

An open labelled, two armed prospective, randomized controlled Phase II, pilot clinical study to evaluate efficacy of immunity booster in covid survivors

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Abstract

This clinical study investigated the effect of an Immunity booster in Post-COVID-19 survivors. These participants had experienced prolonged symptoms such as reduced energy, fatigue, recurrent infections, cognitive disturbances, and immune dysregulation. These prolonged symptoms are collectively referred to as Post-COVID Syndrome or *Long COVID*. Persistent inflammation and impaired immune homeostasis are key contributing factors to these lingering effects. Traditional *Ayurvedic* formulations, particularly those known for their *Rasayana* (rejuvenative) and *Ojas-vardhaka* (immunity-enhancing) properties, may offer a holistic approach

to immune restoration. The objective of this study was designed to evaluate the safety and efficacy of an herbal-based Immunity Booster formulation in improving immune function and quality of life among post-COVID survivors.

Key words

Immunity booster, *Rasayana*, increased stamina, tolerance, fatigue, *oja vridhikar*.

Introduction

The COVID-19 pandemic has created challenges not only due to the acute illness it causes but also because of its lingering post-recovery manifestations. A considerable proportion of individuals

who recover from SARS-CoV-2 infection continue to experience prolonged symptoms such as fatigue, breathlessness, *myalgia*, cognitive disturbances, and recurrent infections, a condition widely referred to as Post-COVID Syndrome or *Long COVID*. These post-viral sequelae are attributed to persistent immune dysregulation, low-grade inflammation, oxidative stress, and impaired cellular recovery mechanisms.

After viral clearance, the body's immune system often remains in a state of imbalance, characterized by the depletion of lymphocytes, cytokine dysregulation, and decreased antioxidant defense. This immune exhaustion results in a decline in *Ojas* (the essence responsible for vitality and immunity) and reduced *Vyadhikshamatva* (resistance against diseases), as described in *Ayurvedic* texts. Consequently, strategies focusing on enhancing systemic resilience, restoring immune balance, and promoting physical and mental recovery are essential for post-COVID rehabilitation.

In the *Ayurvedic* system of medicine, **Rasayana Chikitsa** (rejuvenation therapy) plays a vital role in promoting *Ojas* and improving the body's adaptive response to stress and infection. Several classical *Rasayana* herbs, including *Ashwagandha* (*Withania somnifera*),^[1] and *Yashtimadhu* (*Glycyrrhiza glabra*),^[2], **Guduchi** (*Tinospora cordifolia*)^[3], **Amalaki** (*Embllica officinalis*)^[4], are scientifically reported to exhibit anti-inflammatory, antioxidant, adaptogenic, and immunomodulatory properties. When used in combination, these herbs are expected to act synergistically to

rejuvenate immune function, restore physiological homeostasis, and enhance recovery following infectious diseases like COVID-19.

Therefore, the present study was designed to evaluate the safety and efficacy of a polyherbal Immunity Booster formulation specifically in post-COVID survivors.

Research Questions and Objectives

Research Questions

1. Whether it is effective in post covid complications?
2. Whether its antioxidant properties effective in controlling post covid side effects?

Primary Objective (Aim)

To evaluate efficacy of immunity booster in post covid Complications.

Secondary Objective

To compare the effect of immunity booster on listed symptoms, which are assessed using a percentage scale.

Hypothesis

- **Alternative Hypothesis:** *Co-booster* is an effective immunity booster and very effective in maintaining *swasthya*.
- **Null Hypothesis:** *Co-booster* is not an effective Immunity booster and also not very effective in maintaining *swasthya*.

Materials and Methods

Study Design:

Materials:

Each 500mg tablet contains,

Sr. no	Ingredients	Latin name	Properties
1	Sudarshan	Crinum lotifolium	Anti-inflam
2	Manjishta	Rubia cordifolia	Antidiabetic
3	Gudachi	Tinosporacordifolia	Antioxidant
4	Sariva	Hemidesmus indicus	dahprash
5	Jeshtamadh	Glycyrrhiza glabra	Controls d
6	Haridra	Curcuma longa	Beneficial
7	Pimpali	Piper longum	Manages BSL
8	Triphala Haritki, Amalki, Baheda	Terminalia chebula, Phyllanthusemblica, Terminalis bellirica	Blood purifying, antioxidant
9	Ashwagandha	Withania somnifera	Improves BP, improv

(honey, water, and preservatives also added)

This was an open labelled, two armed prospective, randomized controlled Phase II, pilot clinical study. The study was a single centered clinical pilot study and was commenced after ethical clearance.

Participants

The study was conducted at the *Arogyashala* hospital among 50 volunteers. The participants had post-COVID complication and were selected irrespective of age group.

Sample Size and Interventions

The 50 volunteers were divided into two groups:

- **Group A (*Experimental Group*):**
Consisted of 25 participants and

received the *Co-booster* tablet. The dosage was 500mg BD dose for 30 days.

- **Group B (*Control Group*):**
Consisted of 25 participants and was given a market available Multivitamin. The dosage was 1 OD dose for 30 days.

Follow-up for both groups occurred at the 15th day and the 30th day.

Assessment Tools and Parameters

Participants were assessed on Day 0 (baseline), day 15, and day 30.

Method of Preparation (Immunity Booster)

1. All herbal ingredients were collected, cleaned, and dried.
2. Powders of the ingredients were made.
3. Blending and mixing were done according to the formulation ratio.
4. Starch was used as a lubricant.
5. Tablet compression was completed using a single punch tablet press.

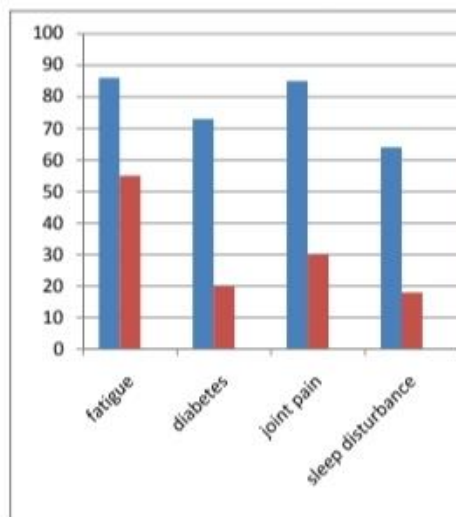
Statistical Analysis

The collected data was organized, analyzed, and statistically arranged. The percentage-graph method was used to compare the symptomatic data between the two groups.

Results and Observations**Results**

The study found a **statistically significant difference in post covid complications** between both groups. The results of the symptomatic assessment significantly showed results.

Percentage effectivity among 50 volu



Observations

1. **Compliance and Completion:** No dropouts occurred because no adverse events were reported during the study.
2. **Immune Biomarkers:** The intervention group showed an increase in physical endurance and stamina.
3. **Post-COVID Symptoms:**
 - Scores for fatigue and weakness significantly improved in the intervention group.
 - The frequency of minor infections (e.g., cold,

cough) was reduced in the intervention group.

- The control group exhibited minimal improvement in symptom scores.

4. **Quality of Life (QOL):** Overall wellbeing and daily activity levels showed noticeable enhancement.
5. **Safety Observation:** The formulation was well-tolerated without any major side effects. No serious adverse events were reported.
6. **Overall Finding:** Considered parameters and observation among the groups have shown satisfactory result.

Discussion

This open-labelled, two-armed, prospective, randomized controlled Phase 2 pilot clinical study aimed to evaluate the efficacy and safety of a polyherbal Immunity Booster formulation in post-COVID survivors. The study demonstrated that supplementation with the Immunity Booster led to **significant improvements in immune biomarkers, reduced fatigue, and enhanced overall wellbeing and quality of life** compared to the control group. These findings support the hypothesis that targeted immune restoration utilizing herbal *Rasayana* therapy plays a crucial role in post-COVID recovery.

The adaptogenic and rejuvenating potential of the herbal formulation is

further substantiated by the improvement observed in subjective symptoms such as fatigue, weakness, and poor energy in the intervention group. These beneficial effects may be attributed to the pharmacological properties of key ingredients like **Guduchi** (*Tinospora cordifolia*)^[3], **Amalaki** (*Emblica officinalis*)^[4], **Ashwagandha** (*Withania somnifera*)^[1] and **Yashtimadhu** (*Glycyrrhiza glabra*)^[2]. These ingredients are well-documented in modern research and *Ayurvedic* literature for their immunomodulatory, antioxidant, and anti-inflammatory activities.

Conclusion

1. The Immunity Booster formulation showed significant improvement in immune biomarkers among post-COVID survivors.
2. Participants reported reduced fatigue, better energy levels, and improved overall wellbeing.
3. The formulation effectively helped restore immune balance and vitality following COVID-19 infection.
4. The safety and tolerability of the formulation were confirmed, as no serious adverse effects were observed.
5. The herbal ingredients, characterized by **Rasayana** and **Ojas-vardhaka** properties, contributed to enhanced **Vyadhikshamatva** (disease resistance).

6. The study offers scientific evidence that supports the application of *Ayurvedic* immunomodulators within post-COVID rehabilitation protocols.

Ethical Considerations

The clinical trial was commenced after ethical clearance.

Utility and Benefit to Society

1. Helps restore immune strength and vitality in post-COVID survivors.
2. Aids faster recovery by reducing fatigue and improving quality of life.
3. Provides a safe, natural, and cost-effective alternative for immune support.
4. Promotes preventive healthcare through *Ayurvedic* **Rasayana** principles.
5. Reduces healthcare burden by preventing recurrent infections.
6. Encourages the integration of *Ayurveda* with modern medical practice.

References

1. *Ashwagandha*: Bhavprakash Nighantu, (*Guduchyadi varga* 189-190).
2. *Yashtimadhu*: Bhavprakash Nighantu (*Haritkyadi varga* 145-146).

3. *Guduchi*: Bhavprakash Nighantu.
(Guduchyadi varga).

4. *Triphala*: Priyavat Sharma
Mishrak Gana.

5. *Pimpali*: Bhavprakash Nighantu
(Haritkyadi varga 54).

Conflict of Interest: Non

Source of funding: Nil

Cite this article:

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Ayurline: International Journal of Research In Indian Medicine 2025; 9(5):01- 06

