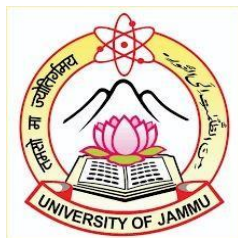


**UNIVERSITY OF JAMMU
JAMMU & KASHMIR**



COMPLETE PROFORMA FOR REGISTRATION OF SUBJECT FOR DISSERTATION

SYNOPSIS BY

DR. APURVA GUPTA

**FOR THE DEGREE OF AYURVEDA VACHASPATI
M.D. (AYURVEDA) IN KAYACHIKITSA
DEPARTMENT OF PG STUDIES IN KAYACHIKITSA,
JAMMU INSTITUTE OF AYURVEDA AND RESEARCH, JAMMU – 181123**

TITLE OF THE SYNOPSIS

**“A RANDOMIZED CLINICAL STUDY ON *KRIMIGHANADI KASHAYA* IN
STHOULYA WITH SPECIAL REFERENCE TO OBESITY”**

GUIDED BY

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CERTIFICATE OF SUPERVISION

This is to certify that we will supervise the thesis/research work of **DR. APURVA GUPTA** 1st Year M.D. student, the synopsis of which titled as “**A RANDOMIZED CLINICAL STUDY ON KRIMIGHANADI KASHAYA IN STHOULYA WITH SPECIAL REFERENCE TO OBESITY**” is enclosed here with, for the research work to be done during the second and third year of M.D *Kayachiktisa*. The Synopsis submitted is selected and prepared under our guidance.

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ENROLLMENT NO.	

DATED :-

SIGNATURE OF SCHOLAR

INTRODUCTION

Ayurveda is the most ancient healing science and ideal approach for an appropriate life style. According to this science, proper choice of *Ahara* and *Vihara* helps to achieve healthy life by maintaining and restoring equilibrium of the body and mind.

Sthoulya is a disorder characterized by an abnormal increase in *Medo Dhatu* predominantly influenced by imbalances in *Kapha*, *Vata* and *Meda*.⁽¹⁾ *Sthoulya* is included under eight undesirable conditions like *Ashtau Nindita*⁽²⁾, *Shleshama Nanatmaja*⁽³⁾, *Samtarpana Nimitija*⁽⁴⁾, *Ati Nindita*⁽⁵⁾ and *Bahu Dosha Janita*⁽⁶⁾

Acharya Charaka has mentioned *Pratyatma Lakshana* of *Sthoulya* as *Medomamsa Ativridhhi*, *Chala Sphika*, *Chala Udara*, *Chala stana*, *Ayatha Upachya*, *Anutshaha* ^[7].

मेदोमांसातिवृद्धत्वाच्चलस्फिगुदरस्तनः।

अयथोपचयोत्साहो नरोऽतिस्थूल उच्यते(च.सू.21/9)^[7]

Due to resemblance in symptoms *Sthoulya* can be correlated with Obesity as both involve excessive adipose tissue due to imbalanced diet, sedentary habits and genetic disorders, leading to metabolic disorders, cardiovascular risks and reduced vitality. Due to unhealthy food habits, lack of physical activity, stress, and irregular lifestyle, Obesity has become one of the most common health issues across the world.

According to WHO Obesity is the fifth leading risk for global deaths Worldwide, the prevalence rate of obesity in 2022 was about 16% among adults (around 890 million people) and 8% among children and adolescents aged 5–19. ⁽⁸⁾

In modern medicine, treatment of Obesity mainly includes Dietary restrictions, Physical exercise, Behavioral modification, Pharmacological agents such as Appetite suppressants, and Bariatric surgery. Although effective to some extent, these methods often show limitations such as poor long-term compliance, weight regain after initial reduction, drug-induced side effects, psychological dependency, and high economic burden, particularly with surgical interventions.

NEED FOR STUDY

In the modern era, Obesity has emerged as a major global health problem, with prevalence increasing alarmingly due to sedentary lifestyle, calorie-dense diets, and stress. According to WHO, worldwide Obesity has nearly tripled since 1975, and it is a known risk factor for Diabetes mellitus, Cardiovascular diseases, Hypertension, Osteoarthritis, and certain cancers. In India, rapid urbanization has contributed to a rise in Obesity even among younger populations.

Despite advances in modern medicine, sustainable and safe management remains a challenge due to side effects of pharmacological agents and poor compliance with lifestyle interventions. *Ayurveda* offers a holistic, multidimensional approach incorporating *Ahara* (dietary regulation), *Vihara* (physical activity), and *Shamana/Shodhana Chikitsa* (palliative and purificatory therapies) aimed at addressing both the root cause (*Nidana Parivarjana*) and the systemic imbalance (*Dosha-Dushya Samurchana*). This study is needed to evaluate these treatments in a systematic way, so that safe, effective, and long-lasting solutions can be provided to people. These approaches aim not only at reducing weight but also at improving metabolic health, preventing complications, and maintaining long-term balance.

Patients are continuously looking with hope towards *Ayurveda*, *Ayurveda* plays an important role in the management of *Sthoulya* as its unique treatment modality provides long lasting results through the basic principles of treatment that is *Nidana Parivarjana*, *Shodhana Chikitsa* and *Shamana Aushadhis* in order to relieve the symptoms.

The Present work is an attempt in this direction - “A Randomized Clinical Study on *Krimighanadi Kashaya* in *Sthoulya* with special reference to Obesity”.

कृमिघ्नत्रिफलाजाजीकट्वीब्योषामूतैः कृतः ।

क्वाथोऽतिस्थौल्यदोषघ्नः मधुगुगुलुसंयुतः ॥[Ref. Sah. Yog. Ksh. Pr.1/1,2]

Krimighanadi Kashaya is described in *Sahasrayogam-Krimighana* (*vidanga*), *Triphala* (*Haritaki, Bibhitaki, Amalaki*), *Ajaji, Katvi, Vayosha* (*Pippali, Maricha, Shunthi*), *Amrita, Madhu, Guggulu* are the ingredients that make up *Krimighanadi Kashaya*⁽⁹⁾

PREVIOUS WORK DONE

IN YEAR 2021

- Govt.Ayurvedic college hospital, Kadamkuan Patna -Effect OF *Lekhaniya Mahakashaya(kadha)* In *Santarpanjanya Vyadhi*(excessive nutritional disease) W.S.R. To *Sthoulya* (OBESITY)

IN YEAR 2019

- PDEAs college of *Ayurved* and Research Centre Akurdi sect 25 pune *Ayurved* Rugnalay and sterling Multispeciality hospital -Standard controlled clinical study of *Haridradi Ghana* and *Medohara Guggulu* in the management of *Sthoulya*.
- TNMC & BYL Nair Hospital, Mumbai Central, Mumbai- An Open, Controlled, Comparative clinical study to assess the efficacy and safety of *Lekhan Basti* and *Navak Guggul* in the management of *Sthoulya* (Obesity) with special regard to biochemical and genetic marker.
- MAM Sumatibhai shah Ayurved college Maharashtra- Comparative Clinical study of efficacy of *Bilvadi vati* with *Haridradi vati* in *Sthoulya*.

IN YEAR 2016

- J.S.*Ayurveda* Mahavidyalaya And P.D.Patel Ayurveda Hospital- A Clinical Study Of *Lekhana Basti Karma* In the Management Of *Sthoulya*.

IN YEAR 2010

- Jammu Institute of Ayurveda and Research-Clinical study to evaluate the efficacy of *Panchkola Phanta* in *Sthoulya* with special reference to Obesity.

AIM AND OBJECTIVES

1. To study the Etiopathogenesis and Symptoms of *Sthoulya* with special reference to Obesity.
2. To evaluate the efficacy of *Krimighanadi Kashaya* in the management of *Sthoulya* with special reference to Obesity.
3. To assess the effect of *Krimighanadi Kashaya* on *Ayurvedic* Parameters of *Sthoulya*.

HYPOTHESIS

❖ **NULL HYPOTHESIS(H₀)**

- There will be no significant effect of *Krimighanadi Kashaya* in the management of *Sthoulya* with special reference to Obesity.

❖ **ALTERNATE HYPOTHESIS (H_A)**

- There will be significant effect of *Krimighanadi Kashaya* in the management of *Sthoulya* with special reference to Obesity.

REVIEW OF LITERATURE

DISEASE REVIEW

Charaka Samhita

Acharya Charaka, has described *Sthaulya* under *Ashtaunindita Purusha* (*Cha. Su.* 21).^[10] The *Ashta Dosha* of *Sthaulya* along with its stepwise Etiopathogenesis are elaborated in *Cha. Su.* 21/3-4.⁽¹¹⁾ *Acharya Charaka* considers a *Madhyama-Pramana Sharira* as ideal (*Cha. Su.* 21/18-19).⁽¹²⁾

Sushruta Samhita

According to *Su. Su.* 24/13, vitiation of *Meda Dhatu* is the prime cause, leading to abnormal fat accumulation.⁽¹³⁾ The symptoms of disturbed *Medovaha Srotas* are explained in *Su. Su.* 9/12, which include heaviness, lethargy, and excessive fat deposition.⁽¹⁴⁾ *Acharya Sushruta* categorizes it under *Rasa Santarpanottha Vyadhi* as mentioned in *Su. Su.* 15/37.⁽¹⁵⁾

Ashtanga Hridaya And Ashtang sangrah

Acharya Vriddha Vagbhata and *Vagbhata* have explained the etiopathogenesis of *Sthaulya* based on the concept of *Ama* formation and impaired *Dhatu Parinaman*. In *Ashtanga Samgraha Sutra Sthana* 19/26.⁽¹⁶⁾

Bhela Samhita

In *Bhela Samhita*, the condition of *Sthaulya* (obesity) is mentioned at two places. In *Sutra Sthana* 11/11, it is described as *Medovyapati Janya Vikara*.

Madhava Nidana

In *Madhava nidana*, there is a separate chapter over *Medoroga*, where he elaborated the pathophysiology of this disease on the basis of fat tissue & fat deposition sites(*Ni* 34/4).

Sharangadhara Samhita

In *Sharangadhara Samhita*, *Sthaulya* is described as a disorder of *Medo Dosha* (*Sha. Pu.* 5/65). It is mentioned that *Sweda* is the *Upadhatu* of *Meda*. (*Sha. Pu.* 5/29)

Yogrnatakar

In *Uttarardha* of this text“*Medo Roga nidanam*” is the specified chapter for the *medoroga*(*sthaulaya*).

DRUG REVIEW

The trial drug under consideration *Krimighanadi Kashaya*⁽⁹⁾ contains *Krimighana*⁽¹⁷⁾, *Haritiki*⁽¹⁸⁾, *Amalaki*⁽¹⁹⁾, *Bibhitaki*⁽²⁰⁾, *Ajmoda*⁽²¹⁾, *Katvi*⁽²²⁾, *Pippali*⁽²³⁾, *Shunthi*⁽²⁴⁾, *Maricha*⁽²⁵⁾, *Amrita*⁽²⁶⁾.

TABEL NO. 1

Ingredients of *Krimighanadi Kashaya*⁽⁹⁾ [Ref. Chapter- *Sahasrayogam Ksh.Pr.1/1,2*]

S.No.	INGREDIENT	LATIN NAME	RASA	GUNA	VEERYA	VIPAKA
1.	<i>Krimighana</i> ⁽¹⁷⁾	<i>Embelia Ribes</i>	<i>Katu, Kashaya</i>	<i>Laghu, Ruksha, Teekshna</i>	<i>Ushna</i>	<i>Katu</i>
2.	<i>Haritiki</i> ⁽¹⁸⁾	<i>Terminalia chebula</i>	<i>Pancharasa (lavanavarjit), Kas hayapradhana</i>	<i>Laghu, Ruksha</i>	<i>Ushna</i>	<i>Madhura</i>
3.	<i>Amalaki</i> ⁽¹⁹⁾	<i>Emblica officinalis</i>	<i>Panchrasa(lavanar ahita), Amlapradhana</i>	<i>Guru, Ruksha, Sheeta</i>	<i>Sheeta</i>	<i>Madhura</i>
4.	<i>Bibhitaki</i> ⁽²⁰⁾	<i>Terminalia Bellirica</i>	<i>Kashaya</i>	<i>Ruksha, Laghu</i>	<i>Ushana</i>	<i>Madhura</i>
5.	<i>Ajmoda</i> ⁽²¹⁾	<i>Umbelli ferae</i>	<i>Katu, Tikta,</i>	<i>Laghu, Rooksha, Tikshna</i>	<i>Ushna</i>	<i>Madhura</i>
6.	<i>Katvi</i> ⁽²²⁾	<i>Picrorhiza kurroa</i>	<i>Tikta</i>	<i>Rooksha, Laghu,</i>	<i>Sheeta</i>	<i>Katu</i>
7.	<i>Pippali</i> ⁽²³⁾	<i>Piper Longum</i>	<i>Katu</i>	<i>Laghu , Snigdha, Tikshana</i>	<i>Anushnas heeta</i>	<i>Madhura</i>
8.	<i>Shunthi</i> ⁽²⁴⁾	<i>Zingiber Officinalis</i>	<i>Katu</i>	<i>Laghu, Snigdha</i>	<i>Ushna</i>	<i>Madhura</i>
9.	<i>Maricha</i> ⁽²⁵⁾	<i>Piper Nigrum</i>	<i>Katu</i>	<i>Laghu, Tikshna</i>	<i>Ushna</i>	<i>Katu</i>
10.	<i>Amrita</i> ⁽²⁶⁾	<i>Tinospora Cordifolia</i>	<i>Tikta, Kashaya</i>	<i>Laghu, Snigdha</i>	<i>Ushna</i>	<i>Madhura</i>

Actions of Krimighanadi Kashaya

S.NO.	INGREDIENT	DOSHGHANTA	KARMA	PART USED	PROPORTION
1	<i>Krimighana</i> ⁽¹⁷⁾	<i>Kaphvataashamaka</i>	<i>Deepana, Pachana, Agnikar</i>	Fruit	1 Part
2	<i>Haritiki</i> ⁽¹⁸⁾	<i>Tridoshshamaka</i>	<i>Shothara, Deepana, Pachana</i>	Fruit	1 Part
3	<i>Amalaki</i> ^[19]	<i>Tridoshara</i>	<i>Deepan, Rochana</i>	Fruit	1 Part
4	<i>Bibhitaki</i> ⁽²⁰⁾	<i>Kaphahar</i>	<i>Shothhar, Deepana, Trishanigrahana,</i>	Fruit	1 Part
5	<i>Ajmoda</i> ⁽²¹⁾	<i>Kapha-Vata Shamaka</i>	<i>Deepana</i>	Fruit	1 Part
6	<i>Katvi</i> ⁽²²⁾	<i>Kaphapittahara</i>	<i>Lekhaniya, Medorogahara, Deepaniya</i>	Root	1 Part
7	<i>Pippali</i> ⁽²³⁾	<i>Kaphavata Shamaka,</i>	<i>Deepana</i>	Fruit	1 Part
8	<i>Shunthi</i> ⁽²⁴⁾	<i>Kapha-Vata Shamaka</i>	<i>Dipaniya, Shothhar, Pachak.</i>	Root	1 Part
9	<i>Maricha</i> ⁽²⁵⁾	<i>Kapha-Vata Shamaka</i>	<i>Lekhan, Dipaniya, Pachaniya</i>	Fruit	1 Part
10.	<i>Amrita</i> ⁽²⁶⁾	<i>Kapha-Vata Shamaka</i>	<i>Trishnanigrahan, Dipaniya, Pachniya, Agnikara</i>	Stem	1 Part

MATERIAL AND METHODS

1. Conceptual Study

Literary aspect of study will be collected from Classical Ayurvedic and contemporary text including the journals and website about the disease and drugs.

2. Clinical Study

- The patients of either sex, suffering from “*Sthoulya*” will be selected from OPD and IPD of Jammu Institute of Ayurveda and Research, Nardani and Urban wing, Janipur.

PLAN OF STUDY

- **Clinical Study** : For Clinical study, patient will be selected from OPD and IPD of Jammu Institute of Ayurveda and Research, Nardani and Urban wing, Janipur.
- ❖ **Type of Study** : A single, open labelled, randomized, pre and post test clinical study.
- **Level of Study** : O.P.D. & I.P.D. level.
- **Period of Study** : 18 months.

FOLLOW UP

- **Follow up** :- on 15th day, 30th day and 45th day.
- **Drug free Follow up** :- on 45th day.

SAMPLE SIZE

Sample size of 30 subjects will be assigned into single group.

GROUP	DRUG	NO. OF PATIENTS
TRIAL GROUP	<i>Krimighanadi Kashaya</i>	30

INCLUSION AND EXCLUSION CRITERIA

❖ INCLUSION CRITERIA

1. Patients of either sex of age between 18years to 60 years.
2. Patients having signs and symptoms of Obesity like large body frame having extra fat around the waist, difficulty in doing daily activities, lethargy, breathlessness increased weight, snoring, having sweating difficulty while sleeping.
3. Patients having classical signs and symptoms of *Sthoulya* like *Chal Udara Stana Sphika, Javoparodha, Kruchvyavaya, Dourbalyta, Atikshudha, Atitrishna* etc.
4. Patients with BMI between 25kg/m² to 39 kg/m²
5. Patients willing to participate and able to provide signed informed consent.

❖ EXCLUSION CRITERIA

1. Patients age less than 18 and more than 60 years.
2. Pathophysiology or Genetic Syndromes associated with *Sthoulya*.
3. Malignancy, poorly controlled diabetes mellitus, hypertension.
4. Patients suffering from pulmonary diseases, cardiac diseases will not be taken from study.
5. Alcoholic and drug abusers, pregnant and lactating women.

DRUG SELECTION AND PREPARATION

✓ **Collection of drugs :-**

- Ingredients of trial drug *Krimighanadi Kashaya* will be procured from the authentic sources, identified and approved by Department of *Dravya Guna*, Jammu Institute of *Ayurveda* and Research, Jammu.

✓ **Preparation :-**

➤ **Trial Drug:- *Krimighanadi Kashaya*⁽⁹⁾**

- The raw ingredients of the *Krimighanadi Kashaya* will be taken in equal parts. *Krimighana*, *Haritiki*, *Bibhitaki*, *Amalaki*, *Ajaji*, *Katvi*, *Pippali*, *Maricha*, *Shunthi*, *Amrita* will be made into coarse powder in the Department of *Rasa Shastra* and *Baishajya Kalpana*, Jammu Institute of *Ayurveda* and Research, Jammu.

METHODS OF DATA COLLECTION

- ❖ **Randomization:-** Randomization will be done by using randomization software from www.randomizer.org .

- ❖ **Sampling Technique:-**

- Subjects will be randomized in a group
- A special Case Report Format (CRF) containing all the necessary details pertaining to the study will be prepared.
- Data obtained in the group will be recorded, tabulated and statistically analysed.

Interventions:-

➤ Trial Group

- **Yoga :-** *Krimighanadi Kashaya*.⁽⁹⁾
- **Dosage :-** 48 ml twice a day before meals.⁽²⁷⁾
- **Duration :-** 30 days
- **Follow up :-** on 15th day, 30th day and 45th day
- **Drug free Follow up :-** on 45th day

ASSESSMENT CRITERIA

❖ SUBJECTIVE CRITERIA⁽²⁸⁾ :-

1. *Dourgandya*
2. *Ang Gourava*
3. *Utsaha Hani*
4. *Kshudra Swasa*
5. *Ati Pipasa*
6. *Chala Spikha Udara Stana*
7. *Dourbalya*
8. *Nidraadhikya*
9. *Swedadhikya*
10. *Snigdhangata*
11. *Alpa Vyavaya*

❖ OBJECTIVE CRITERIA⁽²⁹⁾

• Body Mass Index(BMI)

BMI=Weight(kg)/Height in sq.m.

Underweight -15-19.9

Normal weight -20-24.9

Overweight -25-29.9

Preobesity

Class I obesity -30-34.9

Class II obesity -35-39.9

Class III obesity->=40

GRADING OF THE ASSESSMENT CRITERIA⁽²⁸⁾

1. *Dourgandhya*⁽²⁸⁾

GRADE	SCORE
Absence of bad smell	0
Occasional bad smell in the body removed after bathing	1
Persistent bad smell limited to close areas difficult to with suppress deodorants	2
Persistent bad smell felt from long distance is not suppressed by deodorants.	3
Persistent bad smell felt from long distance even intolerable to the patient himself.	4

2. *Ang Gourava*⁽²⁸⁾

GRADE	SCORE
No heaviness in body	0
Feels heaviness in body but it does not hamper routine work	1
Feels heaviness in body which hampers daily routine work.	2
Feels heaviness in body which hamper movement of the body.	3
Feels heaviness with flabbiness in all over body which causes distress to the person	4

3. *Utsaha Hani*⁽²⁸⁾

GRADE	SCORE
No <i>Alasya</i> (doing work satisfactory with proper vigour in time	0
Doing work satisfactory with initiation late in time.	1
Doing work unsatisfactory with lot of mental pressure & late in time.	2
Not starting any work on own responsibility, doing little work very slow.	3
Does not have any initiation & not wants to work even after pressure.	4

4. *Kshudra Swasa*⁽²⁸⁾

GRADE	SCORE
Dyspnoea after heavy work but relieved after rest.	0
Dyspnoea after moderate work but relieved late & up to tolerance.	1
Dyspnoea after little work but relieved soon & up to tolerance.	2
Dyspnoea after little work but relieved soon & beyond tolerance.	3
Dyspnoea in resting condition.	4

5. *Ati Pipasa*⁽²⁸⁾

GRADE	SCORE
Normal thirst.	0
Up to 1 lit intake of water in 24 hours.	1
1to 2 lit intake of water in 24 hours.	2
2to3 lit intake of water in 24 hours.	3
More than 3 lit. Intake of water in 24 hours.	4

6. *Chala Spikha Udara Stana*⁽²⁸⁾

GRADE	SCORE
Absence of <i>Chalatva</i>	0
Little visible movement after fast movement	1
Little visible movement after moderate movement	2
Movement after mild movement	3
Movement even after changing posture	4

7. *Dourbalya*⁽²⁸⁾

GRADE	SCORE
Can do routine exercise	0
Can do moderate exercise without difficulty	1
Can do only mild exercise	2
Can do mild exercise with very difficulty	3
Cannot be even mild exercise	4

8. *Nidraadhikya*⁽²⁸⁾

GRADE	SCORE
Normal sleeps 6–8 hrs. / Day	0
Sleep up to 8 hrs. / Day with <i>Angagaurav</i>	1
Sleep up to 8 hrs. / Day with <i>Angagaurav & Jrimbha</i>	2
Sleep up to 10 hrs. / Day with <i>Tandra</i>	3
Sleep up to 10 hrs. / Day with <i>Tandra and Klama</i>	4

9. *Swedadhikya*⁽²⁸⁾

GRADE	SCORE
Sweating after heavy work and fast movement or in hot season	0
Profuse sweating after moderate work and movement	1
Sweating after little work and movement	2
Profuse sweating after little work and movement	3
Sweating even at rest or in cold season	4

10. *Snigdhagata*⁽²⁸⁾

GRADE	SCORE
Normal <i>Snigdha</i>	0
Oily complexion of body in summer season	1
Oily complexion of body in dry season	2
Excessive oily complexion of body in dry season can be removed with difficulty	3
Persistent and profuse stickiness all over body	4

11. *Alpa Vyavaya*⁽²⁸⁾

GRADE	SCORE
Unimpaired libido and sexual performance	0
Decrease in libido but can perform sexual act	1
Decrease in libido but can perform sexual act with difficulty	2
Loss of libido and cannot perform sexual act	3

12. BMI⁽³⁰⁾

Up to 25	Desirable
25-29.9	Grade 1
30-40	Grade 2
>40	Grade 3

❖ **LABORATORY INVESTIGATIONS** [To rule out other ailments]:-

- Lipid profile
- Hb% gm
- Urine investigation (Routine, Microscopic)

CRITERIA FOR OVERALL EFFECT OF THERAPY

The result will be categorized as :-

Complete Remission	100% Relief in subjective and objective parameters
Marked Improvement	More than 76% relief in subjective and objective parameters
Moderate Improvement	51%-75% Relief in subjective and objective parameter
Mild Improvement	26%-50% Relief in subjective and objective parameters
Unchanged	Result below 25% will be considered as unchanged

CONCLUSION

Conclusion will be made on the basis of the observation which is done on subjective and objective parameters. Result will be analyzed statistically and discussed accordingly.

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