Research Protocol

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Ayurveda Section

Comparative Efficacy of *Medopachak Yoga* by Three Different Routes (*Basti*, *Udvartan*, Oral Route) in the Management of Obesity (*Sthoulya*): A Research Protocol

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ABSTRACT

Introduction: Obesity, or *Sthoulya*, is a metabolic disorder characterised by excessive fat accumulation that adversely affects overall health. It is defined as a Body Mass Index (BMI) greater than 30 kg/m². The global prevalence varies, with rates reported as 67% in the Americas and 31% in Southeast Asia and Africa. It is estimated that 16% of adults over 18 years of age will be obese by 2027. In Ayurveda, obesity is viewed as a nutritional illness (*Santarpanjanotha Vyadhi*) linked to vitiated *Kapha* and *Medha* due to *Medovaha Srotas Dushti*. *Acharya Charaka* states that *Udvartan*, which includes both dry and unctuous procedures, may contribute to the excessive accumulation of *Meda Dhatu* (fat tissue).

Need of the study: Obesity significantly contributes to numerous co-morbid conditions, including type 2 diabetes, hypertension, dyslipidaemia, osteoarthritis, and various cancers such as colon and breast cancer. Although conventional pharmaceutical and surgical treatments may offer short-term benefits, they are often associated with side effects, high costs, and poor long-term adherence. Ayurveda provides a safe, holistic, and personalised approach to managing *Sthoulya* by addressing both physical and psychological components. The primary therapeutic methods oral medication (systemic modulation), *Udvartan* (external stimulation), and *Basti* (colon cleansing)—have individually demonstrated effectiveness. However, comprehensive comparative studies evaluating their long-term efficacy are lacking. The present study aims to bridge this gap in integrative obesity management and provide scientific evidence for standardised Ayurvedic treatments, potentially influencing public health and clinical practice.

Aim: To evaluate the comparative efficacy of a *Medopachak* formulation (*Yoga*) administered through three different routes—*Basti* (enema), *Udvartan* (local application), and oral *Medopachak Ghana* tablets (*Vati*) in the management of obesity (*Sthoulya*).

Materials and Methods: A randomised controlled trial will be conducted from May 2025 to May 2026 at Mahatma Gandhi Ayurved College, Hospital and Research Centre, Datta Meghe Institute of Higher Education and Research, Salod (H), Wardha, Maharashtra, India A total of 78 patients will be enrolled and treated with the *Medopachak* formulation via three different routes. Group A: *Medopachak* formulation (*Yoga*) administered as *Basti* (enema) through the anal route for eight days. Group B: *Medopachak* formulation (*Yoga*) applied through *Udvartan* (local application) for eight days. Group C: *Medopachak Ghana* tablet (*Vati*), 250 mg two tablets with lukewarm water twice a day for 24 days. Objective parameters Body Mass Index (BMI), body weight, anthropometric measures, serum lipid profile, and skinfold thickness—will be assessed on days 16 and 24. Statistical analysis will include Analysis of Variance (ANOVA) paired t-test, or Wilcoxon Signed-rank test. A p-value <0.05 will be considered statistically significant.

Keywords: Anthropometric parameters, Body mass index, Body weight, Skin fold thickness

INTRODUCTION

Obesity is characterised by an excessive accumulation of body fat to the extent that it poses health risks [1]. A BMI above 30 kg/m² indicates a condition associated with chronic caloric excess [2,3]. In 2000, the World Health Organisation (WHO) recognised obesity as a serious yet underappreciated global public health concern [4]. Due to its established association with several chronic non communicable diseases including cardiovascular disease, type 2 diabetes mellitus, and certain cancers the issue has drawn substantial attention across both developed and developing countries [5]. Both general and abdominal obesity are linked with increased morbidity and mortality rates [6].

In 2022, approximately one billion adults aged 18 years and above were overweight, and over 890 million individuals were obese. Compared to 1990, when 25% of adults in the same age group were overweight, this represents a significant increase. According to the WHO, prevalence varies geographically, with 31% in Southeast Asia and Africa and 67% in the Americas. An estimated 16% of adults worldwide will be obese by 2022 [7]. Obesity is consistently identified as a major risk factor for numerous non communicable diseases, including type 2 diabetes, coronary heart disease, stroke, hypertension, hypercholesterolaemia, and certain cancers [8]. It is generally more common in females than in males [9].

In Ayurveda, obesity (*Sthoulya*) arises due to dysfunction (*Dushti*) of the fat-metabolism channels (*Medovaha Srotas*). It is considered a nutritional disorder (*Santarpanotha Vyadhi*) characterised by abnormal accumulation of *Meda Dhatu* (adipose tissue). According to *Acharya Charaka*, in *Vishama Jwara Chikitsa*, the herbs *Kiratatikta*, *Guduchi*, *Raktachandan*, and *Sunthi* are prescribed. These herbs act on the *Medovaha Srotas* and remove blockages by promoting digestion (Pachana) of *Meda Dhatu* in *Meda Ashrita Jwara*. Based-on the principle of *Dhatwagni Siddhanta*, these drugs may help restore fat metabolism and correct *Medodushti* [10].

REVIEW OF LITERATURE

In Ayurveda, the management of obesity (*Sthoulya*) focuses on enhancing tissue metabolism (*Dhatwagni*), eliminating toxins (Ama), and restoring balance in the fat channels (*Medovaha Srotas*). The proposed *Medopachak* formulation (*Yoga*), comprising *Kiratatikta* (Swertia chirata), *Guduchi* (Tinospora cordifolia), *Raktachandan* (Pterocarpus santalinus), and *Sunthi* (Zingiber officinale), aligns with these principles. This formulation specifically targets the *Medovaha Srotas*, improving the digestion and metabolism (*Pachana*) of *Meda Dhatu*, particularly in conditions such as *Meda Ashrita Jwara* [11].

The application of *Dhatwagni Siddhanta* emphasises optimising tissue-specific metabolic activity to counteract *Medodushti*, the core pathology of obesity. Research by Mushtaq S et al., reported that *Sunthi* contains bioactive compounds—gingerol, shogaol, and zingerone which exhibit thermogenic, hypolipidaemic, and anti-inflammatory effects. Evidence shows that ginger reduces plasma cholesterol, triglycerides, and Low-density Lipids (LDL) levels and is beneficial in metabolic and inflammatory disorders such as hyperlipidaemia, Irritable Bowel Disease (IBS) and obesity. Notably, daily consumption of 3 g of dried ginger powder has been shown to significantly reduce serum cholesterol in hyperlipidaemic patients [12].

Additionally, studies demonstrate the potential of *Raktachandan* (Pterocarpus santalinus) in treating hyperlipidaemia due to its diverse phytochemical composition, which protects against metabolic syndrome and obesity-related complications [13]. Research further underscores *Guduchi*'s established *Dipana* and *Rasayana* properties. While *Meda* and *Kapha* primarily derive from the *Jala* and *Prithvi Mahabhutas*, Dipana herbs are associated with *Agni* and *Vayu Mahabhutas*, providing a balancing effect on impaired fat metabolism.

Consequently, *Guduchi* helps reduce excess fat tissue (*Medas*) and *Kapha* at the level of Srothorodha, enhancing insulin function and thereby facilitating optimal fat and carbohydrate metabolism. Additionally, its combined actions metabolic stimulation (*Deepana*) and rejuvenation (*Rasayana Karma*) contribute to reducing oxidative stress, inhibiting lipid peroxidation, and mitigating free radical formation [14].

Kiratatikta (Swertia chirata) is recognised as a potent bitter tonic with established hypocholesterolaemic and hypotriglyceridaemic effects, significantly reducing serum cholesterol, LDL, and triglyceride levels. Further biochemical analysis of its phytoconstituents may provide deeper insights into the therapeutic mechanisms underlying its lipid-lowering properties [15].

Thus, the *Medopachak* formulation exerts a comprehensive influence on fat metabolism, systemic detoxification, and the clearance of metabolic channels. The route of administration plays a crucial role in determining its overall efficacy [16]. Currently, no standardised data exist regarding the comparative effectiveness of different routes of administration in the management of obesity (*Medoroga*). Accordingly, present study is designed to evaluate the relative efficacy of the *Medopachak* formulation (*Yoga*) through three distinct delivery methods—enema (*Basti*), local application (*Udvartan*), and oral administration via *Medopachak Ghana* tablets (*Vati*)—to determine the most effective approach for managing obesity (*Sthoulya*).

Primary objectives:

- To assess the efficacy of *Medopachak* formulation (*Yoga*) administered as enema (*Basti*) on body weight, BMI, anthropometric parameters, and serum lipid profile.
- To assess the efficacy of *Udvartan* using the *Medopachak* formulation (*Yoga*) on body weight, BMI, and serum lipid profile.
- To assess the efficacy of orally administered *Medopachak* formulation tablets (*Vati*) on body weight, BMI, and serum lipid profile.
- To compare the efficacy of the *Medopachak* formulation (*Yoga*) administered by three different routes—*Basti*, *Udvartan*, and oral route—in the management of obesity (*Sthoulya*).

Null Hypothesis (H0): There will be no significant difference in the efficacy of the *Medopachak* formulation when administered via enema (*Basti*), local application (*Udvartan*), or oral tablets (*Vati*) in managing obesity (*Sthoulya*).

Alternative Hypothesis (H1): *Medopachak Yoga* administered through the anal route (*Basti*) will be more efficacious than the oral route (*Vati*) and local application (*Udvartan*) in the management of obesity (*Sthoulya*).

MATERIALS AND METHODS

A randomised controlled trial will be conducted from May 2025 to May 2026 at Mahatma Gandhi Ayurved College, Hospital and Research Centre, Datta Meghe Institute of Higher Education and Research, Salod (H), Wardha, Maharashtra, India. The study has been approved by the Institutional Ethics Committee at DMIMS, Wardha, Maharashtra, India (Approval No.: MGACHRC/IEC/Jun-2024/847), and registered with the Clinical Trials Registry–India (CTRI/2024/07/071258). The study will commence once written informed consent is obtained from all participants.

Inclusion criteria: Patients diagnosed with obesity as per the International Classification of Diseases (ICD) criteria [17]. Participants willing to participate and able to provide written informed consent. Subjects of either sex aged 20-40 years. BMI≥30-40 kg/m^2. Patients deemed fit to undergo all three interventions: *Basti*, *Udvartan*, and oral administration of the study drug.

Exclusion criteria: Patients with Diabetes Mellitus (DM), cardiovascular disease, kidney disorders, known cases of hypothyroidism, or drug-induced obesity. Pregnant or breastfeeding women. Participants who develop additional ailments during the course of treatment. Patients contraindicated for *Udvartan*. Patients contraindicated for *Basti*.

Sample size calculation: Sample size will be calculated using Cohen's effect size by comparing two means for BMI.

1.6 reduction in BMI in experimental group,

1.4 reduction in BMI in control group as per the pilot study findings,

Pooled standard deviation is 0.25,

Effect size=d=$\frac{\mu_2-\mu_1}{\sigma}$=0.8,

Considering large effect size difference=0.8 (Large effect size)

Sample size $N = \left(\frac{1+r}{r}\right)\frac{(Z_{1-\alpha/2}+Z_{1-\beta})^2}{d^2} + \frac{Z^2_{1-\alpha/2}}{2\,(1+r)}$

$Z_{1-\alpha/2}$ at 5 % level of significance = 1.96

$Z_{1-\beta}$ at 80 % Power = 0.84

Ratio allocation (Group-2/Group-1) = 1

Sample size $n = \left(\frac{1+1}{1}\right)\frac{(1.96+0.84)^2}{0.8^2} + \frac{(1.96)^2}{2\,(1+1)} = 26$ per group.

A total of 78 subjects will be enrolled in the trial and divided into three groups: A, B, and C. Group A will receive the *Medopachak* formulation (*Yoga*) enema (*Basti*) through the anal route for eight days. Group B will receive *Medopachak* formulation *Udvartan* through local application for eight days. Group C will receive *Medopachak* formulation *Yoga* tablets (*Ghana Vati*) orally, 250 mg two tablets twice daily with lukewarm water for 24 days.

Raw materials for the *Medopachak Yoga Dravya* will be collected from the local market and authenticated by Dattatreya Ayurveda Rasashala, Salod (H), Wardha [Table/Fig-1].

Study Procedure

Preparation of *Medopachak Ghana Vati* (Tablet) [18]: The preparation begins with the collection, cleaning, and grinding of all

S. No.	Ingredient	Botanical name	*Rasa*	*Guna*	*Virya*	*Vipaka*	*Doshaghanta*	Reference
I	*Sunthi*	*Zingiber officinale*	*Katu*	*Lagha Snighdha*	*Ushna*	*Madhur*	*Kapha Vataghna Agnideepan Amapachak*	*Bhavaprakasha Nighantu*
II	*Guduchi*	*Tinospoa cordiofolia*	*Kashay Tikta*	*Laghu Snighdha*	*Ushna*	*Madhur*	*Balance tridosha Agnideepan Aamhara pramehhara*	*Bha. Pra. Nighantu*
III	*Kiratatikta*	*Swertia chiraita*	*Tikta*	*Laghu ruksha*	*Sheeta*	*Katu*	*Tridoshaghna*	*Bha. Pra. Nighantu*
IV	*Rakta Chandana*	*Terocarous sanataliums*	*Tikta, Madhur*	*Guru ruksha*	*Sheeta*	*Katu*	*Kapha pitta shamaka*	*Bha. Pra. Nighantu*

[Table/Fig-1]: Details of the drug used for the preparation of *Medopachak yoga* with its Latin name and properties *Bhavaprakasha Nighantu* (*Bha. Pra. Nighantu*).

ingredients using a *khalva yantra*, a traditional grinding tool. The finely powdered components are placed in a large vessel and mixed with eight parts of water. The mixture is gently heated on a mild flame until its volume reduces to one-fourth. After reduction, the liquid is strained through a clean cloth into another container. The resulting thick extract (*Ghana*) is then moulded into tablets of the required size, dried in the shade, and stored in an airtight container to maintain its quality.

***Basti* preparation method** [19]:

Ingredients:

- *Madhu* (Honey): 192 mL
- *Saindhava* (Rock salt): 12 gm
- *Sneha* (Medicated oil or *ghee):* 192 mL
- *Kalka* (*Medopachak Yoga Dravya* paste): 96 mL
- *Kwath* (*Medopachak Yoga Dravya* decoction): 480 mL

Procedure:

- Honey addition: Place 192 mL of honey in a clean vessel.
- Add *Saindhava*: Add 12 g of rock salt and mix thoroughly.
- Add *Sneha*: Incorporate 192 mL of medicated oil or ghee and blend to a uniform consistency.

4. Add *Kalka*: Add 96 mL of the *Medopachak Yoga Dravya* paste and mix well.
5. Prepare *Kwath*: Boil 120 g of *Medopachak Dravya* in 4 L of water and reduce it to 480 mL. Add the *Kwath* to the mixture and mix thoroughly.

This sequential method ensures proper emulsification, which is essential for the therapeutic efficacy of the *Basti* formulation. The final mixture is filtered through a clean cloth and placed in a vapour bath to warm it before administration [20].

Details of the sequence of *Niruha Basti* and *Anuvasan Basti* are provided in [Table/Fig-2] [21].

Days	1	2	3	4	5	6	7	8
Basti	*Niruha*	*Niruha*	*Niruha*	*Anuvasn*	*Niruha*	*Niruha*	*Nruha*	*Anuvasan*

[Table/Fig-2]: Details of sequence of *Niruha Basti* and *Anuvasan Basti* [21].

Enema (*Basti*): Before administering the medicine via the anal route, all equipment and materials must be prepared. The procedure room should be clean, free from dust and direct airflow, well-lit, and equipped with a massage table, *Basti dravya*, towels, cotton, a rubber catheter, massage oil (*Abhyangarth Taila*), and sudation materials.

Informed consent will be obtained before the examination and procedure. Patient evaluation is essential to determine the most suitable *Basti Yoga*, considering *Dosha-Dusya*, *Satmya, Agni*, *Satva, Vaya, Bala*, and *Avastha*.

Before administering *Basti*, the patient should have an empty stomach. Full-body massage and fomentation (*sarvanga snehan* and *swedan*) are performed. The patient is positioned in the left lateral position (*Vama Parshva*) with the right leg flexed. The lubricated catheter is inserted one-fourth of its length into the anal canal, and lukewarm *Basti dravya* is administered slowly using the *Basti Putaka*, infusing 960 mL of *Kwath* once daily for eight days.

The *Basti Putaka* is held high to avoid obstruction, and the catheter is withdrawn gently. Care will be taken to prevent complications of *Basti Vayapad*.

After the procedure (*Paschat Karma*), the patient remains in a supine position for 48 minutes.

Partyagaman kaal of *Niruha Basti* is 48 minutes

Post-procedure diet: *Mamsa Rasa* or *Yusha*, followed by warm water (*Ushna Jala*) or *Dhanyanagara Siddha Jala*.

The adequacy of *Basti* will be assessed using *Samyaka* and *Asamyaka Lakshanas*.

***Udavartan* collection of material (*Sambhar Sangraha*):** All equipment and *Medopachak Yoga Choorna* should be prepared in advance. The room must be clean, free from direct airflow, and properly lit. The room where *the* procedure *Udvartan* has to be performed should be free from dust and direct flow of air, with appropriate lighting, massage table*, and Choorna.*

Examination of patient (*Rogi pariksha*): Consent will be obtained. The patient is examined to document *Prakriti, Vikriti,* and morbidity details. The patient thoroughly examined the basic constitution *(Prakriti*) and *(vikriti)* details of morbidity, which are documented in detail.

Main procedure (*Pradhan Karma*): The patient lies in the supine position. *Medopachak Yoga Choorna* is applied, and massage is performed simultaneously on both sides to ensure uniformity.

Post procedure (*Paschat Karma*): The herbal powder is removed using a sterile cloth or cotton. Steaming (*Swedana*) is then performed for about 15 minutes or as per the patient's *Prakriti* and *Vikriti*.

***Medopachak Ghan Vati*:** Patients will take two tablets (250 mg each) before meals with lukewarm water.

Details of grouping, posology, treatment duration, and follow-up periods are provided in [Table/Fig-3].

Group	Sample size	Intervention	Dose and frequency	Duration	Follow-up
A	26	*Medopachak Yoga Basti* regime *(Niruha basti* with *Medopachak yoga+Anuvasan Basti* with *Til Taila* 60ml), i.e.3 *Niruha* followed by 1 *Anuvasan* i.e. total 6 *Niruha* and 2 *Anuvasan*	960 mL (*Niruha Basti*) 60 mL (*Anuvasan Basti*)	8 days	0,16th, 24th day
B	26	*Udavartan Medopachak Yoga*	250 mg L/A once a day	8 days	0,16th, 24th day
C	26	Oral route *Medopachak Yoga Ghana Vati*	250 mg 2-tab BD with lukewarm water before food	8 days	0,16th, 24th day

[Table/Fig-3]: Detail of grouping and posology along with the treatment period and follow-up period.

Outcomes

1. **Body weight:** Measured in kilograms using a CROWN Victoria deluxe manual analogue weighing scale (Ramon Surgical Company, ISO-9001 certified). Measurements will be taken in similar clothing and in a fasting state at baseline, Day 16, and Day 24.
2. **Body Mass Index (BMI):** Calculated using international BMI criteria [22].

3. **Anthropometric Assessment/body circumference** [23]: Measurements will be taken before and after treatment at: Chest (at nipple level); Abdomen (at umbilicus); Hip (largest buttock circumference); Mid-thigh (mid-point between knee and pelvis); Mid-arm (mid-point between shoulder and elbow).
4. **Lipid profile** [24]: Serum Cholesterol: <200 mg/dL

Serum Cholesterol: <200 mg/dL

Triglycerides: <150 mg/dL

High-density Lipid (HDL): >60 mg/dL

LDL: <130 mg/dL

Very Low-density Lipid (VLDL): <30 mg/dL

Outcomes will be assessed at baseline, Day 16, and Day 24. The research methodology timeline has been depicted in [Table/Fig-4].

Scholar/Investigator	Dr. Shubham Kalode							
Title	Evaluation of comparative efficacy of *Medopachak Yoga* by three different routes (*Basti, Udvartan,* Oral Route) in the Management of obesity (*Sthoulya*).							
Steps	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
Approval from IEC								
Literature of review								
Preparation of drug								
Enrolment of patient								
Collection of data								
Statistical analysis								
Thesis writing								
Submission								

[Table/Fig-4]: The reesearch methology timelime.

STATISTICAL ANALYSIS

Statistical analysis will be performed using Statistical Packages of Social Sciences (SPSS) version 7.0. One-way ANOVA will compare mean values across the three groups. Post-hoc tests (e.g., Tukey's Honestly Significant Difference (HSD) will be performed if, ANOVA indicates a significant difference. A p-value<0.05 will be considered statistically significant.

Criteria for discounting or modifying allocated intervention: Any adverse effects will be reported to the ethics committee. Appropriate treatment will be provided for adverse events. If participants choose to withdraw, they will be asked to specify their reasons.

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