SYNOPSIS

***for the thesis on***

***Assessing the benefits of participation in structured weight reduction program focused on obese knee Osteoarthritis: An observational study***

***Submitted for the***

***Partial fulfilment of degree of***

***Doctor of Medicine (Ayu.) Kayachikitsa***

**

**Investigator**

**Dr. DIVYA ASTHANA**

B.A.M.S. (R.A.C Varanasi)

**Supervisor**

**Dr. SANJEEV RASTOGI**

M.D. (Ay.) Kaya Chikitsa, D.H.H.M., Ph.D. (Ay.),

HOD & Associate Professor

P.G. Department of Kaya Chikitsa,

State Ayurvedic College & HospitalLucknow.

Formerly: Director, Rashtriya Ayurveda Vidyapeeth, New Delhi

**Co-Supervisor**

POST GRADUATE DEPARTMENT OF KAYACHIKITSA, STATE AYURVEDIC COLLEGE AND HOSPITAL, LUCKNOW/ FACULTY OF AYURVEDA,

LUCKNOW UNIVERSITY, LUCKNOW, (U.P.) INDIA.

*Enrollment no: - Year: - 2022-23*

To,

###### APPLICATION TO UNIVERSITY

The Principal cum Dean,

State Ayurvedic College & Hospital, Faculty of Ayurveda,

Lucknow University, Lucknow

**Through: *The Head, Post Graduate Department of Kayachikitsa, State Ayurvedic College & Hospital, Lucknow.***

**Subject:** *Submission of Synopsis for completion of thesis for partial fulfillment of degree of Doctor of Medicine (Ayurveda) in Kayachikitsa.*

Respected Sir,

I would like to submit the enclosed Synopsis to follow a plan of my research work, which I proposed to undertake subsequently to be presented in the form of thesis for the degree of

M.D. (Ay.) Kayachikitsa. **Dr. Sanjeev Rastogi (**H.O.D.), P.G. Department of Kayachikitsa, State Ayurvedic College and Hospital, Lucknow

Lucknow has given their kind consent to work as supervisor and co-supervisors respectively on given topic.

Therefore, I would like to request you to kindly consider and present my Synopsis before the research committee of Department of Kayachikitsa and also forward it to the faculty of Ayurveda, Lucknow University for their kind approval.

I shall be very grateful to you for your kind permission and necessary support for conducting the proposed research work.

Thanking you.

Date........ Yours faithfully,

###### Dr. DIVYA ASTHANA

M.D (Ayu.) 1st year scholar,

P.G. Department of Kayachikitsa, State Ayurvedic College & Hospital, Lucknow.

###### APPLICATION TO INSTITUTIONAL ETHICAL COMMITTEE FOR APPROVAL

To,

The Institutional Ethics Committee, State Ayurvedic College and Hospital, Lucknow.

Subject: Submission of Research proposed for I.E.C. approval.

Through: H.O.D. Department of Kayachikitsa, State Ayurvedic College & Hospital, Lucknow. Sir,

I would like to submit the Synopsis titled ***“Assessing the benefits of participation in structured weight reduction program focused on obese knee osteoarthritis : An observational study ”*** under the supervision of **Dr. Sanjeev Rastogi** and co-supervision of **Dr.** for the completion of thesis for partial fulfillment of Degree of Doctor of Medicine (Ay.) Kayachikitsa.

Kindly find the enclosed Synopsis and my curriculum vitae and take appropriate action for the clearance of my proposed work.

Thanking you.

Date……… Yours faithfully,

###### Dr. Divya Asthana

(M.D. 1st Year Scholar PG Department Kayachikitsa,

State Ayurvedic College & Hospital, Lucknow.)

**CERTIFICATE FOR RESEARCH TOPIC APPROVAL**



It is certified that the research work entitled ***“Assessing the benefits of participation in structured weight reduction program focused on obese knee osteoarthritis: An observational study .”*** has been allotted, after approval from departmental research committee, to *Dr. Divya Asthana* under the supervision of **Dr. Sanjeev Rastogi** and co-supervision of **Dr.**  It would be a further advancement in the field of Ayurveda.

###### Dr. Sanjeev Rastogi

###### (H.O.D),

###### P.G. Department of Kayachikitsa,

State Ayurvedic College and Hospital, Lucknow.

**REGISTRATION OF TITLE OF THESIS FOR MD (AY.) KAYACHIKITSA**

**1-a) Name of candidate** : Dr. DIVYA ASTHANA

1. **Name of course** : M.D. (Ay.) Kayachikitsa
2. **Year and month of Admission** : March, 2023
3. **Year and month of final examination**: March, 2026
4. **Enrollment No. :**

**2.Title of proposed thesis:** - Assessing the benefits of participation in a structured weight reduction program focused on obese knee Osteo arthritis “An Observational Study”.

1. **Name and Designation of the Supervisor: -**

**Dr. Sanjeev Rastogi**

(H.O.D), P.G. Department of Kayachikitsa,

State Ayurvedic College and Hospital, Lucknow.

###### Name and Designation of the Co-Supervisor

###### Institution where thesis work will be carried out: -

State Ayurvedic College and Hospital, Lucknow & CBMR, SGPGI, Lucknow.

###### Department where thesis work will be carried out: -

Department of Kayachikitsa

### CURRICULUM-VITAE

###### Career Objective: -

**Dr. DIVYA ASTHANA**

Naiganj , jaunpur

Uttar Pradesh (222002)

Contact No.: 7355789485

* 1. To work hard with full determination and to be involved in work where I can utilize skill and creatively involved with system that effectively contributes to the growth of organization.
  2. To serve the people by using my medical qualification and experience and my desire is to help/guide them in maintaining good health.

**Education**: -

###### Professional Qualification: -

B.A.M.S**.** from State Ayurvedic College and Hospital, Varanasi. Affiliated to Sampurnanand Sanskrit University.

###### Marks in B.A.M.S.: -

|  |  |
| --- | --- |
| **Professional Year** | **Marks** |
| Final Year | *62.28%* |
| Third Year | *63.44%* |
| Second Year | *63.8%* |
| First Year | *68.36%* |
| **Average of all Professional Years** | **64.47%** |

**Date of Completion of rotatory internship:** - 30/ 9 / 2022

**Registration No :-** 68098

**Personal Details: -**

Name : Dr. DIVYA ASTHANA

Date of Birth : 10/11/1995 Father's Name : Mr. S.C.Asthana

Mother’s Name : Mrs. Manju Asthana

Nationality : Indian

Gender : Female Marital Status : Unmarried

Languages Known : Hindi, English & Sanskrit

Address : 363, Naiganj Jaunpur

U.P. (222002)

##### Declaration: -

I hereby declare that above information given by me is correct to best of my knowledge.

Date:

Place:

###### Dr. DIVYA ASTHANA

M.D. (1st) year Scholar,

P.G. Department of Kayachikitsa,

State Ayurvedic College & Hospital, Lucknow.

**SYNOPSIS**

**Introduction**

**Study background** –

Obesity has been a critical confounding factor in arthritis . Its impact are more apparent in conditions like knee OA but it affects the net outcome in almost every type of arthritis .

Knee osteo arthritis ( OA ) affects mostly older adults and its primary risk factor is obesity. This study sought to understand weight control strategies, facilitators and barriers toward weight control in older adults with knee OA.

Knee OA is a major cause of joint pain and problems in daily functioning. These patients of knee pain and physical functioning have been predicted to deteriorate based on their knee characteristics, clinical factors and physiological factors. Among these factors, obesity is the primary risk factor of knee OA.

People clinically defined as obese (body mass index [ BMI ]> 30 kg/m2) were four times more likely to have knee OA than those with BMI in a desirable range (≤25kg/m2).

The degree of obesity in early life was also associated with the risk of developing knee OA later in life.

Overweight or obese adults with knee OA who participated in behavioral weight loss interventions in a systemic review and meta-analysis of randomized controlled trials showed moderate improvements in pain and physical functions

In other words, disability improved significantly when weight loss was >5.1% or a reduction rate of 0.24% per week.

All obese people with knee OA age≥ 45 years old, with activity related joint are recommended to receive weight- loss treatment. Overweight obesity are well known to increase the risk of KOA by mechanical load on weight bearing joints.

Recent study showed that waist circumference could be one of the main risk factor for limiting ambulation speed in adults with KOA.

**1.Study on benefits of weight reduction program** –

Structured weight reduction plans in arthritis have been able to show the clinical benefits associated with weight loss. Such benefits have often been found closely related with the extent of weight loss. Strategies adopted for weight loss in arthritis population largely consist of calorie reduction, meal replacements and behavioral strategy.

weight loss in knee OA patients significantly reduces disability and found that a critical amount of weight loss (at least 10%) is needed to give a large clinical effect .It is largely accepted that weight loss should be the first-choice therapy for obese adults in all kind of arthritis including knee OA.

**2.Challenges in sustaining weight loss for knee OA patients –**

Maintaining the lost weight is even more challenging than weight reduction alone. Such weight maintenance requires a long term support and motivation to reinforce diet, physical activity and behavioral changes.

**3.Execution of the program**-

In order to deliver what was conceived as the essential component of weight reduction program for arthritis patients, a workshop was organized aiming at obese arthritis people not having any specific medical reason underlying their obesity.

To develop the essential components of our weight reduction strategy and create a comprehensive execution plan, we have conducted several brainstorming sessions at our center.

**4. Developing an Effective Weight Reduction Strategy for Obese Patients in Arthritis Clinical Practice: Addressing Misconceptions and Understanding Caloric Intake –**

In our arthritis clinical practice, we have noticed that approximately 15-20% of the patients visiting us fall into the overweight to morbidly obese category. Maximum individual adult weight reported in this clinic is 125 kg. Interestingly, during the initial consultations, we found that most of these obese patients were eager to receive medication that could assist them in losing weight. Moreover, they were confident that they were not consuming any additional calories that could contribute to their weight gain. This observation has highlighted two important areas that require our attention in developing an effective weight reduction strategy.

1. It is crucial to dispel the misconception that weight reduction can be achieved solely through medication, without the active involvement of the individual. We need to emphasize the importance of personal commitment and effort in the weight loss journey.
2. we must gain a better understanding of the actual daily calorie intake of these patients. This knowledge will enable us to identify and address any unnoticed sources of excessive calorie consumption.

**5.Practical demonstrations of various activities related to weight loss –**

It focused upon the practical demonstration of modified cooking methods like zero oil coking, roasting, steaming, boiling, sprouting etc . lt was showing the practical methods of modified cooking with less energy intake but essentially without compromising the nutritive value of the food.

Practical demonstration of yoga techniques like kapala bhati and bhastrika was also given as an addition to weight reduction to overweight arthritis patients who are not able to do strenuous physical exercises due to their limited joint mobility.

**6. Barriers to weight control –**

Barriers to losing the desired amount of weight were lack of motivation, knee-joint pain, pain in other joints, and lack of time.

* Their commonly reported barriers were desiring high-fat/high-calorie foods, difficulty managing overeating at restaurants and evening snacks. Among these studies, the only common barrier was lack of time.
* Some barriers to weight control identified in other studies, e.g. problems with calorie counts and food intake record , not preparing meals by oneself , lack of time for eating .

**Previous Observations –**

* Most obese knee-OA outpatients (89%) surveyed in the UK had tried to lose weight by changing their diet, trying to exercise more, and joining a support group.
* All obese/overweight people with OA, ≥45years old, with activity-related joint pain, and without morning joint related stiffness or morning stiffness lasting < 30 min are recommended to receive weight-loss treatment.
* Osteoarthritis (OA) is the most common joint disorder all over the world. Symptomatic knee OA occurs in 10% men and 13% in women aged 60 years or older. The number of people affected with symptomatic OA is likely to increase due to the aging of the population and the obesity
* **Obesity Is a Risk Factor** – Data from the **first National Health and Nutrition Examination Survey (HANES I)** indicated that for Osteoarthritis -

**Overweight women** have **nearly 4 times** the risk of knee OA and for **overweight men** the risk is **5 times greater**.

**Disease Review** : **Ayurvedic Aspects–**

* In the present era Sandhivata is the most common disease affecting a large population. When Vata lodges in Sandhi (joints), it is characterized by pain, swelling, and restriction of joint movement. The clinical presentation of Sandhivata closely mimics with the disorder called Osteoarthritis which is the second most common rheumatologic problem.
* Sandhivata is the disease mentioned in Ayurveda and is a type of Vatavyadhi which most commonly occurs in Vridhavastha due to Dhatukshaya.

**Symptoms of Sandhivata**

वातपूर्णदृतिस्पर्शः शोथः सन्धिगतेऽनिले | प्रसारणाकुञ्चनयोः प्रवृत्तिश्च सवेदना || (Ch.chi. 28/37)

1. Common clinical symptoms

* वातपूर्णहतिस्पर्श (Crepitus)
* संधिशूल (Pain in or around the knee joint)
* प्रसारणाकुन्चनयोप्रवृत्तिश्चसवेदना (Painful flexion and extension of knee
* सन्धि शोध (Oedema)

2. Additional symptoms

* Tenderness of knee joint.
* Morning stiffness (<half an hour)
* Increased walking time
* Synovial effusion
* Management of Sandhivata As in Ayurveda the first line of treatment is Nidan parivarjana so the first aim should be lifestyle modification which can be achieved through change in dietary habits, Yoga and regular exercise and weight control .

**AHARA** -:Laghu, katu, tikta snegdha, diet should be given.

**Yoga**- Yoga has proven positive effect on both physiological and mental status in treatment of chronic conditions.

**Obesity -** Obesity is the closest entity used for Sthoulya and Atisthula person is included under Ashta Nindita purusha.

Acharya Charaka describe the 8 causes of Atisthulata .As we moved into rapid modernization, lifestyle of an individual has become sedentary along with lack of exercise and there is increased popularity of fast foods leading to impairment of metabolism in an individual making them prone to series of disorders called lifestyle disorders.

**The Benefits of Weight Loss** –

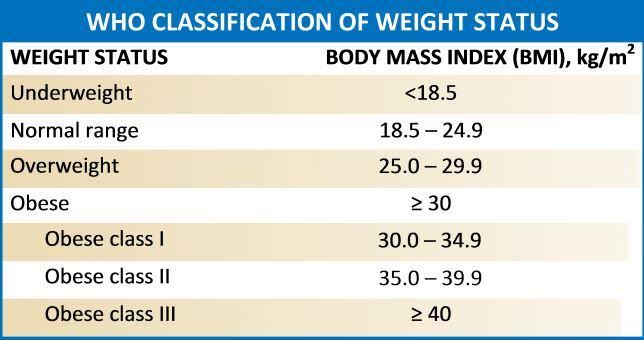
In the Framingham study, Felson and colleagues noted that among women with a baseline body mass index (BMI) greater than or equal to 25, weight loss was associated with a significantly lower risk of knee OA. For a woman of normal height, for every 11 lb weight loss (approximately 2 BMI units), the risk of knee OA dropped > 50%.

**Assessment of obesity-**

**1. Body Mass Index (BMI) –**

overweight is a BMI of 25-29.9 while obesity is a BMI of 30 or greater. (A BMI of 30 is about 30 lbs overweight)

BMI provides a reasonable estimate of body fat.



**2. Waist Circumference** - Waist circumferences is closely linked with abdominal fat , which is an independent predictor of disease risk. A waist circumference of greater than 40 inches (102 cm) in men and greater than 35 (88 cm) in women signifies increased risk in those who have a BMI of 25 to 34.9.

**3.Risk For Obesity- Related Diseases** –such as elevations in blood pressure or blood cholesterol ,or family history of obesity-related disease.

**How Can I Help My Patients to Manage Their Weight More Effectively?**

* Assess weight and advise all overweight and obese persons to lose weight.
* Review health benefits emphasizing the link between weight loss, exercise and improvement in joint pain
* Suggest an initial weight loss goal of 10% and a safe rate of weight loss.
* Review changes in eating, behavior, and physical activity that are necessary to lose weight.
* Monitor progress with follow-up visits.

**Need of study:**

1. Obesity is strongly linked to knee OA and is considered as a risk factor for both incidence and progression.
2. Weight loss is advocated as the treatment of choice for obese knee OA patients ,as it yields clinically significant reduction in pain and improvements in function.
3. Despite of these facts there had not been any specific strategies recommended to the obese KOA patients which can help them reducing the weight. No specific and personalized recommendations

For obese OA patients which can eventually help them reaching to the objectives of reducing pain.

**Research question and proposed hypothesis –**

Do the knee osteoarthritis obese patient got benefited of participation in a structured weight reduction program based upon Ayurvedic principles??

**Null hypothesis –**

Knee osteoarthritis obese patients attending weight reduction program have equal chances to lose their weight comparing to non-attending knee osteoarthritis obese patients.

**Alternate hypothesis**

Knee osteoarthritis obese patients attending weight reduction program have more chances to lose their weight comparing to non attending knee osteoarthritis obese patients.

**Aim -** To evaluate the benefits of structured weight reduction program based upon ayurvedic principle in obese knee osteoarthritis patients.

**Objectives**

**\*Primary Objective –**

1.To evaluate the benefits in terms of weight reduction

2. To evaluate the stability of reduced weight during the follow-up time period.

3. To evaluate the compliance of structured weight reduction program and two observe any limiting factor leading to non compliance.

**\*Secondary Objective** –

* To corelate the benefits of weight reduction in terms of functional improvement in KOA.

**Plan of study**

**Type of study -** An observational type of Cohort study.

Cohort 1 -The Cohort which is actively participating in the weight reduction program.

Cohort 2 - They are fulfilling all the criteria of inclusion except that they are not participated in the program and they are kept in the wait list .

**SITE OF STUDY - Department of Kayachikitsa**

**A-ATARC OPD**

**DURATION OF STUDY – 3 month from the date of actual conduction of the workshop**

**Selection criteria-**

**On the basis of Radiological Investigation -**

* **Diagnostic criteria for Obesity-**

BMI (WHO criteria)

* **Diagnostic criteria for knee OA –**

Clinical Diagnosis as well as Radiological Diagnosis X-Ray

**On the basis of Clinical Criteria –**

* Restricted movement due to capsular thickening or blocking by osteophyte.
* • Palpable, sometimes audible, coarse crepitus due to rough articular surfaces
* • Bony swelling around joint margins
* • Deformity, usually without instability
* • Joint-line or periarticular tenderness
* • Muscle weakness and wasting
* • Mild or absent synovitis.

**Every participant should have both of these conditions.**

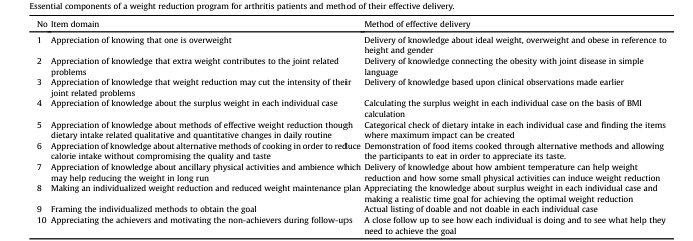
**Inclusion criteria** -

1. Age: 30-70 years
2. Sex: Both Male & Female.
3. Socio economic status: All.
4. Patients having any other systemic illness like Diabetes, HTN & other Endocrinal Disorders.
5. Patient should not be genetic obese.
6. Patient join the workshop along with their spouse/ family member in order to optimize their benefits through mutual support.
7. Patient having other Co-existing illness and Auto-immune disorders.
8. Those who are willing to participate and ready to give their consent.

**Exclusion Criteria of the patient -**

1. Patients who have endocrine disorder.
2. Patients who have genetic disorder.
3. Patient who are not willing to give consent.

**Components of study and its execution plan**

* The weight reduction program would be design on the basis of ayurvedic principles of aptarpan chikitsa.
* The prospective obese and OA patients who are attending the A-ATARC OPD would be invited to participate in a structured workshop which is design for weight reduction.
* For this purpose ,the registry would be maintained. The Registry of the prospective patients, who are willing to participate in such kind of workshop could be maintained. This Registry would contain the demographic details of the patients and their contact details .
* All the prospective patients who have shown their interest in participating such workshop would be individually screen for their possibility of getting included in this study on the basis of inclusion and exclusion criteria . Those who are fulfilling the inclusion and exclusion criteria would further be asked for the informed consent.
* Every such prospective participant who has given their consent to participate in the study would be invited on the specific day when the workshop is planned and their will be required to bring the spouses or some family member to participate in the study. They would also be advised the workshop will run for around 2 to 3hrs. so they would be required to stay there for 3 hrs.
* Following the workshop every steady participant would be follow regularly or monthly basis for the assessment of outcome, compliance of the recommendations and any reason of non- compliance. If there is any reason of non-compliance identified during a follow-up every such reason would be tried to get resolve with the help of the principal investigator.
*  Final Assessment of the outcomes in terms of primary and secondary outcome would be reported after the completion of the study.

**Outcome assessment parameter**

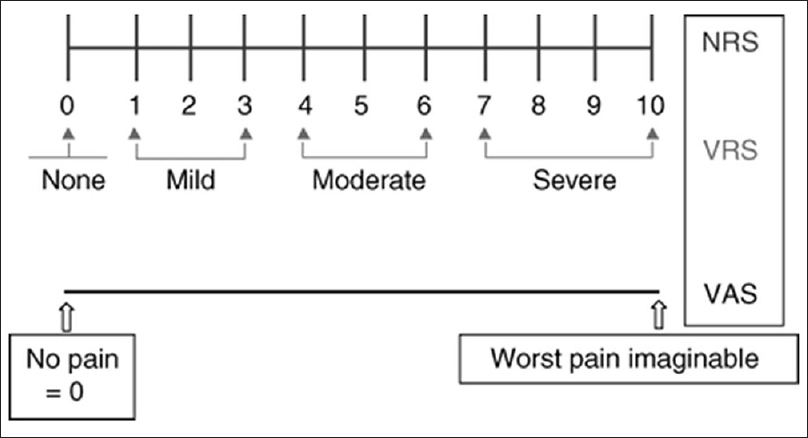
1. **Obesity Assessment –**

* Consider weight
* Hip waist Ratio
* Skin fold measurement

1. **Osteoarthritis Assessment –**

* Visual analogue assessment

0-10 NUMERIC PAIN RATING SCALE



The resolution-resolution defined as 50% reduction in target joint pain score.

**Increased walking time (for fixed distance before and after)**

**⚫ Subjective parameter**: All the signs and symptoms are graded on the basis of their inter severity given by patients on complained and confirmed by clinical examination before intervention

The clinical improvement during and after the therapy will also be correlated with intensity of sign and symptoms.

A. Essential symptoms

1. Vatapurnadritisparsa (joint crepitations)-

Grade 0-Never

Grade 1 - rare

Grade 2- occasionally

Grade 3- Always

2. Sandhi Shotha (joint swelling) -

Grade 0-No swelling

Grade 1 - Mild swelling

Grade 2- Moderate swelling

Grade 3- Severe swelling

5. Sandhi Shoola (joint pain) -

Grade 0- No pain

Grade 1 - Mild pain

Grade 2- Moderate pain

Grade 3- Severe pain

6. Prasaran akkunchanaana pravriti savedana (pain during flexion and extens

Grade 0 - No pain

Grade 1- Pain without winching of face

Grade 2- Pain with winching of face

.Grade 3- Prevent compere flexion

A. Additional symptoms

1. **Tenderness of knee joints**

Grade 0 None-palpation is non-painful even when asked about it.

Grade 1 Mild- palpation is painful only when asked about it.

Grade 2 Moderate Indicates palpation is painful by wincing during palpation or say so.

Grade 3 On palpation tries to withdraw the limb or is clearly distressed by any pressure. (Jump sign)

1. **Morning stiffness (<half an hour)**

Grade 0- No Joints stiffness

Grade 1-Stiffness lasting for 10 minutes

Grade 2- Stiffness lasting for 20 minutes

Grade 3 - Stiffness lasting for 30 minutes

* Pain, Swelling, mobility

1. **Co – existing Illness** – Co- existing illness is present.
2. **Safety Assessment –** 
   1. LFT
   2. CBC
   3. KFT
   4. Lipid Profile

**Data assembly and analysis**

**Translational relevance of the study –**

1. It addresses the significant health burden posed by obesity and knee osteoarthritis.

2. Findings can directly impact clinical practice by improving diagnosis, management, and treatment.

3. It has implications for public health policies and interventions to reduce obesity rates and prevent osteoarthritis.

4. Economic considerations are important, as obese knee osteoarthritis has substantial healthcare costs and economic burdens.

**Approvals from the authorities -**

1. 1.Study will be started only after a DRC and IEC approval followed by prospective CTRI registration.
2. All patients registered in the study and receiving Ayurvedic intervention will be regularly evaluated**.**

**Ethical issues related to study –**

1. The study will be abided by the ethical norms and standards laid down by national and international authorities related to human trials.

2. Each prospective participant will be given complete information about the nature of the study, it’s possible benefits and limitations.

3. The participants will be enrolled in the study only after they voluntarily give their consent to participate.

4. Patients, who are unsatisfied or wish to withdraw from the study for some reasons, will be allowed to do so without compromising their therapy which they might have received had they not been registered in the study.

5. No unfair practices will be adopted to increase the patient participation in the study.

**PROFORMA FOR THE REGISTRATION OF PATIENT M. D. (Ay.) RESEARCH WORK**

***Assessing the benefits of participation in structured weight reduction program focused on obese knee Osteoarthritis : An observational study***

*Submitted for the partial fulfillment of degree of Doctor of Medicine (Ay.)*

*Kayachikitsa*

**

##### Investigator

###### Dr. DIVYA ASTHANA

B.A.M.S. (Sampurnanand Sanskrit University)

##### Supervisor

###### Dr. SANJEEV RASTOGI

(H.O.D), P.G. Department of Kayachikitsa, State Ayurvedic College and Hospital, Lucknow.

##### Co-Supervisor

**Prof. Girdhar Agrawal**

Dept. of statistics

Lucknow university

POST GRADUATE DEPARTMENT OF KAYACHIKITSA, STATE AYURVEDIC COLLEGE AND HOSPITAL, LUCKNOW/

FACULTY OF AYURVEDA,

LUCKNOW UNIVERSITY, LUCKNOW, (U.P.) INDIA.

*Enrollment no: - Year: - 2020-21*

## PATIENT'S CONSENT FOR THE STUDY

I… exercise my free favor, choice, hereby given my consent to

be observed for any clinical changes in my disease profile during my treatment course, recommended by my treating physician at Kayachikitsa Department OPD & Arthritis Treatment and Advanced Research Center, State Ayurvedic College and Hospital, Lucknow. I have been informed to my satisfaction by attending physician about the purpose of the study and follow up to monitor and safe guard my interest.

I am also aware of right to opt out of study at any time, during the course of study without having to give the reasons for doing so.

I will not claim any compensation for adverse effect if any during or after the trial.

Signature of Patient: Signature of Investigator: Signature of Guardian:

चिकित्सालयी औषधि परीक्षण हेतु रोगी सहमति प्रमाण पत्र

मैं……………….. उम्र …………… निवासी राजकीय आयुर्वेदिक कॉलेज लखनऊ में किये जा रहे शोध परीक्षण हेतु अपनी पूर्ण सहमति देता/देती हूँ। मुझे चिकित्सक द्वारा इस चिकित्सालयी औषधि परीक्षण एवं उससे होने वाले शारीरिक/मानसिक परिवर्तनों के बारे में स्पष्ट रूप से बता दिया गया है।

मैं उपर्युक्त सहमति बिना किसी दबाव में दे रहा/रही हूँ | एवं इस परीक्षण से किसी भी समय बिना कारण

स्पष्ट करे निष्कासित किया जा सकता/सकती हूँ । यदि शोध परीक्षण के दौरान शोध औषधि के कुछ

अह्ति प्रभाव होते है, तो मैं उस अवस्था में किसी भी प्रकार का क्षति पूर्ण दावा नहीं करूंगा/करूंगी।

गवाह के हस्ताक्षर रोगी के हस्ताक्षर

(रोगी का साथी)

चिकित्सक के हस्ताक्षर