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Research Protocol

Ayurveda Section

# Efficacy of *Mushkakadi Gana Udvartana* versus *Triphala Gana Udvartana* in the Management of Obesity (*Sthoulya*): A Randomised Control Trial Protocol

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## ABSTRACT

**Introduction:** Obesity, as defined by the World Health Organisation (WHO), is a condition characterised by excessive fat accumulation, marked by a Body Mass Index (BMI) of 30 kg/m² or higher, and associated with substantial health complications. Its global prevalence is heterogeneous, affecting approximately 67% of the population in America and 31% in Southeast Asia and Africa. By 2027, it is estimated that 16% of adults will be classified as obese. This condition adversely impacts both physical and mental health and serves as a precursor to numerous co-morbidities, including diabetes, hypertension, atherosclerosis, gallstones, osteoarthritis, and infertility. In Ayurveda, obesity is correlated with *Sthoulya*, a metabolic disorder resulting from impaired anabolic processes.

**Need of the study:** Obesity, recognised as a global epidemic by WHO, is primarily driven by sedentary lifestyles. It is strongly associated with an increased risk of hypertension, type 2 diabetes, coronary heart disease, hyperlipidaemia, arthritis, and several cancers, including those of the colon, gallbladder, biliary tract, breast, endometrium, and cervix. As obesity rates continue to rise, exploring natural remedies such as dry powder massage (*Udvartana*) is essential for effective weight management and symptom relief while minimising adverse side-effects. Pharmacological selection plays a crucial role in Ayurvedic management. The *Mushkakadi Gana* group of drugs, known for its Kapha-pacifying (*Kaphagna*) and fat-reducing (*Medogna*) properties, shows therapeutic potential. However, clinical trials evaluating its efficacy are limited.

**Aim:** To evaluate the efficacy of *Mushkakadi Gana Udvartana* and *Triphala Gana Udvartana* in the management of obesity (*Sthoulya*).

**Materials and Methods:** This study is designed as a randomised controlled trial and will be conducted at Mahatma Gandhi Ayurved College, Hospital, and Research Centre, Salod, Hirapur (H), Maharashtra, India over a period of 18 months (January 2025 to January 2026). A total of 60 patients will be enrolled and randomly divided into two groups. Group A (n=30): Will receive *Udvartana* with *Triphala Gana Churna* (control group). Group B (n=30): Will receive *Udvartana* with *Mushkakadi* Gana Churna (experimental group). The intervention will be administered for a duration of 15 days. Therapeutic outcomes will include reduction in body weight, BMI, skin fold thickness, anthropometric measurements, and serum lipid profile. Statistical analysis will be performed using Statistical Package for the social sciences (SPSS) version 17.0 software. An independent sample t-test will be used to compare baseline characteristics between groups, and a paired t-test will be applied for within-group comparisons. A p-value <0.05 will be considered statistically significant.


**Keywords:** Body mass index, Diabetes, Fat-reducing, Kapha-pacifying

## INTRODUCTION

Obesity is defined by WHO as a bodily disorder characterised by excessive fat accumulation to the extent that it significantly impairs health [1]. It is clinically defined as a Body Mass Index (BMI) of 30 kg/m² or above [2]. Excessive fat accumulation adversely affects both physical and mental wellbeing. Obesity is a leading cause of disability and a major risk factor for a variety of disorders, including diabetes, hypertension, atherosclerosis, cholelithiasis, osteoarthritis, and infertility. Previously, it was considered a condition confined to industrialised nations; however, urbanisation and the westernisation of lifestyles have made it increasingly prevalent in developing countries, particularly among individuals belonging to higher socioeconomic groups. In India, obesity has emerged as a significant public health concern in the 21st century, with morbid obesity affecting approximately 5% of the population [3]. It is estimated that about 41.5% of the world's adult population suffers from abdominal obesity, yet it remains one of the most neglected health issues [4]. According to the WHO (2016), the global prevalence of obesity has been rising steadily since 1975. In 2016, 39% of adults aged 18 years and older were overweight, and 13% were obese [5]. Recent surveys indicate that approximately 16% of adults worldwide were obese in 2022 [6].

Obesity can be prevented through public awareness campaigns that emphasise the health risks of obesity and the importance of a healthy lifestyle, including balanced nutrition and regular physical activity [7]. Modern medical science offers various therapeutic approaches for obesity management, including dietary modification, physical exercise, pharmacotherapy, and surgical interventions. However, these methods often have notable limitations, such as neurological and psychological side-effects, gastrointestinal disturbances (e.g., oily stools, faecal urgency), and deficiencies in fat-soluble vitamins [8]. Therefore, there is a need to explore simple yet effective treatment options in alternative systems of medicine, such as Ayurveda. In Ayurveda, obesity corresponds to *Sthoulya*, a *Kapha*-predominant disorder. It is categorised as a disease arising from impaired anabolic (metabolic) processes [9]. Descriptions of *Sthoulya* are found in *Charaka Samhita* under *Ashtouninditiya Adhyaya* (the chapter describing eight undesirable body constitutions), where individuals with obesity are described as suffering from disproportionate body parameters and social disapproval.

The Ayurvedic line of treatment for *Sthoulya* includes both *Shamana* (pacification) and *Shodhana* (detoxification) therapies. *Shodhana* can be classified into internal and external purification methods. Among these, *Udvartana*- a form of external detoxification (*Bahya*

*Shodhana*)- is particularly beneficial for obesity management. This therapy eliminates vitiated doshas through the skin and promotes fat reduction. *Udvartana* possesses *Kapha*-reducing (*Kaphahara*) and fat-reducing (*Medohara*) properties. In the treatment of obesity, *Udvartana* is performed using herbal powders (*Churna*) in a dry form rather than oils, enhancing its efficacy in reducing fat and improving metabolic balance.

## REVIEW OF LITERATURE

Ayurvedic literature on the management of *Sthoulya* reveals that considerable research has been conducted on the effectiveness of various Ayurvedic treatment approaches. Wadnerwar NN, evaluated the impact of medicated oil enema (*Shigru Taila Vasti*) in the management of obesity (*Sthoulya*), focusing on objective parameters such as body weight, BMI, and body circumferences. The study reported reductions in all measured parameters, with particularly notable improvements in abdominal and hip circumferences. These findings suggest that Shigru Taila Vasti has the potential to enhance fat metabolism, promote internal cleansing processes, and thereby prove effective in the management of *Sthoulya* [3]. Verma S et al., performed a comparative analysis of *Gomaya Mashi Udvartana* and *Rodhradi Gana Udvartana*, both combined with *Peti Swedana*, for the management of obesity. The study focused on objective parameters such as body weight, BMI, skinfold thickness, and general body measurements. Both treatment modalities showed significant reductions in obesity-related markers; however, *Gomaya Mashi Udvartana* demonstrated slightly superior outcomes [8]. Patil UA, conducted a comparative study on *Triphaladi Taila Abhyanga* and *Triphala Churna Udvartana* for the management of *Sthoulya*, assessing objective parameters such as body weight, BMI, skinfold thickness, and body circumferences. Both treatments yielded significant results; however, *Triphala Churna Udvartana* demonstrated greater reductions in weight, BMI, and skinfold thickness. The study highlights the superior efficacy of dry powder massage (*Udvartana*) as a natural therapeutic approach for obesity management [10].

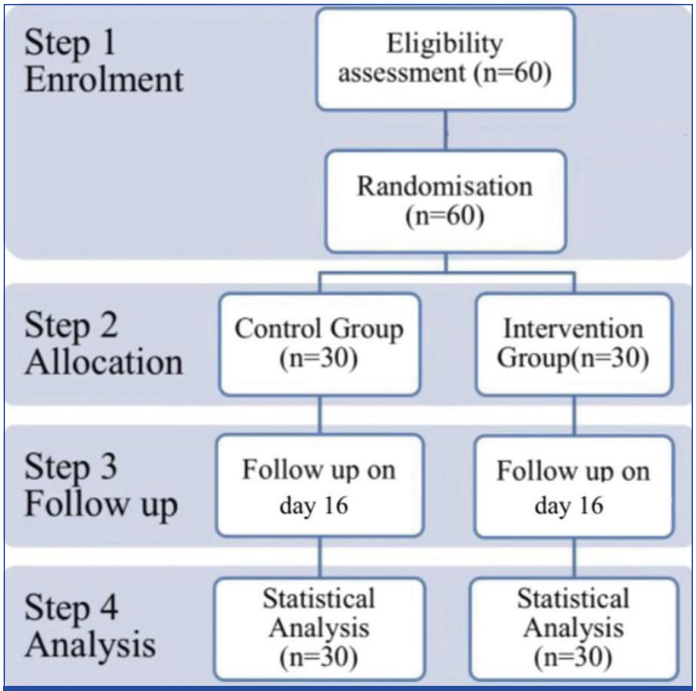
### Objective

1. To assess the efficacy of *Mushkakadi Gana Udvartana* in obesity (*Sthoulya*) in terms of weight (kg), BMI (kg/m$^2$), anthropometric measurements (cm), and skinfold thickness (cm).
2. To assess the efficacy of *Triphala Gana Udvartana* in obesity (*Sthoulya*) in terms of weight (kg), BMI (kg/m$^2$), anthropometric measurements (cm), and skinfold thickness (cm).
3. To compare the efficacy of *Mushkakadi Gana Udvartana* and *Triphala Gana Udvartana* in obesity (*Sthoulya*) in terms of weight (kg), BMI (kg/m$^2$), anthropometric measurements (cm), and skinfold thickness (cm).
4. To assess and compare the efficacy of *Mushkakadi Gana Udvartana* and *Triphala Gana Udvartana* in obesity (*Sthoulya*) in terms of biochemical parameters-specifically, the serum lipid profile.

## MATERIALS AND METHODS

This study is designed as a randomised controlled trial and will be conducted at Mahatma Gandhi Ayurved College, Hospital, and Research Centre, Salod, Hirapur (H), Maharashtra, India over a period of 18 months (January 2025 to January 2026). Ethical clearance for the study has been obtained from the Institutional Ethics Committee of Datta Meghe Institute of Medical Sciences (DMIMS), Wardha, Maharashtra, India (Approval No.: MGACHRC/IEC/Jun-2024/845). The trial has also been registered with the Clinical Trials Registry of India (CTRI/2024/07/071330). The study will commence after obtaining written informed consent from all participants.

Participants for this trial will be selected from specialised peripheral camps as well as from the Mahatma Gandhi Ayurved College, Hospital and Research Centre, Salod (H), Wardha, Maharashtra. [Table/Fig-1] shows CONSORT flowchart. A total of 60 participants will be enrolled and divided into two groups:




**[Table/Fig-1]:** CONSORT flowchart.

**Group A (n=30):** *Udvartana* with *Triphala Gana Churna* for 15 days (Control group).

**Group B (n=30):** *Udvartana* with *Mushkakadi Gana Churna* for 15 days (Experimental group) [Table/Fig-2].

| Group | Sample size | Intervention | Dose and frequency | Procedure time | Duration | Follow-up |
|---|---|---|---|---|---|---|
| A | 30 | *Udvartana* with *Triphala Gana churna* | 250 grams per day | 30-45 min | 15 days | 16$^{th}$ day |
| B | 30 | *Udvartana* with *Mushkakadi Gana* | 250 grams per day | 30-45 min | 15 days | 16$^{th}$ day |

**[Table/Fig-2]:** Shows grouping and posology along with the treatment period and follow-up period.

**Inclusion criteria:** Patients willing to participate in the study after signing informed consent. Patients between the age group of 20-60 years, of either sex. Patients having BMI between 30-40 kg/m$^2$ will be included in the study.

**Exclusion criteria:** Known cases of diabetes mellitus, cardiovascular disorders, or renal disorders. Drug-induced obesity. Patients with hypothyroidism, PCOS, or PCOD. Patients with any skin ailments. Pregnant or lactating women. Patients not willing to continue the treatment. Patients who develop any other illness during the course of treatment will be excluded from the study.

**Sample size calculation:** Formula for sample size calculation for comparing two proportions (overall efficacy of marked improvement) [10]:

$$n \geq \{(Z_{(1-\alpha/2)} \sqrt{(p(1-p)(1+1/r)} + Z_{(1-\beta)} \sqrt{(p_1(1-p_1) + p_2(1-p_2)/r)}\}^2 / (p_2 - p_1)^2$$

Where: n: Sample size per group. Z (1-α/2): Z-score corresponding to the significance level (α)= α=0.05: $Z_{(1-\alpha/2)}$=1.96 (two-tailed test). $Z_{(1-\beta)}$: Z-score corresponding to the power (β)=0.84 $p_1$: Proportion in Group-1 =13%=$p_1$=0.1333: Proportion in Group 1 [10].

Considering 30% clinical superiority level $p_2$: Proportion in Group 2= 43% $p_2$=0.4333: Proportion in Group-2. p: Average proportion {($p_1$ + $rp_2$)/(1+r)}. r: Ratio of Group-2 to Group-1 (allocation ratio).

Calculate the average proportion (p): $p=(p_1 + rp_2) / (1 + r)=(0.1333 + 1\times0.4333) /(1 + 1)=0.2833$

$n \geq \{(1.96) \sqrt{} (0.2833(1-0.2833) (1+1/1)) + 0.84\sqrt{}(0.1333(1-0.1333) + 0.4333(1-0.4333)/1))\}^2 / (0.4333- 0.1333)^2$

Minimum sample size required per group: 35, Total sample size required: 70.

## Details of Drug Preparation

**Drug collection/Authentication:** *Mushkakadi Gana Dravya* will be procured from the local market and authenticated by Dattatreya Ayurveda Rasa Shala, Salod (H), Wardha [Table/Fig-3] [11].

| Name | Latin name | *Rasa* | *Guna* | *Veerya* | *Vipaka* | *Doshgati* |
|---|---|---|---|---|---|---|
| *Mushkaka* | *Schrebera swietenioides* | Pungent, bitter (*Katu, Tikta*) | Absorptive (*Grahi*) | Hot (*Ushna*) | Pungent (*Katu*) | Pacifies *Kapha and vata* (*Kapha-vatashamak*) |
| *Snuhi* | *Euphorbia nerifolia* | Pungent (*Katu*) | Light, Sharp (*Lagutikshna*) | Hot (*Ushna*) | Pungent (*Katu*) | Pacifies *Kapha and vata* (*Kapha vatahara*) |
| *Amalaki* | *Emblica officinalis* | Sour dominant taste (*Amla Pradhan Pancharasa*) | Light, Dry (*Laghuruksha*) | Cold (*Sheeta*) | Sweet (*Madhur*) | Balances all three doshas (*Tridoshashamak*) |
| *Haritaki* | *Terminalia chebula* | Astringent dominant (*Kashaya Pradhan pancharasa*) | Light, Dry (*Laghu ruksha*) | Hot (*Ushna*) | Sweet (*Madhur*) | Balances all three doshas (*Tridoshashamak*) |
| *Vibhitaki* | *Terminalia bellirica* | Astringent (*Kashaya*) | Light, Dry (*Laghu ruksha*) | Hot (*Ushna*) | Pungent (*Katu*) | Balances all three doshas (*Tridoshashamak*) |
| *Chitraka* | *Plumbago zeylanica* | Pungent (*Katu*) | Light, Dry (*Laghu ruksha*) | Hot (*Ushna*) | Pungent (*Katu*) | Pacifies *Kapha and vata* (*Kapha-vatashamak*) |
| *Palash* | *Butea monosperm* | Pungent bitter (*Katutikta*) | Light, Dry (*Laghu ruksha*) | Hot (*Ushna*) | Pungent (*Katu*) | Pacifies *Kapha and vata* (*Kapha-vatashamak*) |
| *Dhav* | *Anogeissus latifolia* | Astringent (*Kashaya*) | Light, Dry (*Laghu ruksha*) | Cold (*Sheeta*) | Pungent (*Katu*) | Pacifies Kapha and pitta (*Kapha-pitta shamak*) |
| *Shimshipa* | *Dalbergia sissoo* | Astringent pungent bitter (*Kashaya katu tikta*) | Light, Dry (*Laghu ruksha*) | Hot (*Ushna*) | Pungent (*Katu*) | Balances all three doshas (*Tridoshashamak*) |

**[Table/Fig-3]:** Shows the name of the drug used in the preparation of *Mushkakadi Gana Churna* with its Latin name and properties [11].

**Preparation method:** Fine powders of all the drugs will be taken in equal quantities and thoroughly mixed. The prepared combination will be stored in airtight containers for use during the study.

***Udvartana karma***

**1. Preprocedure *(PoorvaKarma)***

**Collection of material and instruments *(Sambar Sangraha)*:** The procedure should be conducted in a clean, well-lit area, free from airborne pollutants such as smoke or dust. All required materials and equipment should be collected prior to the procedure, including *Mushkakadi Gana Churna* and *Triphala Gana Churna*.

**Examination of patient *(Rogi Pariksha)*:** The procedure will be explained to each patient in detail, and informed consent will be obtained beforehand. A thorough examination will be conducted based on *Prakriti* (body constitution) and *Vikriti* (morbidity), and findings will be documented.

**2. Main procedure *(Pradhanakarma)*:** The patient should wear minimal clothing and lie comfortably on the procedure table in a supine position. *Udvartana* will be performed in all seven prescribed positions. The massage will be carried out simultaneously and synchronously on both sides of the body to maintain uniform pressure and rhythm. The herbal powders used will be *Mushkakadi Gana Churna* and *Triphala Gana Churna*.

***Postprocedure* (*Paschatakarma*):** After completing *Udvartana*, the patient's body will be cleansed using a sterile cloth, tissue, or cotton to remove any remaining herbal powder. Full-body steam therapy (*Swedana*) will then be administered. The duration of *Swedana* will vary depending on the patient's *Prakriti* and *Vikriti*.

**Assessment parameters:** Fasting blood glucose levels will be recorded as one of the biochemical assessment parameters.

**Objective Parameters:**

1. **Body weight:** The patient's body weight (in kilograms) will be measured on an empty stomach, with minimal clothing.
2. **BMI:** BMI will be calculated according to the World Health Organisation (WHO) international criteria [12].

   Weight Status and BMI (kg/m$^2$):

   Underweight: <18.5

   Normal range: 18.5-24.9

   Overweight: 25.0-29.9

   Obese: >30

   Class I Obesity: 30.0-34.9

   Class II Obesity: 35.0-39.9

   Class III Obesity: >40
3. **Anthropometric measurements [13]:** The following body parts, where adiposity is typically found, will be measured using a non stretchable measuring tape before and after treatment:
   - Chest circumference: Measured at the level of the nipples during normal expansion.
   - Abdominal circumference: Measured at the level of the umbilicus.
   - Hip circumference: Measured at the point of maximum buttock protrusion.
   - Mid-thigh circumference: Measured midway between the knee and pelvic joints.
   - Mid-arm circumference: Measured midway between the shoulder and elbow joints. Mean values for each measurement and circumference will be recorded before and after treatment, along with body weight.
4. **Serum lipid profile [14]:** The following biochemical parameters (in mg/dL) will be assessed and compared with their normal reference ranges:

| Parameter | Normal range (mg/dL) |
|---|---|
| Serum Cholesterol | <200 |
| Serum Triglycerides (TG) | <150 |
| Serum HDL | >60 |
| Serum LDL | <130 |
| Serum VLDL | <30 |

5. **Skin fold thickness (in cm):** Skin fold thickness will be measured at four sites- abdomen, mid-axilla, quadriceps, and triceps- using a skin fold caliper, before and after treatment.

**Outcome Measures**

**Primary outcome:** Reduction in body weight (in kg) and BMI (in kg/m$^2$).

**Secondary outcome:** Reduction in anthropometric measurements (in cm), skin fold thickness (in cm), and biochemical parameters (serum lipid profile). The Gantt chart is shown in [Table/Fig-4].

| Scholar/Investigator | Dr. Kashmira N Bhaidkar | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Title | Evaluation of Comparative Efficacy of *Mushkakadi Gana Udvartana* Vs. *Triphala Gana Udvartana* in the management of Obesity (*Sthoulya*) | | | | | | | |
| Steps | Q1 | Q2 | Q3 | Q4 | Q5 | Q6 | Q7 | Q8 |
| IEC authorisation | | | | | | | | |
| Overview of the literature | | | | | | | | |
| Medicine preparation | | | | | | | | |
| Patients enrolled | | | | | | | | |
| Collection of data | | | | | | | | |
| Analysis | | | | | | | | |
| Writing of thesis | | | | | | | | |
| Submission | | | | | | | | |

**[Table/Fig-4]:** Participant timeline.

## STATISTICAL ANALYSIS

Statistical analysis will be performed using SPSS version 17.0 software. Independent sample t-test will be applied for comparison of baseline characteristics between the two groups. Paired t-test will be used for within-group comparisons. A p-value of <0.05 will be considered statistically significant.

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