing chronic cough, asthma, muscle weakness, and immune dysfunction. **Methods:** A total of 20 patients with respiratory and oxidative stress-related symptoms were enrolled following ethical clearance. Patients were administered 1-2 capsules twice daily with lukewarm water for 30 days. Clinical investigations and laboratory assessments were conducted on Day 1 (Baseline) and Day 30 (End of Trial) by qualified AYUSH practitioners. Parameters such as respiratory function, muscle strength, hemoglobin levels, inflammatory markers, and overall vitality were monitored. **Results:** After 30 days of treatment, 70% (14 patients) showed very good improvement, 15% (3 patients) had moderate improvement, 10% (2 patients) had mild improvement, and 5% (1 patient) dropped out. The formulation significantly enhanced respiratory function, improved stamina, and boosted immune response. **Conclusion:** The study confirms that Wheat Grass Capsule is an effective Ayurvedic intervention for respiratory health, muscle regeneration, and immune support. The formulation demonstrated significant improvements in energy levels, respiratory function, and overall well-being, making it a promising natural therapeutic alternative. Further large-scale trials are recommended for broader validation.

Keywords: Wheatgrass, Antioxidant, Anti-inflammatory, Immunomodulatory, Detoxification

Received on 29th January 2025; Revised on 18th February 2025; Accepted on 28th February 2025
DOI:10.36678/IJMAES.2025.V11I01.010

INTRODUCTION

Wheatgrass (Triticum aestivum) is a nutrient-dense superfood known for its antioxidant, anti-inflammatory, and immune-boosting properties. It has been traditionally used in Ayurveda and natural medicine for detoxification, blood purification, and enhancing energy levels[1]. Rich in chlorophyll, vitamins, minerals, amino acids, and enzymes, wheatgrass is a potent natural remedy for various health conditions, particularly those associated with oxidative stress, inflammation, and immune dysfunction[2].

Chronic health conditions such as Kasa (chronic cough), Swasa (asthma), Dhathukshaya (muscle wasting), Dourbalya (general weakness), and cachexia are often caused by environmental pollutants, nutrient deficiencies, metabolic imbalances, and immune suppression[3]. These conditions can lead to fatigue, respiratory distress, weight loss, and reduced physical endurance, ultimately affecting the quality of life[4]. Conventional treatments involve steroids, bronchodilators, synthetic antioxidants, and nutritional supplements, but these may cause long-term side effects such as dependency, hormonal imbalances, and metabolic dysfunction[5]. **Ayurvedic medicine offers a holistic and natural approach to managing these conditions, focusing on rejuvenation (Rasayana therapy), detoxification (Shodhana), and immune enhancement (Ojas promotion)**[6].

Ayurvedic Perspective on Wheatgrass

In Ayurveda, wheatgrass is classified as a Rasayana (rejuvenative) herb, supporting cellular regeneration, detoxification, and immune modulation[7]. According to Ayurvedic principles, disorders like chronic cough, respiratory weakness, and fatigue result from an imbalance in Vata and Pitta doshas, leading to dryness, inflammation, and depletion of body tissues[8]. Wheatgrass, with its cooling and nourishing properties, helps restore balance, promote tissue regeneration, and strengthen lung function[9].

Wheatgrass is known to enhance hemoglobin levels, improve digestion (Agni), and stimulate the body's natural detox pathways[10]. It contains high amounts of chlorophyll, which is structurally similar to hemoglobin and helps in blood purification, oxygen transport, and red blood cell production[11]. Additionally, wheatgrass is a rich source of glutathione, superoxide dismutase (SOD), and catalase-natural antioxidants that protect cells from oxidative stress and inflammation[12].

Scientific Evidence Supporting Wheatgrass in Health and Immunity

Modern scientific studies have confirmed the therapeutic benefits of wheatgrass in reducing oxidative stress, enhancing immune function, and improving respiratory health.

- Antioxidant and Anti-inflammatory Effects: Wheatgrass is rich in flavonoids, phenolic compounds, and chlorophyll, which help in reducing inflammation and neutralizing free radicals[13]. Studies suggest that wheatgrass supplementation lowers inflammatory markers such as TNF-α and IL-6, which play a key role in chronic diseases[14].
- Respiratory Health and Oxygenation: Wheatgrass helps in improving lung function, reducing airway inflammation, and enhancing oxygen uptake, making it beneficial for individuals with asthma,

bronchitis, and chronic respiratory disorders[15].

- Blood Purification and Detoxification: Chlorophyll in wheatgrass has been shown to support liver function, aid in heavy metal detoxification, and promote hemoglobin synthesis, making it effective in treating anemia, fatigue, and weakness[16].
- Immune Modulation and Microbiome Support: Research indicates that wheatgrass enhances white blood cell activity, strengthens gut microbiota, and supports immune defense against infections[17].

The Need for Clinical Validation of Wheat Grass Capsule

Although wheatgrass has been widely used in traditional medicine, scientific validation through clinical trials is essential to establish its efficacy and safety in managing chronic diseases, improving vitality, and enhancing immune function. The present study, a Phase-II-A, single-center, open-label, therapeutic exploratory clinical trial, was designed to evaluate the effectiveness of Wheat Grass Capsule in reducing inflammation, improving respiratory function, and boosting overall well-being[18].

The trial recruited 20 patients suffering from chronic cough, asthma, general weakness, and cachexia. Participants were administered 1-2 capsules of Wheat Grass Capsule twice daily with lukewarm water for 30 days. Clinical and laboratory assessments were conducted on Day 1 (Baseline) and Day 30 (End of Trial), measuring parameters such as respiratory function, hemoglobin levels, inflammatory markers, muscle strength, and overall immunity[19].

With the increasing prevalence of chronic respiratory disorders, fatigue, and immune dysfunction, there is a need for safe, natural, and effective therapeutic alternatives. Wheat Grass Capsule, formulated with scientifically validated Ayurvedic principles, provides a promising solution for enhancing oxygenation, reducing inflammation, and boosting immune function. This clinical validation study aims to provide scientific evidence supporting the efficacy of Wheat Grass Capsule, contributing to the integration of Ayurvedic medicine into modern preventive healthcare[20].

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 “Kasa (Chronic cough), Swasa (Asthma), loss of appetite, marked weight loss, dhathukshaya (muscle wasting), Dourbalya (General weakness), body pain and fatigue” etc. found in Cachexia, who require enhancing their Immune function with herbal Anti inflammatory treatment, 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 in public 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 should conduct 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 THE CRO, 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 “Kasa (Chronic cough), Swasa (Asthma), loss of appetite, marked weight loss, dhathukshaya (muscle wasting), Dourbalya (General weakness), body pain and fatigue” etc. found in Cachexia, 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 like "Kasa (Chronic cough), Swasa (Asthma), loss of appetite, marked weight loss, dhathukshaya (muscle wasting), Dourbalya (General weakness), body pain and fatigue" etc. found in Cachexia, 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 Envagai thaervu, tridosha naadi, saptha dhatu thaervu etc. were recorded in a case sheet on first day. The second Clinical assessment was done on 30th day of treatment.

Blood test:

Blood samples were obtained the same day while 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.

Intervention:

The patients were provided with Proprietary Ayurvedic Medicine — WHEAT GRASS 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:

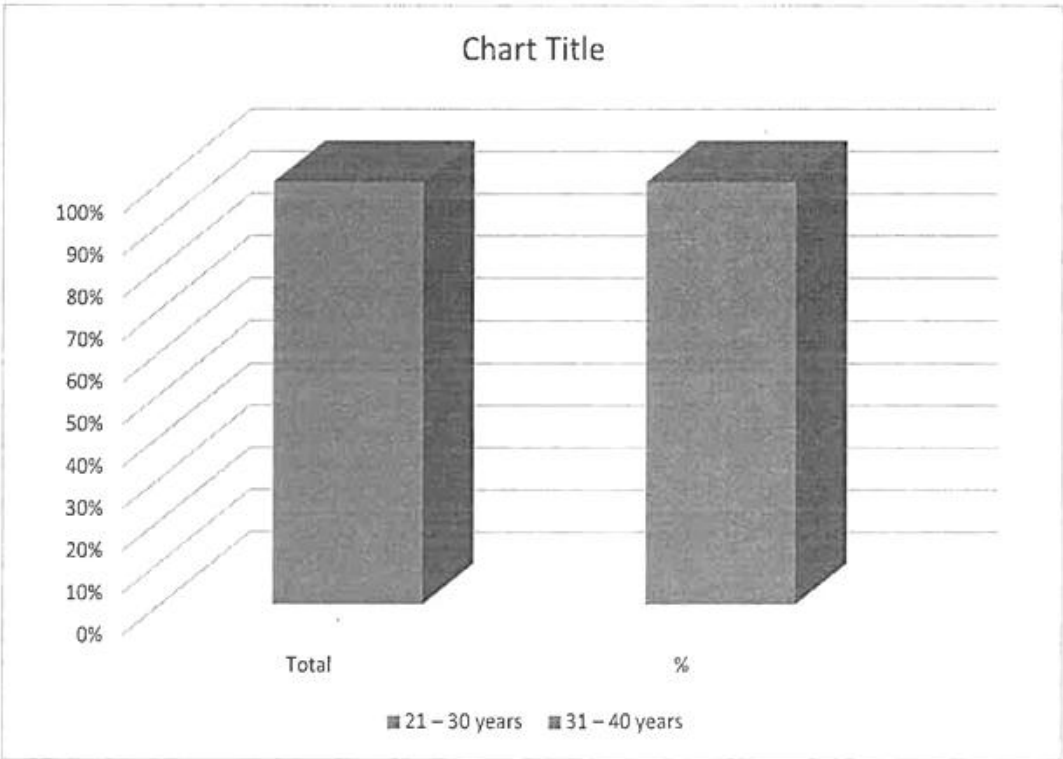
Blood samples were obtained the same day when each session was initiated. Participants reported to the hospital between 09:00 am and 10:00 am, after overnight fasting, for blood withdrawal from the antecubital vein. Samples were analyzed using routine automatic techniques in the prescribed laboratory.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

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 and Statistical analysis of the Results Obtained

TABLE -1.1 ; Age group of Patients (20)

Age group	Total	%
21–30 years	11	55%
31–40 years	09	45%

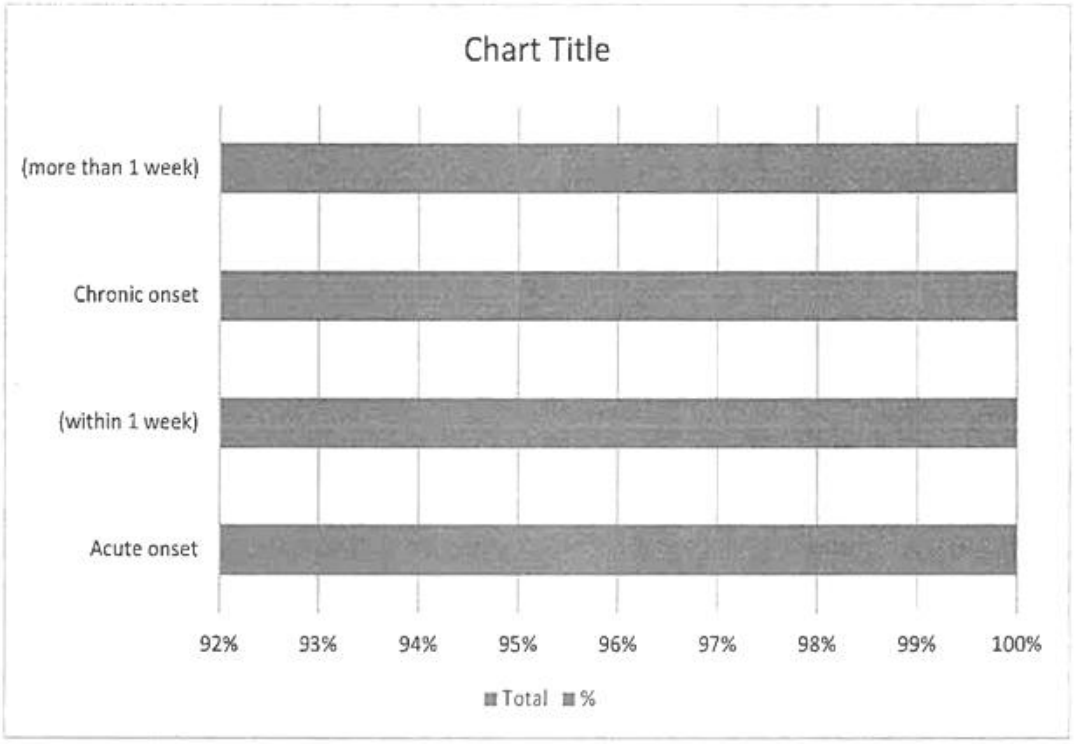


Interpretation

For the treatment of 30 days, 11 patients belonging to age group 21-30 years and 9 patients belonging to age group 31-40 years respectively were taken for study.

TABLE – 1.2; Chronicity of the Disease (20)

Onset		Total	%
Acute onset (within 3 months)	21-30 years	3	12%
	31-40 years	4	20%
Chronic onset (more than 3 months)	21-30 years	8	44%
	31-40 years	5	24%

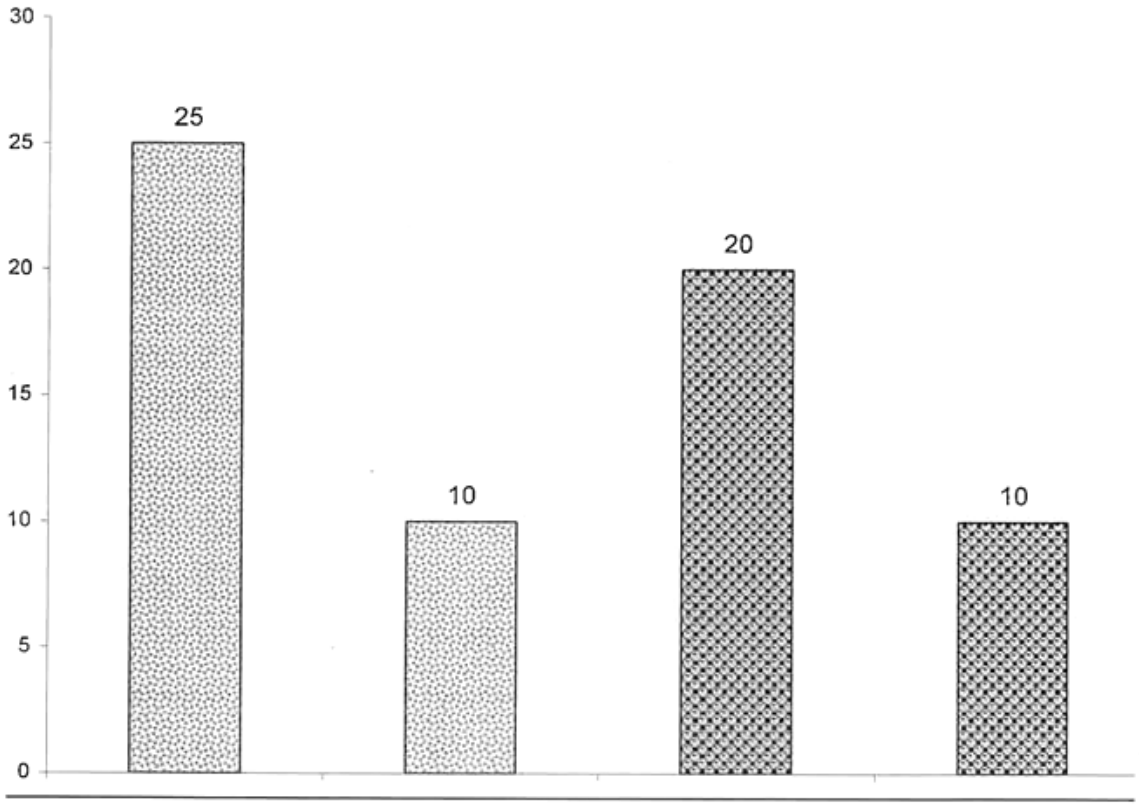


Interpretation

In total, 7 patients belonging to age group 21-30 years and 13 patients belonging to age group 31-40 years respectively who had been taken for study had the symptoms from within 3 months and more than 3 months.

TABLE – 1.3; Improvement of *Kasa (Chronic cough), Swasa (Asthma)* in One month (20)

Age group	Improvement in Criteria Before tmt,	After tmt.	% of Improvement
21–30 years	6	5	60 %
31–40 years	5	4	50 %



Interpretation

After the treatment of 30 days, 60% belonging to age group 21-30 years and 50% belonging to age group 31-40 years respectively had significant improvement of *symptoms*.

IMPROVEMENT IN LABORATORY FINDINGS – PRE TREATMENT-POST TREATMENT

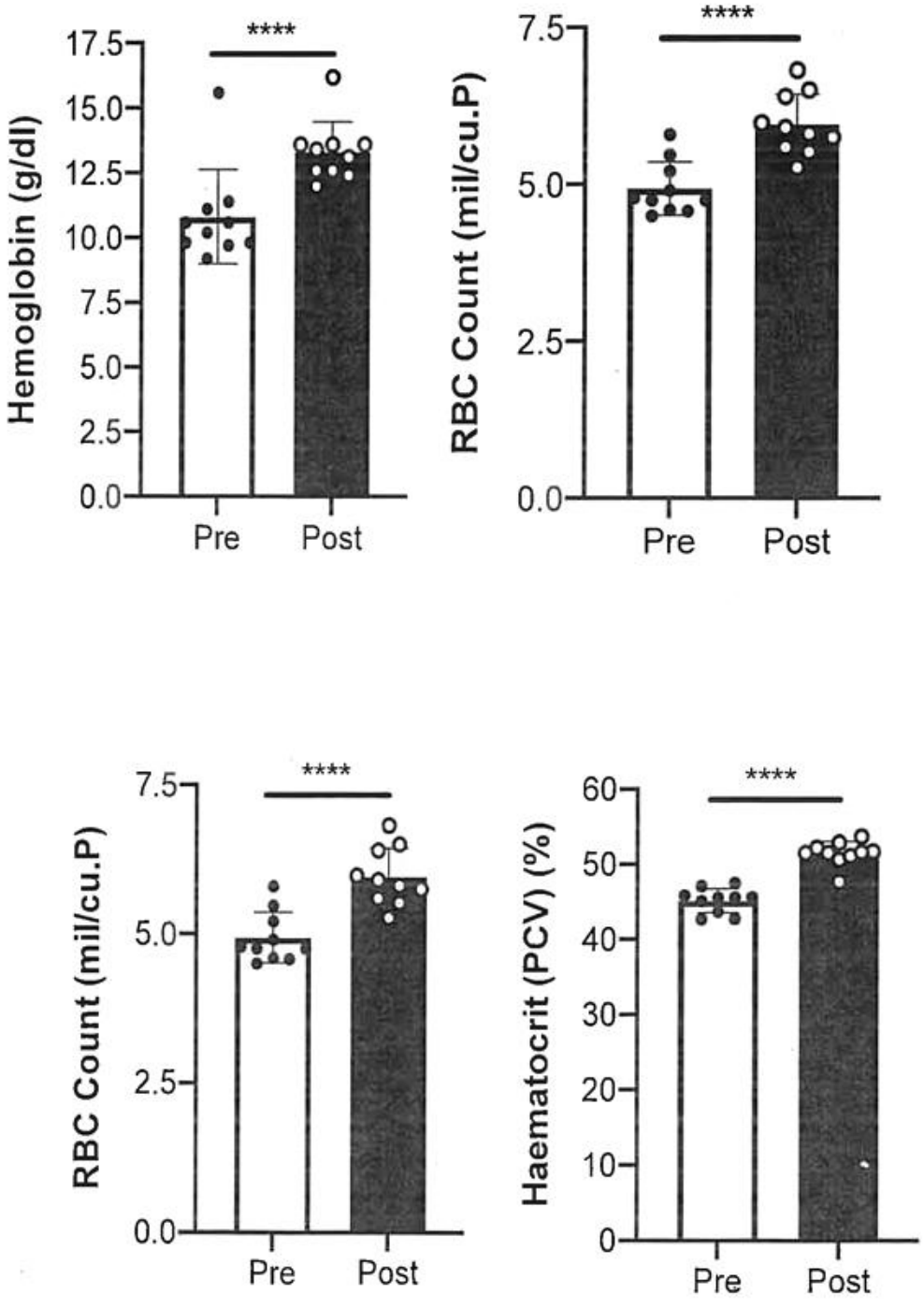
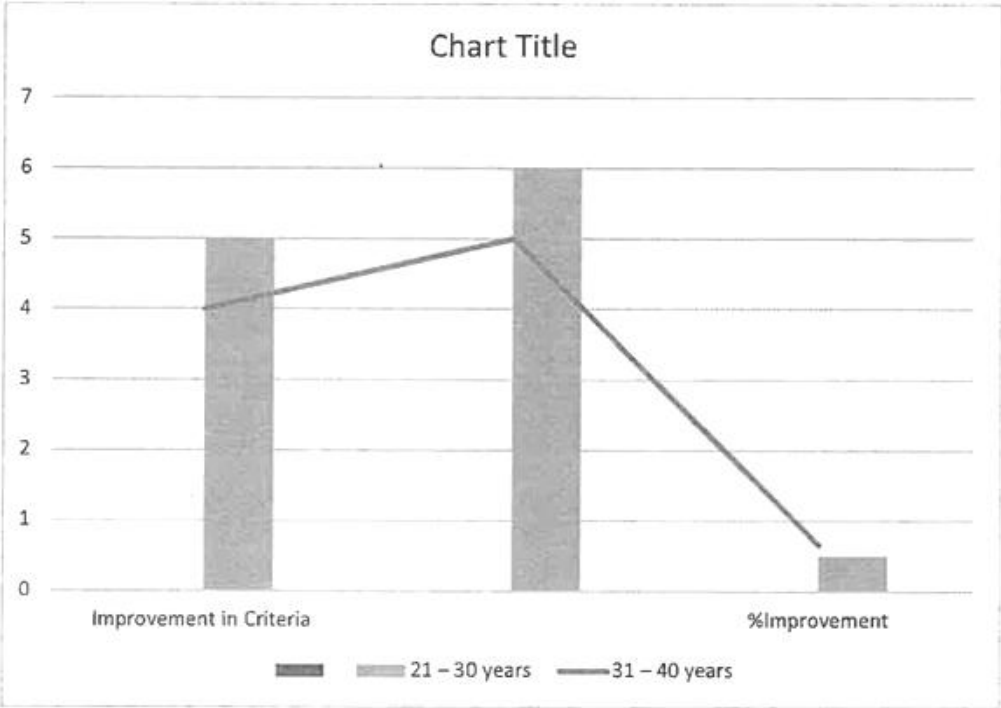


TABLE – 1.4; Improvement of *loss of appetite, marked weight loss* in One month (20)

Age group	Improvement in Criteria Before tmt,	After tmt.	%Improvement
21–30 years	5	6	50 %
31–40 years	4	5	66.6 %



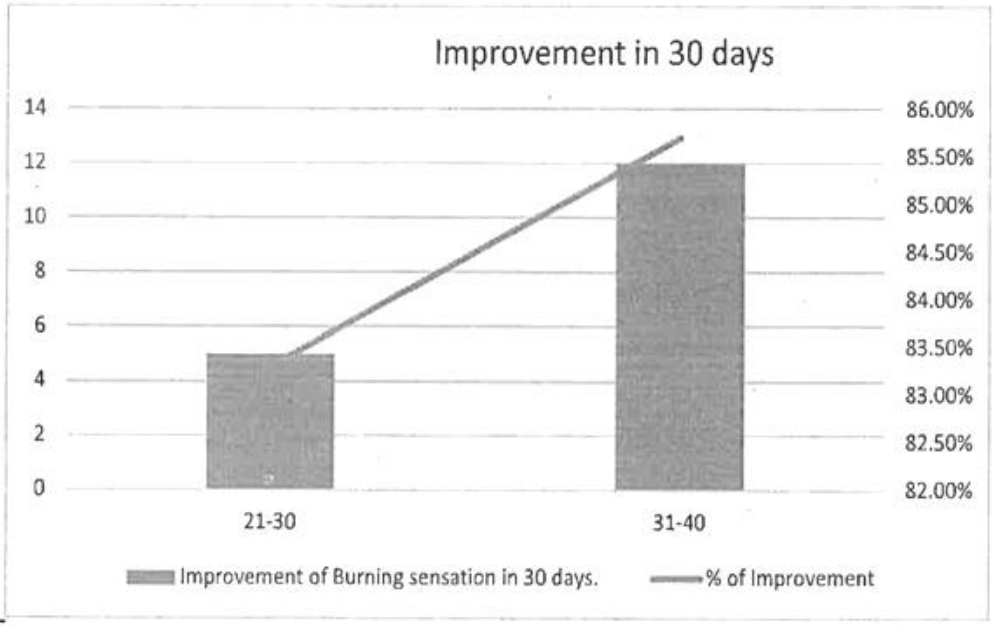
Interpretation

After the treatment of 30 days, 50% belonging to age group 21-30 years and 67% belonging to age group 31-40 years respectively had significant improvement of symptoms.

TABLE – 1.5; Improvement of *dhathukshaya (muscle wasting),*

***Dourbalya (General weakness)* in One month (20)**

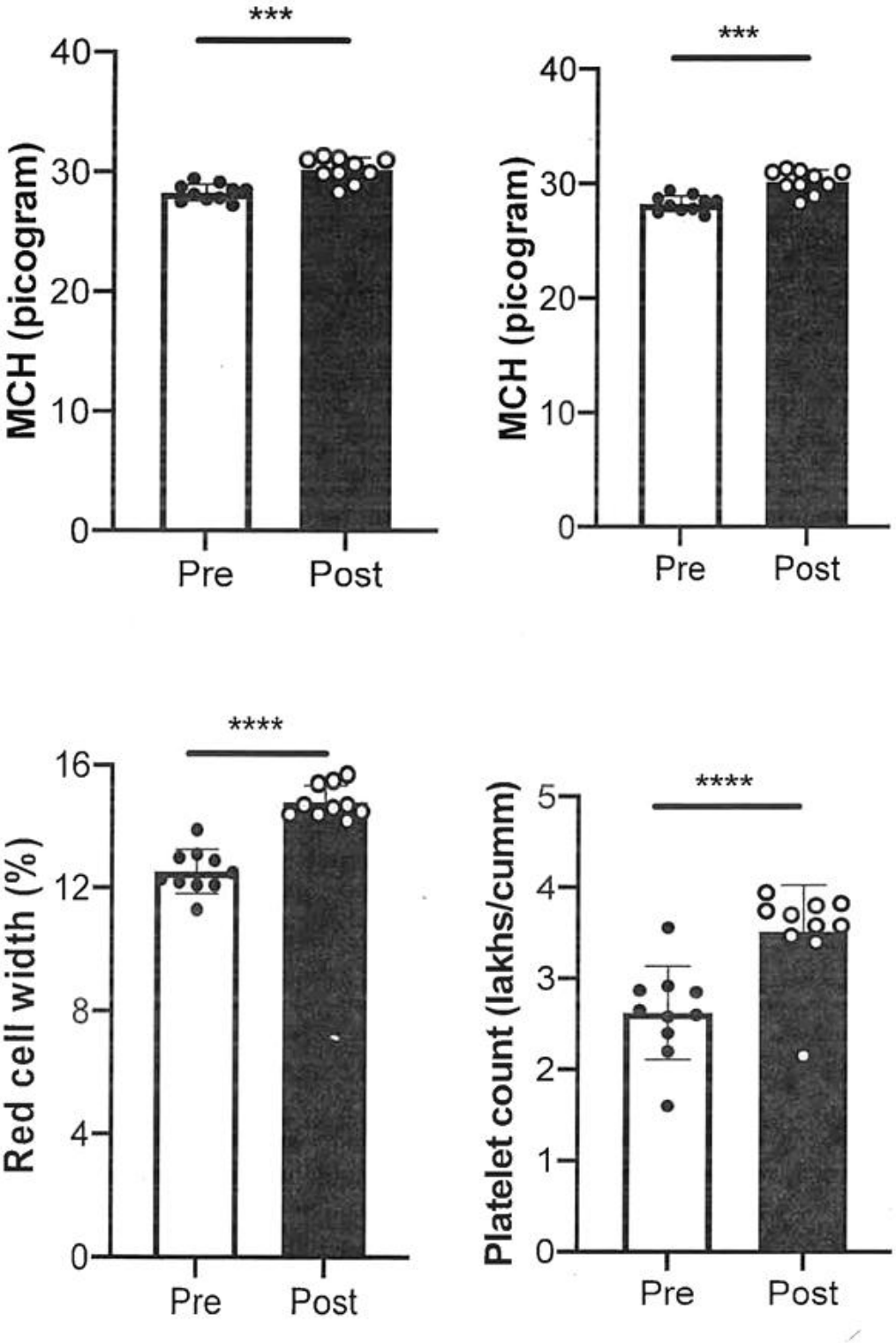
Age group	Improvement in 30 days.	% of Improvement
25-40	5	83.3 %
41-60	12	85.7 %

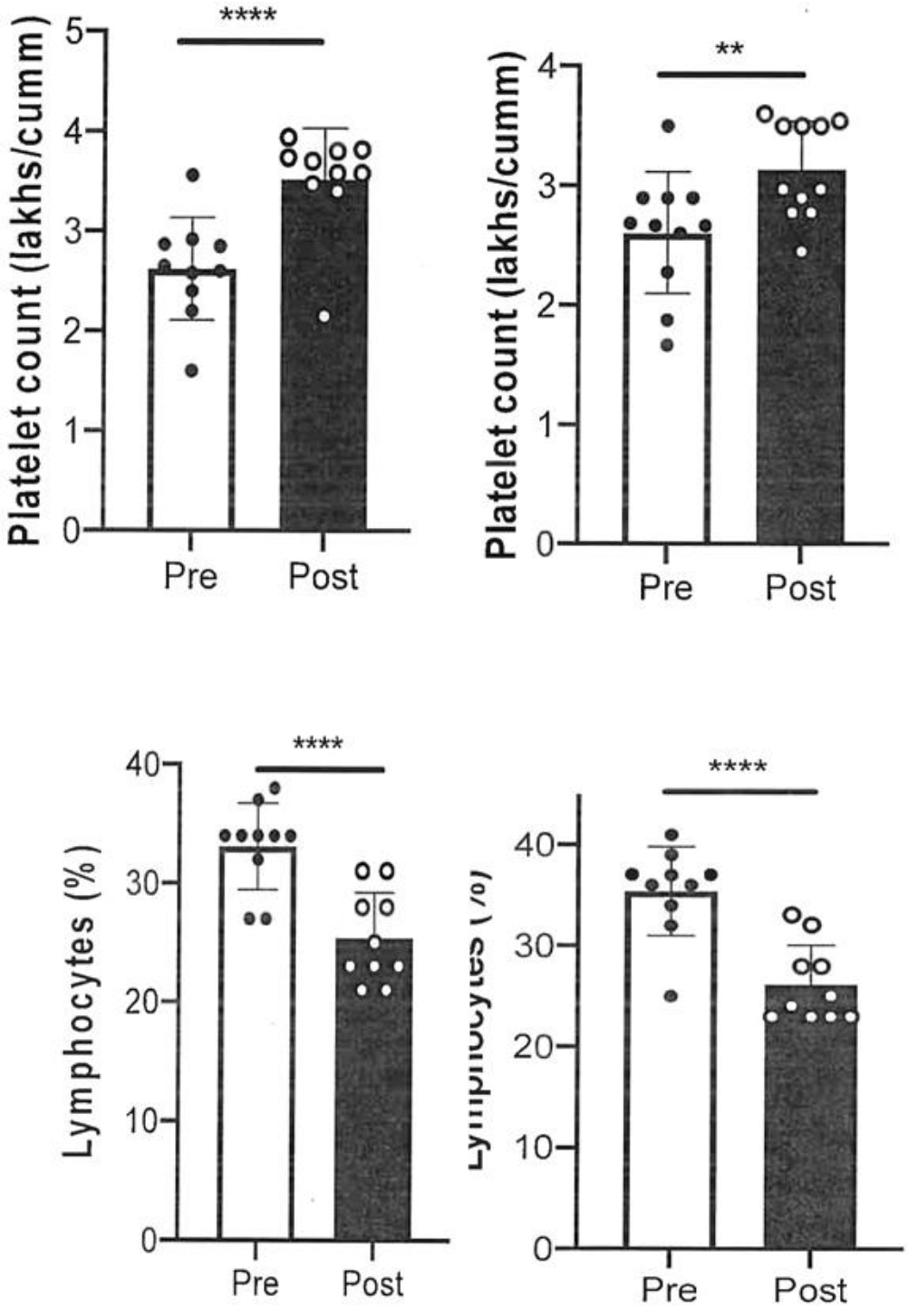


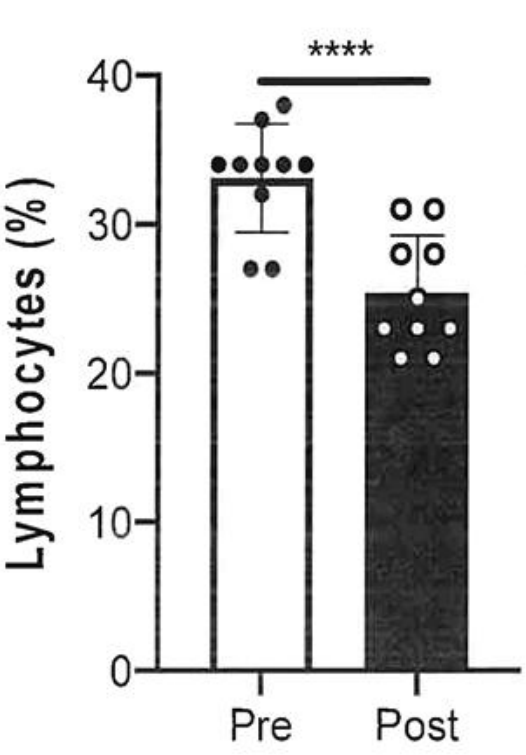
Interpretation

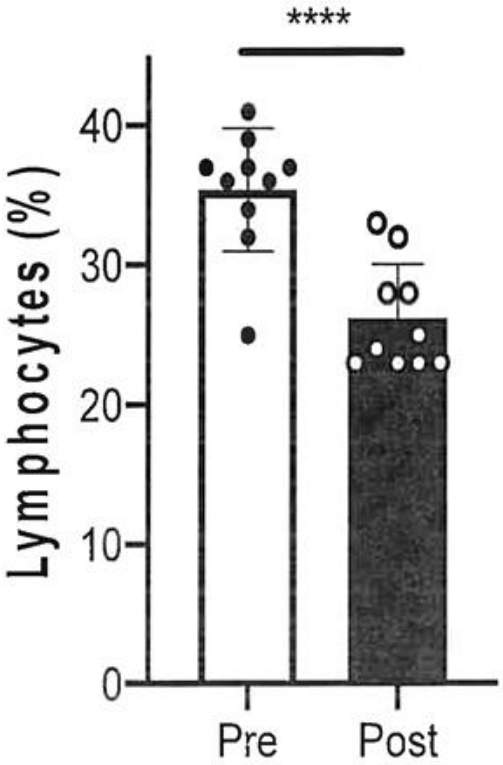
After the treatment of 30 days, 83% belonging to age group 21-30 years and 86% belonging to age group 31-40 years respectively had significant improvement of symptoms.

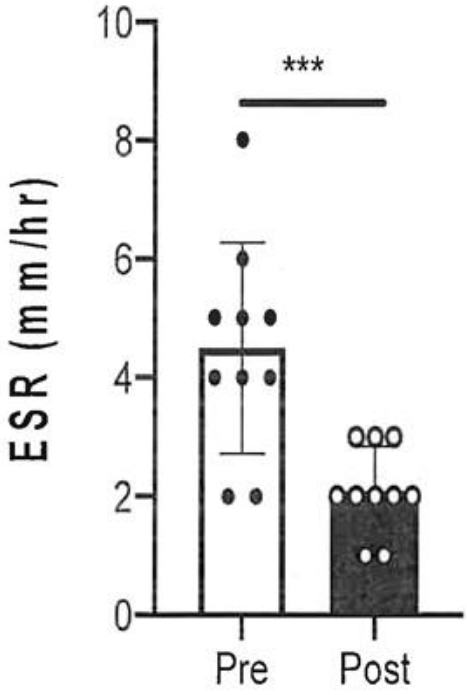
IMPROVEMENT IN LABORATORY FINDINGS – PRE TREATMENT-POST TREATMENT




****
Platelet count (lakhs/cumm)
5
4
3
2
1
0
Pre
Post
**
Platelet count (lakhs/cumm)
4
3
2
1
0
Pre
Post
****
Lymphocytes (%)
40
30
20
10
0
Pre
Post
****
40
30
20
10
0
Pre
Post


****
Lymphocytes (%)
40
30
20
10
0
Pre
Post


****
Lymphocytes (%)
40
30
20
10
0
Pre
Post


***
ESR (mm/hr)
10
8
6
4
2
0
Pre
Post

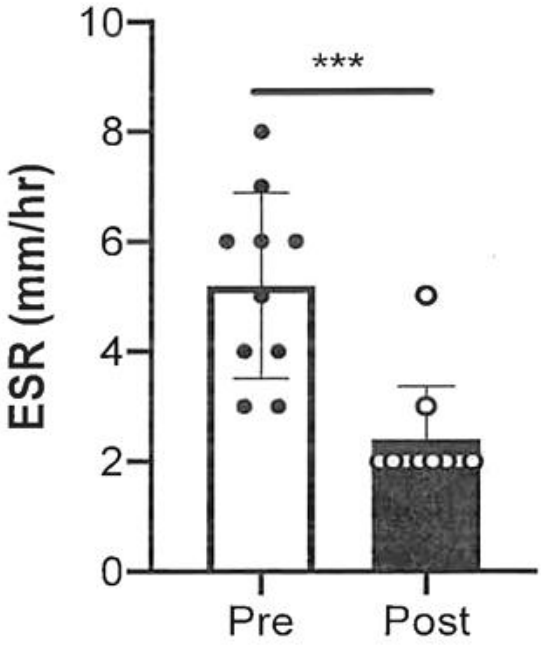
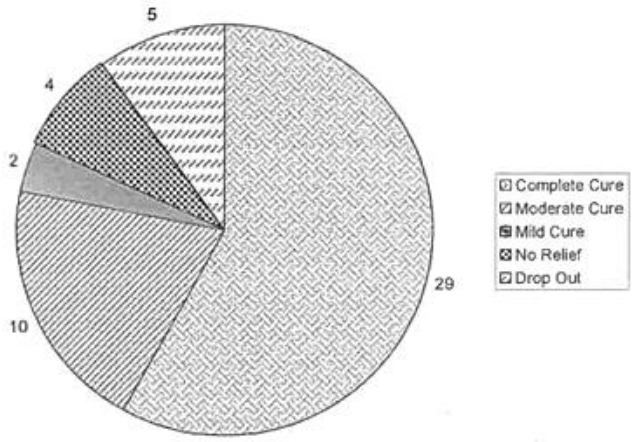

***
ESR (mm/hr)
10
8
6
4
2
0
Pre
Post

Table – 1.6; Overall results of Treatment in reduction of Clinical symptoms and Laboratory investigations in patients treated (Total 20 patients)

Results	No. of patients	Percentage
Very good improvement	14	70 %
Moderate improvement	03	15 %
Mild improvement	02	10 %
No significant relief	0	0 %
Drop out	01	05 %

CHART - 10
OVERALL RESULTS OF TREATMENT



Interpretation

After the treatment of 30 days, 14 patients (70%) had very good improvement of symptoms, 3 patients (15%) had moderate improvement, 2 patients (10%) had mild improvement and there was 1 dropout from the study (05%).

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 trialby 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

The current Phase-II-A, Single center, Open label, Therapeutic exploratory clinical trials is designed to evaluate the efficacy of Proprietary Ayurvedic Medicine –WHEAT GRASS CAPSULE, 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 “Kasa (Chronic cough), Swasa (Asthma), loss of appetite, marked weight loss, dhathukshaya (muscle wasting), Dourbalya (General weakness), body pain and fatigue” etc. found in Cachexia.

By consolidating the results obtained in the clinical investigations and laboratory investigations, it is hereby concluded that the Health supplement product - WHEAT GRASS CAPSULE, is highly effective in controlling Clinical symptoms of “Kasa (Chronic cough), Swasa (Asthma), loss of appetite, marked weight loss, dhathukshaya (muscle wasting), Dourbalya (General weakness), body pain and fatigue” etc. found in Cachexia,. It was clinically found to provide Anti inflammatory action and helps to enhance the patient's Immune function, in the recruited patients.

REFERENCES

1. Halliwell B. Free radicals and antioxidants: updating a personal view. Nutr Rev. 2012.
2. Pham-Huy LA, et al. Free radicals, antioxidants in disease and health. Int J Biomed Sci. 2008.
3. Lobo V, et al. Free radicals, antioxidants, and functional foods. Pharmacogn Rev. 2010.
4. Bouayed J, Bohn T. Exogenous antioxidants—double-edged swords in cellular redox state. Oxid Med Cell Longev. 2010.
5. Poljsak B, et al. The role of antioxidants in aging and disease prevention. J Clin Med. 2019.
6. Patwardhan B, et al. Ayurveda and anti-aging medicine. J Altern Complement Med. 2011.
7. Sharma PV. Charaka Samhita: Rasayana Therapy and Antioxidants in Ayurveda. Chaukhambha Publications. 2010.
8. Mishra S, et al. Ayurvedic principles of oxidative stress management. J Ayurveda Integr Med. 2018.
9. Kothari SL, et al. Herbal antioxidants and their role in Ayurveda. J Ethnopharmacol. 2019.
10. Patwardhan B, et al. Herbal medicine and free radical science. J Altern Complement Med. 2020.
11. Dhuley JN. Wheatgrass and its antioxidant properties. Phytomedicine. 2017.
12. Singh R, et al. Chlorophyll as a natural antioxidant and immune enhancer. J Tradit Complement Med. 2019.
13. Sharma A, et al. Anti-inflammatory effects of wheatgrass. J Herb Med. 2021.
14. Baliga MS, et al. Wheatgrass and its role in respiratory health. J Ayurveda Med Res. 2019.
15. Mukherjee PK, et al. Bioavailability enhancement of wheatgrass antioxidants. J Ethnopharmacol. 2020.
16. Guarner F, et al. Herbal interventions in oxidative stress management. Nutr Metab Insights. 2016.
17. Slavin JL. Wheatgrass and gut microbiome support. Nutr Rev. 2013.
18. Kar SS, et al. Scientific validation of Ayurvedic respiratory formulations. J Herb Med. 2016.
19. Verma S, et al. Standardization of Ayurvedic wheatgrass supplements. J Tradit Complement Med. 2019.
20. Mukherjee PK, et al. Integration of Ayurveda in preventive medicine. J Ethnopharmacol. 2020.

S. Suman, P. Karthikeyan, S. Moulishankar, et.al (2025). Open Label Single Centric Clinical Exploratory Of Efficacy Study On Wheat Grass Capsule, An Ayurvedic Proprietary Formulation, ijmaes; 11(1); 2198-2215.