



A randomised, placebo-controlled preclinical study on the Efficacy and Safety of Good Health Capsules by Dr. Biswas Ayurveda as a Rasayana and Immunity Booster

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Abstract:

This randomized, placebo-controlled clinical study aimed to evaluate the efficacy and safety of Good Health Capsules by Dr. Biswas Ayurveda as a Rasayana and immunity booster. The study involved a 8-week intervention period and assessed white blood cell (WBC) count as a marker of immune function. The results indicated no significant differences between the test group and the control group at baseline. However, after 8 weeks, the test group showed a statistically significant increase in WBC count compared to the control group. These findings suggest a potential positive impact of Good Health Capsules on immune function. No significant adverse events or side effects were reported, indicating a favorable safety profile. While these results are encouraging, further research is needed to validate these findings, explore underlying mechanisms, and assess long-term effects. Caution should be exercised, and healthcare professionals consulted before incorporating any new supplement into one's routine.

Keywords: Good Health Capsules, Dr. Biswas Ayurveda, Rasayana, Immunity

INTRODUCTION:

Ayurveda, an ancient medical system, operates based on the principles of life and lifestyle. It has significant potential to serve as an effective public healthcare delivery system. Ayurveda is among the oldest and well-established forms of P4 (predictive, preventive, personalized, and participatory) medicine.¹ In Ayurveda, the concept of immunity can be associated with Vyadhikshamatva, which pertains to the body's ability to prevent the occurrence and progression of diseases.² Immunity can also be understood in terms of Bala, which signifies bodily strength, and Ojas, the essence of the body's seven Dhātu. Bala represents the body's strength, predominantly provided by Prakruta Kapha, while Charaka considers Bala as ojas.^{3,4}

Rasayana Tantra is one of the eight specialized fields within Ayurveda, focusing on nutrition, natural resistance, and geriatrics. It encompasses the concept of enhancing nourishment, leading to improved immunity and youthfulness. Rasayana can take the form of medicines, dietary practices, or even lifestyle choices, known as Acar, all aimed at achieving these desired outcomes. The purpose of Rasayanas is to strengthen Oja and Bala, which represent vitality and biostrength,

providing natural defense against aging and illness. It is believed to contribute to the overall health of body tissues and thus promote longevity. Additionally, this therapy is known for its ability to enhance memory, intelligence, youthfulness, radiance, complexion, and voice. The various techniques employed in this therapy are referred to as Rasayana because they contribute to the restoration and replenishment of Rasa and other bodily tissues.⁵

Ashwagandha, a member of the Solanaceae family, is popularly referred to as "Indian Winter cherry" or "Indian Ginseng." With its extensive health benefits, this herb holds significant importance in Ayurveda, the traditional Indian system of medicine. For centuries, Ashwagandha has been utilized as a Rasayana, providing a wide array of advantages for overall well-being. By enhancing cell-mediated immunity, Ashwagandha strengthens the body's ability to fight against diseases. Additionally, it exhibits strong antioxidant properties, safeguarding cells from damage caused by free radicals.⁶

Hemidesmus indicus, commonly known as Indian Sarsaparilla or Anantamul, belongs to the Asclepiadaceae family. It is a widely recognized traditional medicinal plant extensively utilized in Ayurveda, Siddha, and Unani medical systems for the treatment of various ailments. These include dysentery, diarrhea, syphilis, indigestion, leucoderma, diuretic effects, blood purification, body burning sensation, persistent fever, asthma, liver diseases, sexually transmitted infections, leprosy, urinary tract infections, arthritis, bronchitis, epileptic seizures, hypertension, skin conditions such as eczema and psoriasis, rheumatism, chronic nervous disorders, impotence, and immune disorders.⁷

Draksha, commonly known as grapes or *Vitis vinifera*, has been attributed with various health benefits, including potential effects on immunity. Grapes are rich in antioxidants such as resveratrol, flavonoids, and vitamin C, which possess immune-enhancing properties by combating oxidative stress and reducing inflammation in the body. These antioxidants help protect immune cells from damage and support their optimal functioning.⁸ Studies have suggested that grape extracts can modulate the immune system by stimulating the production and activity of immune cells such as lymphocytes and natural killer (NK) cells. These immune cells play a crucial role in defending the body against infections and diseases.⁹

Brahmi, scientifically known as *Bacopa monnieri*, is an herb traditionally used in Ayurvedic medicine. It is believed to have various effects on the body and brain. Brahmi has been traditionally used for its potential cognitive-enhancing properties, including improved memory, learning, and concentration. Studies have suggested that Brahmi extracts may enhance certain cognitive functions and improve overall cognitive performance.¹⁰ Brahmi contains compounds that exhibit anti-inflammatory and antioxidant properties. These properties help in reducing oxidative stress and inflammation, which are implicated in various chronic diseases.¹¹

Satamuli, scientifically known as *Asparagus racemosus*, is an herb commonly used in traditional medicine systems such as Ayurveda. It is believed to possess various therapeutic properties. Satamuli has been studied for its immunomodulatory effects, which can help regulate and enhance immune function. It may stimulate immune cells and improve immune response.¹² Satamuli contains antioxidants that can help neutralize harmful free radicals and protect cells from oxidative damage. This antioxidant activity may contribute to its overall health benefits.¹³

Yastimadhu, known as Licorice or *Glycyrrhiza glabra*, is a medicinal herb that has been traditionally used in various systems of medicine for its potential health benefits. Yastimadhu contains compounds like glycyrrhizin and liquiritin, which possess anti-inflammatory properties. These compounds have been shown to inhibit inflammation and modulate immune responses in

various studies.¹⁴ Yastimadhu has been studied for its gastroprotective effects, particularly in the context of gastric ulcers. It has been found to help reduce ulcer formation, promote the healing of gastric mucosa, and protect against damage caused by factors like stress and nonsteroidal anti-inflammatory drugs (NSAIDs).¹⁵

Jatamansi, scientifically known as *Nardostachys jatamansi*, is a medicinal herb that has been traditionally used in Ayurvedic medicine for its various therapeutic properties. Jatamansi has been studied for its anxiolytic (anti-anxiety) and antidepressant properties. It has shown potential in reducing anxiety and depressive behaviors by modulating neurotransmitters and regulating stress response pathways in animal models.¹⁶ Jatamansi has been investigated for its cardioprotective properties, including antioxidant and anti-inflammatory effects. It has shown potential in protecting the heart from ischemic injury and improving cardiac function.¹⁷

Shankhpushpi, also known as *Convolvulus pluricaulis*, is an herb commonly used in traditional Ayurvedic medicine. It has been attributed with various health benefits, including potential effects on cognitive function and overall well-being. It has been traditionally used to enhance cognitive function, including memory, learning, and concentration. Some studies in animal models have suggested that Shankhpushpi extracts may have neuroprotective and memory-enhancing effects.¹⁸ It contains antioxidant compounds that help scavenge free radicals and reduce oxidative stress in the body. Antioxidants play a crucial role in maintaining overall health and supporting various bodily functions.¹⁹

Vidang, scientifically known as *Embelia ribes*, is an herb commonly used in traditional Ayurvedic medicine. It has been associated with various potential health benefits, including effects on digestion, parasites, and respiratory health. It has shown antimicrobial properties against certain bacteria and fungi. It may inhibit the growth of pathogenic microorganisms, which could be beneficial for combating infections.²⁰ It has been used to support digestion and address gastrointestinal issues. It may possess carminative and digestive stimulant properties, potentially aiding in the relief of indigestion and flatulence.²¹

Gokshura, also known as *Tribulus terrestris*, is an herb commonly used in traditional Ayurvedic medicine. It has been studied for its potential effects on various aspects of health, including its impact on the immune system. It has been reported to possess immunomodulatory properties, meaning it can help regulate and enhance immune system function. It may stimulate the production and activity of immune cells, such as macrophages and lymphocytes, which are essential for the body's defence against infections and diseases.²² It contains antioxidants that can help combat oxidative stress and protect immune cells from damage. By reducing oxidative stress, it may support overall immune system function.²³

Amalaki, also known as Indian gooseberry or *Emblia officinalis*, is a widely used fruit in Ayurvedic medicine known for its potential health benefits. It is rich in vitamin C and other antioxidants, which help protect the body against oxidative stress and enhance the immune system's functioning.²⁴ It has been traditionally used to improve digestion and enhance gut health. It may help stimulate digestive enzymes, improve gut motility, and relieve digestive disorders such as indigestion and constipation.²⁵

AIMS AND OBJECTIVES:

- The aim is to assess the safety and effectiveness of Good Health Capsules in individuals with low immunity.

MATERIAL AND METHODS:

Dr. Biswas Ayurveda's Good Health Capsules, which contain herbal extracts of various herbs as mentioned below in the table, were used as the investigational drug in the pre-clinical trial. The composition of Dr. Biswas Ayurveda's Good Health Capsules consists of dry extracts of:

Name	Latin Name	Quantity	Part Used
Ashwagandha	<i>Withania somnifera</i>	70 mg	Root (Dry Extract)
Anantmoola	<i>Hemidesmus indicus</i>	50 mg	Root (Dry Extract)
Draksha	<i>Vitis vinifera</i>	40 mg	Fruit
Brahmi	<i>Bacopa moneri</i>	30 mg	Whole plant
Satamuli	<i>Asparagus racemosus</i>	40 mg	Root
Yastimadhu	<i>Glycyrrhiza glabra</i>	40 mg	Root
Jatamansi	<i>Nordostachys jatamansi</i>	40 mg	Rhizome (Dry Extract)
Shankhpushpi	<i>Convulvulus pluricaulis</i>	50 mg	Whole plant
Vidang	<i>Embelia ribes</i>	40 mg	Fruit
Gokshur	<i>Tribulus terrestris</i>	30 mg	Root and Fruit
Amlaki	<i>Emblica officinalis</i>	50 mg	Fruit

These capsules are manufactured by Doctor Biswas Ayurveda International Pvt. Ltd., located at Plot No. 278, Sector 2, HSIIDC Industrial Area Saha, Distt Ambala (HARYANA) INDIA. Following the consumption of Good Health Capsules to establish standardization, a batch of 50,000 capsules was selected. The capsules were subjected to analytical testing while still in their sealed packaging. The manufacturer provided a complete dossier of the drug, specifically referring to the Ayurvedic Pharmacopoeia of India.

Patients were chosen from the outpatient department (OPD) of Rasa Shastra Evum Bhaishajya Kalpana Department at Shri Krishna Govt. Ayurvedic College in Kurukshetra, Haryana, India (pin code 136118). Patients who met the eligibility criteria, regardless of their age, sex, or religion, were included in the study. Participants within the age range of 20 to 60 years were chosen. A regular blood test was conducted to exclude any other medical conditions and to ensure that blood values were within normal limits.

INCLUSION CRITERIA:

- Male and females aged between 40 and 65.
- Patient with WBC level below $6.0 \times 10^9/uL$.
- Patient who volunteered to participate in the study.

EXCLUSION CRITERIA:

- Patients who declined to participate in the study.
- Patients who were either under the age of 40 or over the age of 65.
- Patients who were prescribed an immunosuppressive drug within 6 months of the first visit.
- Patients with disease-related complications.
- Patients with a history of alcohol or drug abuse.

DURATION OF THE TRIAL:

- The total duration of the trial was 8 weeks

METHOD OF STUDY:

The study obtained informed consent from the participants to enrol them in the trial. The clinical trial comprised 100 registered individuals who were randomly assigned in a 1:1 ratio. Specifically, 50 participants were assigned to the control group (placebo), and 50 participants were assigned to the experimental group (testing Dr. Biswas Ayurveda's Good Health Capsules). The materials for both the experimental and control groups were packaged identically. The participants were blinded to their group assignments, as were the researchers and clinicians involved in the study.

Trial Group I - (50 Patients)

The objective was to evaluate the effects of Good Health Capsules, in the form of an immunity-booster, on specific signs and symptoms of low immunity in a group of 50 patients. All 50 patients were included in this study, and only one patient dropped out, leaving 49 patients who completed the trial.

Trial Group II - (50 Patients)

In order to investigate the collective impact of certain symptoms present in disorders, a group of 50 patients was formed to observe the effects of a placebo as an immunity-booster. The study included all 25 patients and all patients completed the trial.

Drug and Dose:

One capsule of Good Health Capsules is given at morning and evening after meal.

RESULTS:

After being randomly assigned, 100 participants were divided into two groups with a 1:1 ratio between the test and control groups. One participant from test group dropped out of the study, leaving 99 subjects for per-protocol (PP) analysis. Changes in the total number of WBCs after the intake of the test substance for 8 weeks are shown in the table given below. The results indicate that the use of Dr. Biswas Ayurveda's Good Health Capsules leads to a gradual improvement in WBC's counts compared to the placebo group. The p-value in placebo group is 0.9635 and in test group is 0.0179 after 8 weeks, indicating that the test treatment was more effective than the placebo. The statistical results of the hypothesis testing are presented in the table below.

	Test (n=49)		Placebo (n=50)	
	Week 0	Week 8	Week 0	Week 8
WBC's Count	4.67 ± 0.88	5.10 ± 1.22	4.96 ± 0.79	4.96 ± 0.91
Mean SD	0.43 ± 1.23		0.01 ± 0.86	
p-value (group)	0.0179		0.9635	
p-value	0.0490			

DISCUSSION:

The present study aimed to evaluate the efficacy and safety of Good Health Capsules by Dr. Biswas Ayurveda as a Rasayana and immunity booster. The study followed randomized, placebo-

controlled design, which is considered the gold standard in clinical research. This design ensures that neither the participants nor the researchers are aware of who is receiving the active intervention or the placebo, minimizing bias and enhancing the reliability of the results.

Table shows the measurements of changes in white blood cell (WBC) count after an 8-week period of taking the test substance. Initially, there was no notable difference between the groups. However, after 8 weeks, the test group exhibited an average count of 5.10 ± 1.22 , while the control group showed an average count of 4.96 ± 0.91 . There was no significant statistical distinction between the two groups. Nevertheless, when comparing the baseline to the 8-week mark, the test group experienced a significant increase in WBC count compared to the control group ($p = 0.0490$).

The study findings revealed several important aspects regarding the effectiveness and safety of Good Health Capsules. The results showed that there were no statistically significant differences in baseline characteristics between the test group and the control group, indicating a well-balanced randomization process.

After an 8-week intervention period, the white blood cell (WBC) count was measured as a marker of immune function. The analysis showed that there was no statistically significant difference between the test group and the control group at the end of the intervention. However, when comparing the baseline values to the values at 8 weeks, the test group exhibited a significant increase in WBC count compared to the control group.

This finding suggests that Good Health Capsules may have a positive impact on immune function by potentially enhancing WBC production or activity. This aligns with the purported claims of the product as a Rasayana and immunity booster. However, further studies with larger sample sizes and longer intervention periods are warranted to confirm these results and establish the underlying mechanisms of action.

In addition to efficacy, the study also investigated the safety profile of Good Health Capsules. Throughout the 8-week study duration, no significant adverse events or side effects were reported in either the test group or the control group. This indicates that the intervention was well-tolerated and suggests a favorable safety profile for the tested product.

CONCLUSION:

In conclusion, the randomized, placebo-controlled pre-clinical study on the efficacy and safety of Good Health Capsules by Dr. Biswas Ayurveda as a Rasayana and immunity booster provides initial insights into the potential benefits of this product. The study's findings suggest that Good Health Capsules may have a positive impact on immune function, as indicated by a significant increase in white blood cell count in the test group compared to the control group after 8 weeks of intervention.

Although these results are promising, it is important to recognize the limitations of the study, such as the relatively short duration and the specific population studied. Further research with larger sample sizes, longer follow-up periods, and diverse participant groups is necessary to validate these findings and provide a more comprehensive understanding of the product's efficacy and safety.

Furthermore, the study demonstrated that Good Health Capsules were well-tolerated, with no significant adverse events or side effects reported during the 8-week intervention period. This suggests a favorable safety profile for the tested product.

Overall, while this study provides preliminary evidence supporting the potential of Good Health Capsules as a Rasayana and immunity booster, additional research is needed to confirm and expand upon these findings. Continued investigation into the underlying mechanisms of action

and long-term effects will contribute to a more comprehensive understanding of the product's benefits and safety.

It is important to consult with healthcare professionals and consider individual health needs before incorporating any new supplement or product into one's routine.

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