DOI: 10.7860/JCDR/2026/79972.23361

Research Protocol

Internal Medicine Section

Efficacy of *Haritaki Vati* (*Terminalia Chebula Retz.*) in *Sthaulya* (Overweight): A Randomised Controlled Trial Research Protocol

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ABSTRACT

Introduction: Overweight or *Sthaulya* is one of the *Ashtaunindita Purusha* or eight undesirable body constitutions according to *Ayurveda*. It is directly associated with non-communicable diseases like diabetes, cardiovascular disease, and hypertension, therefore being one of the most important health factors in modern medicine.

Need of the study: Overweight is among the major causes of non-communicable diseases and decreased quality of life worldwide. Current treatments have very high costs and adverse effects. *Haritaki* is an *Ayurvedic* herbal medicine that is easily affordable, widely available, and safe for chronic use. However, there is a notable lack of studies assessing its effectiveness through rigorous methodologies, such as placebo-controlled and double-blind clinical trials. This study is specifically designed to fill this gap in research.

Aim: To evaluate the efficacy of *Haritaki Vati* (*Terminalia Chebula Retz*.) vs routine care in the management of *Sthaulya* (overweight).

Materials and Methods: This double-blind, randomised, placebo-controlled clinical trial will be conducted from December 2024 to December 2026 at Mahatma Gandhi Ayurved College Hospital and Research Centre, Salod (H), Wardha. 60 participants, aged between 19 and 30 years and having a Body Mass Index (BMI) ranging from 25 to 29.9 kg/m^2, will be enrolled and randomly assigned to two groups. Group-A will receive *Haritaki Vati* at a dose of two grams per day, administered in two divided doses, while Group-B will receive starch-based placebo tablets. The intervention period for both groups will be 90 days, with follow-up evaluations scheduled on days 30, 60, and 90. Anthropometric parameters such as BMI, waist-to-hip ratio, and mid-upper arm circumference will be recorded at baseline and during each follow-up. Statistical analysis will be carried out using paired and unpaired t-tests, and results will be considered statistically significant at a p-value of less than 0.05.

Keywords: *Deepana*, Obesity, *Pachana anulomana, Santarpanottha vyadhis*

INTRODUCTION

Sthaulya is described as one of the *Ashtaunindita Purusha* in *Ayurvedic* scriptures [1]. According to *Acharya Charaka*, it is mentioned among the *Santarpanottha Vyadhis* [2]. In view of the treatment principle of *Sthaulya,* Heavy/unctuous and non-nourishing therapies are indicated for the management of obesity, while nourishing measures are indicated for emaciated persons [3]. *Haritaki*, as described in the *Dhanvantari Nighantu* under the *Guduchyadi Varga*, may be effective in the management of Sthaulya due to its *Deepana*, *Pachana*, *Anulomana*, and *Lekhaniya* properties [4]. *Sthaulya* can be correlated with overweight/obesity. Its prevalence in India is increasing rapidly, and it is predicted that between 2010 and 2040, the prevalence of overweight among Indian adults aged 20 to 69 years will double [5]. In both rural and urban India, it is associated with an increased risk of non-communicable diseases such as metabolic syndrome, cardiovascular disease, hypertension, hyperlipidaemia, and type 2 diabetes mellitus [6]. Currently, medicines like Orlistat, and Naltrexone are being used; however, the FDA recommends their use only for individuals with a BMI ≥29.9 kg/m^2, due to their potential side-effects. Hence, attention must be given to the management of patients with BMI between 25-29.9 kg/m^2 to prevent further worsening of the condition [7]. Over the past several decades, there has been a marked rise in the prevalence of overweight and obesity, resulting in an increasing need for interventions that are safe, affordable, and supported by scientific evidence. Among *Ayurveda's* promising remedies, *Haritaki* (*Terminalia chebula*) is noted for its well-documented *Lekhaniya* (fat-reducing) action [8].

REVIEW OF LITERATURE

Gomutra Haritaki is a classical Ayurvedic combination comprising *Gomutra*, a traditionally revered *Rasayana* with fat-metabolising properties, and *Haritaki* (Terminalia chebula), possessing *Deepana*, *Pachana*, and *Anulomana* properties.

Apart from Haritaki, other Ayurvedic formulations such as Triphala, a synergistic blend of *Terminalia chebula*, *Terminalia bellerica*, and *Emblica officinalis*, have demonstrated significant antioxidant, anti-diabetic, and anti-obesity properties. Wankhede SD et al., concluded that Gomutra Haritaki in managing *Sthaulya* (obesity) yielded notable improvements in fat metabolism, including a mean weight reduction of 3.5 kg and a BMI decrease of approximately 1.5 kg/m^2 [8]. The intervention also led to favourable changes in lipid profiles, with reductions in cholesterol and triglyceride levels. Additionally, waist circumference and obesity-associated symptoms such as fatigue and breathlessness showed marked improvement. The study emphasised Haritaki's potential in enhancing digestion and supporting healthy body weight.

Gurjar S et al., highlighted Triphala's efficacy in mitigating oxidative stress, improving dyslipidaemia, and enhancing metabolic activity, positioning it as a promising adjuvant in obesity management [9]. Similarly, Joglekar AA et al., investigated the therapeutic potential of *Abhaya Ghana Vati* (a concentrated extract of Haritaki) in conjunction with dietary and lifestyle modifications [10]. Their findings revealed reductions in BMI and waist circumference, along with improvements in metabolic parameters, underscoring

the synergistic benefits of Haritaki when integrated with holistic lifestyle interventions.

The phytochemical attributes of Haritaki and its role in addressing obesity-related complications have been further elaborated in recent reviews and clinical trials. Sultan MT et al., provided a comprehensive overview of *Terminalia chebula*, noting its capacity to regulate fat accumulation through polyphenolic compounds [11]. Salunke M et al., substantiated these findings through a double-blind, placebo-controlled clinical trial, which demonstrated significant reductions in anthropometric parameters and body composition indices [12]. Furthermore, Kakadiya J et al., explored the synergistic anti-obesity effects of Haritaki when combined with other herbal agents, concluding that its inclusion could substantially enhance weight reduction outcomes [13].

Haritaki thus emerges as a safe, natural, and cost-effective therapeutic option for managing overweight and obesity. Nevertheless, further rigorous clinical trials are essential to validate its long-term safety and efficacy across diverse populations. The present study aims to assess the effectiveness of *Haritaki Vati* based on reduction in weight, waist-hip ratio, and mid-arm circumference in overweight individuals.

Primary objectives:

- To assess the effect of *Haritaki Vati* on body weight (kg), BMI, waist-hip ratio, and mid arm circumference in the winter season only.
- To assess the effect of placebo on body weight (kg), BMI, waist-hip ratio, mid arm circumference in winter season only.
- To compare the effects of *Haritaki Vati* and placebo on weight (kg), BMI, waist-hip ratio, and mid arm circumference in the winter season only.

Null hypothesis (H0): *Haritaki Vati* will be equally or less efficacious than the standard treatment in the reduction of BMI in overweight.

Alternate Hypothesis (H1): *Haritaki Vati* will be more efficacious than the standard treatment in the reduction of BMI in overweight.

MATERIALS AND METHODS

This double-blind, randomised, placebo-controlled clinical trial will be conducted at Mahatma Gandhi Ayurved College Hospital and Research Centre, Salod (H), Wardha from December 2024 to December 2026. The Institutional Ethical Committee (IEC) provided the ethical approval (MGACHRC/IEC/Jun-2024/842). The study is registered under CTRI/2024/08/073134.

Inclusion criteria:

- Patients willing to give written informed consent to participate in the study.
- Age between 19 to 30 years of either sex.
- Patients having BMI in between 25-29.9 kg/m^2 [7].

Exclusion criteria:

- Subjects with drug-induced overweight or obesity.
- Subjects currently receiving anti-lipidaemic drugs or steroid medications.
- Subjects with a known case of hypothyroidism, diabetes mellitus, cardiovascular disease, renal disorders, or hypertension.
- Pregnant and lactating women.
- Subjects with any serious concomitant illness or systemic disease that is clinically significant and requires high-dose medication.
- Subjects with a history of alcohol consumption, drug dependence, or dependence on caffeine or nicotine.
- Subjects engaged in regular gym-based exercise or structured weight-loss programmes.

Withdrawal criteria:

- Subject is not willing to continue treatment.
- In the event of an adverse event, the subject will be withdrawn from the study. Any adverse event resulting from the study drug will be managed at no cost to the participant until resolution.

Sample size calculation: Baseline mean hip circumference: 114.60 cm

- Post-treatment mean hip circumference (day 84): 110.68 cm
- Mean difference (delta): 3.92 cm
- Standard Deviation (SD): 7.35 [14]

Statistical parameters assumed:

- Alpha (Type I error): 0.05
- Power (1 - Beta): 0.80
- Test: two-tailed, unpaired t-test
- Effect Size (Cohen's d): Delta/SD=3.92/7.35 ≈ 0.533 (moderate effect size)

Sample size formula: $n=((Z1\text{-alpha}/2+Z1\text{-beta})\times SD / Delta)^2\times 2$

Substituting the values: $n=((1.96+0.84)\times 7.35 / 3.92)^2\times 2$

$=(5.25)^2\times 2\approx 27.56\times 2=55.12\sim 56$

After adjusting for 5% dropout:

Adjusted total=56 / 0.9≈60, i.e., 30 per group

Subjects will be randomly divided into two groups using the lottery method. Group-A will receive *Haritaki Vati* at a dose of 2 g/day in divided doses, and Group-B will receive a placebo, starch tablets. The duration of both interventions will be 90 days [Table/Fig-1]. Both the subjects and assessors will be blinded to avoid bias.

Groups	Sample size	Treatment	Frequency	Treatment period	Assessment	Follow-up
Group-A	30	*Haritaki Vati*	2 tablets (500 mg each) twice daily	90 days	BMI, body weight, waist-hip ratio, mid-arm circumference	Days 30, 60, and 90
Group-B	30	Placebo (starch tablets)	2 tablets (250 mg each) twice daily	90 days	BMI, body weight, waist-hip ratio, mid-arm circumference	Days 30, 60, and 90

[Table/Fig-1]: Grouping and posology.

The raw materials, including *Haritaki* and starch, will be obtained from trusted suppliers and duly verified for authenticity by the Department of *Dravyaguna*, Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod (H), Wardha.

Overall, a thorough understanding of drug properties is fundamental for optimising therapeutic outcomes while minimising risks to patient health. The properties of *Haritaki* are detailed in [Table/Fig-2].

S. No.	Drug	Taste (*Rasa*)	Properties (*Guna*)	Potency (*Virya*)	Post digestive effect (*Vipaka*)	Therapeutic uses (*Karma*)
1.	*Haritaki [14]*	Sweet *(Madhur)*, Sour *(Amla)*, Pungent *(Katu)*, Bitter *(Tikta)*, Astringent *(Kashaya)*	Light *(Laghu)*, Dry *(Ruksha)*	Hot *(Ushna)*	Sweet *(Madhur)*	*Tridoshahara, Deepan, pachana, anulomana*

[Table/Fig-2]: Analytical properties of the Haritaki.

Preparation of the drug: The medicine will be prepared at the college Rasashala following established guidelines for medicine preparation. The trial drug, *Haritaki Vati*, is produced by shade-drying Haritaki (Terminalia chebula Retz.), followed by pulverisation

and sieving through a fine mesh to achieve a uniform powder. Wet granulation is conducted using gum acacia as a binder. The granules are then blended with talc as a lubricant, dried under controlled temperatures, resized, and compressed into uncoated tablets, each weighing 500 mg. These tablets are stored in airtight containers.

The placebo is prepared separately using pharmaceutical-grade starch as the main ingredient, following the same process. The placebo is compressed into tablets, each weighing 250 mg, and is also dried and packed in airtight containers to ensure stability until use [15].

Assessment criteria: Improvement in overweight patients will be evaluated using the following parameters:

1) Body weight will be measured on an empty stomach using a calibrated digital weighing scale accurate to 0.1 kg, with participants in light clothing, on days 0, 30, 60, and 90.
2) Body circumference- (chest, mid-arm, mid-thigh) [16].
   - Chest circumference:

     Chest circumference will be measured by encircling the tape around the most prominent area of the chest just below the armpits and across the shoulder blades while the participant stands upright with arms relaxed at the sides.
   - Arm circumference (usually mid-upper arm):
   - Position: The person should stand or sit with their arm relaxed and hanging by their side.
   - Location: The measurement should be taken at the midpoint between the acromion (shoulder tip) and the olecranon (elbow tip).
   - Procedure: A flexible, non-elastic measuring tape should be used, carefully wrapped around the arm without exerting pressure or compressing the skin. The measurement should be recorded in either centimetres or inches.
   - Mid-thigh circumference:

     Measure around the midpoint between the top of the thigh (inguinal crease) and the top of the knee (patella) while the person is standing with weight evenly distributed.
3) BMI- will be assessed on 0th, 30th, 60th, and 90th day [7,14] BMI change (kg/m^2) and the corresponding percentage improvement is illustrated in [Table/Fig-3].

Reduction in BMI (kg/m^2)	Improvement
<1	<25%
1-2	25-50%
2-3	50-75%
>3	>75%

[Table/Fig-3]: BMI change (kg/m^2) and the corresponding percentage improvement.

STATISTICAL ANALYSIS

All data will be analysed using SPSS version 17 (IBM Corp., Armonk, NY, USA) and presented in the form of tables and graphical representations for better interpretation. Continuous variables, including BMI, body weight, waist-to-hip ratio, and mid-upper arm circumference, will be expressed as mean±SD. Within-group changes will be evaluated using paired t-tests, while between-group comparisons will be conducted using unpaired t-tests. A p-value of less than 0.05 will be considered statistically significant.

Informed consent: Written informed consent will be obtained from all participants prior to their enrolment in the study. The consent form will clearly explain the study's purpose, procedures, duration, potential benefits, and possible risks. It will emphasise that participation is entirely voluntary and that individuals have the right to withdraw from the study at any time without any negative consequences. Confidentiality of participant information will be strictly maintained, and participants will be encouraged to ask questions to ensure clarity. Consent forms will be provided in both English and the local language to facilitate complete understanding [Table/Fig-4] presents the Gantt chart.

Scholar/Investigator	Dr. Vishal Chinchone					
Title	Evaluation of Efficacy of *Haritaki Vati* (*Terminalia Chebula Retz.*) vs Routine care in the management of *Sthaulya* (Overweight)- Randomised Controlled Trial					
Steps	Q1	Q2	Q3	Q4	Q5	Q6
Approval from IEC						
Review of literature						
Drug preparation						
Enrolment of the patients						
Data collection						
Statistical analysis						
Thesis writing						
Submission						

[Table/Fig-4]: Study protocol's Gantt chart.

Acknowledgement

The authors sincerely express their gratitude to Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod (H), Wardha, for providing the essential infrastructure and support required to carry out this work. Special appreciation is extended to the Department of *Dravyaguna* for their support in the authentication and preparation of *Haritaki Vati*. The authors also acknowledge all individuals who participated in the study. The contributions of the clinical and statistical teams are gratefully acknowledged for their support throughout the study.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Apr 23, 2025
- Manual Googling: Dec 01, 2025
- iThenticate Software: Dec 03, 2025 (1%)

ETYMOLOGY: Author Origin

EMENDATIONS: 6

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. Yes

Date of Submission: **Apr 17, 2025**
Date of Peer Review: **Jul 16, 2025**
Date of Acceptance: **Dec 05, 2025**
Date of Publishing: **May 01, 2026**