**SYNOPSIS**

***for the thesis on***

***Assessing the benefits of participation in structured weight reduction program based upon Ayurvedic principle and focusing upon 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 & Hospital Lucknow.

Formerly: Director, Rashtriya Ayurveda Vidyapeeth, New Delhi

**Co-Supervisor**

**Prof. GIRDHAR AGRAWAL**

Prof. Emeritus

Dept. Of Statistics

University Of Lucknow.

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 based upon ayurvedic principle and focusing upon obese knee osteoarthritis : An observational study ”*** under the supervision of **Dr. Sanjeev Rastogi** and co-supervision of **Prof. Girdhar Agrawal** 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 based upon Ayurvedic principle and focusing upon 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 **Prof. Girdhar Agrawal**  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 structured weight reduction program based upon Ayurvedic principles and focusing upon obese knee Osteoarthritis “An Observational Study”.**

**3.Name and Designation of the Supervisor: - Dr. Sanjeev Rastogi**

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

State Ayurvedic College and Hospital, Lucknow.

###### 4. Name and Designation of the Co-Supervisor - Prof. Girdhar Agrawal

###### Prof. Emeritus

###### Dept. of Statistics

###### University of Lucknow

###### 5. 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**

D/O SATISH CHANDRA ASTHANA

363 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.

**Educational Qualification**: -

###### Professional Qualification: -

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

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

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

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

**Registration No :-** 68098

**ACADEMIC QUALIFICATION -**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Qualification - | College/School | Uni./Board | Year | Percentage |
| SECONDARY  SCHOOL | Harihar Singh Public School Jaunpur | U.P board | 2010 | 62.3 % |
| SENIOR SCHOOL  CERTIFICATE | Harihar Singh Public School Jaunpur | U.P Board | 2012 | 72.2 % |

**Personal Details: -**

|  |  |
| --- | --- |
| Name | Dr. Divya Asthana |
| Father's Name | Shri. Satish Chandra Asthana |
| Mother's Name | Smt. Manju Asthana |
| Date of Birth | 10/11/1995 |
| 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
* Obesity is a primary risk factor for Knee osteoarthritis ( OA ). Therefore to understand weight control strategies, measures and barriers toward weight control in patients having knee OA is crucial.
* Knee OA is a major cause of limitation of daily functioning. This eventually affects the quality of life adversely.
* Obese people (body mass index [ BMI ]> 30 kg/m2) are four times more likely to develop knee OA than those having a 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.
* Participation in weight loss intervention program is associated with moderate improvements in pain and physical functions as is shown in systemic review and meta-sanalysis of randomized controlled trials.
* This suggests that the disability improves significantly when achieved weight loss is >5.1% or a reduction rate is ~ 0.24% per week .
* All obese people with knee OA age are commonly recommended to reduce weight as a first intervention.
* Ayurveda has its own principles of weight management based upon inclusion and exclusion diet, exercise and local applications. Such principles have not yet been fully explored for their benefits obtainable in cases of obese knee OA patients.
* Ayurvedic concepts of weight reduction are having a possibility to be explored on such patients by explaining these in the form of a workshop. The concept of guru and laghu food, use of Kapha reducing food, avoiding daytime sleep *(Divaswapna*), promoting proper night sleep and avoiding *Ratri Prajagaran* and use of food like roasted food could be the components to be shared with the workshop participants.
* Utilizing these principles of obesity management in ayurveda and utilizing the principles of arthritis management, A-ATARC has already designed and executed one weight reduction program which is focusing upon all arthritis patients. The benefits of participating in this program however have not yet been reported.
* So the assessment of benefits among those obese suffering with arthritis and are participating in a structured weight reduction program based upon ayurvedic principles seems to be an important step towards its serious inclusion in arthritis management strategies in ayurveda clinics across the country.

**Need of Study?**

1. Studies have been conducted on ayurvedic principles of weight management and its relation with knee osteoarthritis.

2. Sthoulya (Obesity) having a good description in ayurveda. Ayurveda has a kind of specific treatment approach like aptarpan chikitsa to deal with such patients. Unfortunately , these treatment principles have not been utilized for the weight reduction in Obese Knee Osteoarthritis . So this study is going to be a kind of Observational exploratory study to see if the Ayurvedic Principle Of Management can help weight reduction in patients who are suffering with Knee OA.

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

**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 Sample Size - 30 + 30 = 60**

**Research question and proposed hypothesis –**

**Research Question -**

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 AND OBJECTIVES –**

**Aim of the study –**

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

**Objectives –**

**\*Primary Objectives -**

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 Objectives** –

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

**Material and Method –**

1. **Designing the structure of the workshop –**

* 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.

Already this kind of workshop has been conducted and this is the structure of workshop. We would be conducting in the same manner as it has been conducted earlier and these are the structural component of the workshop which was being conducted .

**Essential components of a weight reduction program for arthritis patients and method of their effective delivery -**

|  |  |  |
| --- | --- | --- |
| **No.** | **Item Domain** | **Method of effective delivery** |
| 1. | Appreciation of knowing that one is overweight. | Delivery of knowledge about ideal weight, overweight and obese in reference to height and gender. |
| 2. | Appreciation of knowledge that extra weight contributes to the joint related problems. | Delivery of knowledge connecting the obesity with joint disease in simple language. |
| 3. | Appreciation of knowledge that weight reduction may cut the intensity of their joint related problems. | Delivery pf knowledge based upon clinical observations made earlier. |
| 4. | Appreciation of knowledge about the surplus weight in each individual case. | Calculating the surplus weight in each individual case on the basis of BMI calculation. |
| 5. | Appreciation of knowledge about methods of effective weight reduction though dietary intake related qualitative and quantitative changes in daily routine. | Categorical check of dietary intake in each individual case and finding the items where maximum impact can be created. |
| 6. | Appreciation of knowledge about alternative methods of cooking in order to reduce calorie intake without compromising the quality and taste. | Demonstration of food items cooked through alternative methods and allowing the participants to eat in order to appreciate its taste. |
| 7. | Appreciation of knowledge about ancillary physical activities and ambience which may help reducing the weight in long run. | Delivery of knowledge about how ambient temperature can help weight reduction and how some small physical activities can induce weight reduction. |
| 8. | Making an individualized weight reduction and reduced weight maintenance plan. | Appreciating the knowledge about surplus weight in each individual case and making a realistic time goal for achieving the optimal weight reduction. |
| 9. | Framing the individualized methods to obtain the goal. | Actual listing of doable and not doable in each individual case. |
| 10. | Appreciating the achievers and motivating the non- achievers during follow ups. | A close follow up to see how each individual is doing and to see what help they need to achieve the goal. |

**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.

1. **Registering the prospective participants for the upcoming workshop –**

We suggest all the patients suffering from arthritis, seeking treatment and relief to register in- person. To ensure efficient registration, we ask participants to provide the following details:

1. Name

2. Address

3. Contact Number

4. Age

5. Gender

6. Height and Weight

7. Position of Illness

We will assure them that all provided information will be kept confidential and used solely for the purpose of organizing the workshop and providing appropriate treatment.

**Additional Points:-**

* The workshop aims to provide valuable information and practical techniques for managing arthritis effectively.
* Various renowned experts in the field of arthritis will be conducting the workshop sessions.
* The workshop will include interactive sessions, demonstrations, and hands-on exercises to enhance your understanding and skills.
* Participants will have the opportunity to connect with fellow arthritis patients, share experiences, and learn from one another.
* We will inform them to arrive at the workshop venue on time.

We will look forward for active participation in the workshop, as it promises to be a **significant step towards better arthritis management and improved quality of life.**

**3.Selection of the prospective participants for the study on the basis of pre defined inclusion and exclusion criteria-**

* **METHOD OF SELECTION OF PARTICIPANTS** –
* The prospective participants will be selected from the departmental registry which is already maintained by the department regarding the demographic details of obese osteoarthritis patients willing to participate in the workshop
* First 30 patients from the registry who are fulfilling the exclusion and inclusion criteria would be invited to participate in the program
* In case if someone shows his or her inability to join the program on the specified date they would be kept as wait-list program .
* Among those who are registered but did not get an opportunity to participate in the first program will be kept as Wait list control after checking the inclusion and exclusion criteria.
* **Inclusion Criteria** -

1. Age: 30-70 years
2. Sex: Both Male & Female.
3. Socio economic status: All.
4. Patients having BMI > 30 with osteoarthritis
5. Patients who are diagnosed any other systemic illness like Diabetes, HTN may also be included in the study.
6. Participants who are ready to 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 .
8. Those who are willing to participate and ready to give their consent.

* **Exclusion Criteria -**

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

* Inclusion Criteria for the Actual Participant of the workshop.
* Inclusion Criteria for the wait list control .

**Wait LIST Control**- They are not ready to participate in the program.

* **Selection of participant on the basis of other criteria-**

**On the basis of Radiological Criteria –**

* **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**

**4. Actual conduction of the workshop -**

1. First, we will invite all the selected prospective participants to attend the workshop on a specific date.
2. Two or three days prior to the workshop, we will inform the selected participants about the date, time, and venue of the workshop through WhatsApp or phone.
3. One day before the workshop, we will confirm the participants' attendance. If any of them are unable to attend, we will select another patient from the registry who meets the inclusion criteria and invite them instead. We will inform all the relevant parties about this change.
4. We will remind the participants to come to the workshop in comfortable clothing and bring their spouse or at least one family member. They should also bring a notebook or copy to take notes.
5. In this structured weight reduction program, we will initially focus on the participants' weight and obesity criteria by calculating their BMI individually.
6. We will then motivate them to join the weight reduction program.
7. During the program, we will recommend them to consume low-calorie, roasted, boiled, and oil-free food, as well as sprouts. We will also provide knowledge about light exercises and yoga practices such as Kapal Bhati and Bhastrika.
8. Monitoring the participants of the workshop through follow-up in the OPD (Outpatient Department) will help demonstrate the effectiveness of such programs in achieving weight reduction. Additionally, it will show increased motivation and clarity in explaining the benefits of adaptable activities

We will call the participant one day before from workshop date and explain about assessment criteria.

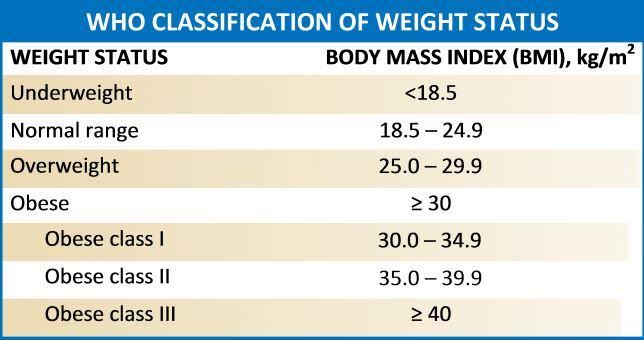
In this meeting we will explain under following roadmap -

**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.

**6. Post workshop follow up of the participant** –

Post-workshop follow-up is an essential component of a structured weight reduction program to reinforce the knowledge and skills acquired during the workshop and provides ongoing support for participants in their weight loss journey.

After the workshop, each participant will undergoes an individual assessment to evaluate their progress. This assessment will include measurements of weight, body composition, and other relevant parameters. The assessment may also involve discussing any challenges or concerns of the participants have encountered since the workshop.

To monitor the progress and provide ongoing support, participants will go under monthly regular check-in sessions. During check-ins, facilitators review the participants, address any difficulties or questions, and provide encouragement and motivation.

Overall, the post-workshop follow-up for a structured weight reduction program aims to provide ongoing support, accountability, and education to participants.

In this post follow-up we asses the weight reduction on the basis of outcome assessment parameter given below -

**Outcome assessment parameter –**

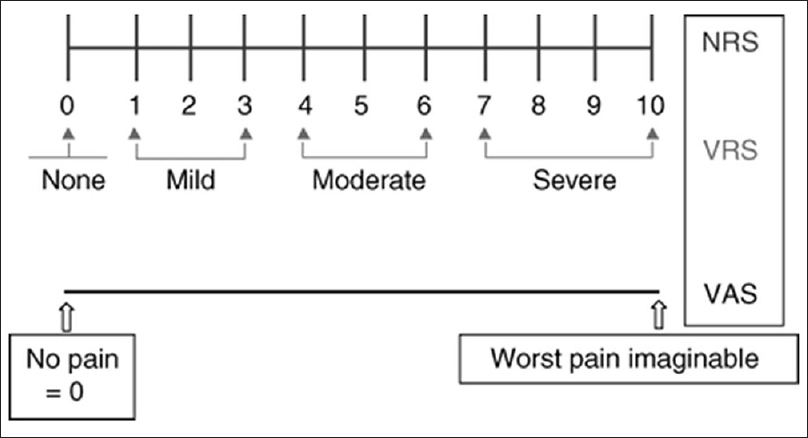
1. **Obesity Assessment –**

* Change in weight
* Change in Hip waist Ratio
* Change in Skin fold measurement**.**
* Change in Quality of life improvement associated with obesity

**2. Osteoarthritis Assessment – Objective Parameter-**

1. **Pain intensity in affected joint -** Visual analogue assessment

0-10 NUMERIC PAIN RATING SCALE



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

1. **Increased walking time (for fixed distance before and after)**
2. **Change in range of movement**

**⚫ Subjective parameter**: All the signs and symptoms are graded on the basis of their 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.

1. **Vatapurnadritisparsa (joint crepitus)-**

Grade 0-Never

Grade 1 - rare

Grade 2- occasionally

Grade 3- Always

1. **Sandhi Shotha (joint swelling) –**

Grade 0-No swelling

Grade 1 - Mild swelling

Grade 2- Moderate swelling

Grade 3- Severe swelling

**3. Sandhi Shoola (joint pain) -**

Grade 0- No pain

Grade 1 - Mild pain

Grade 2- Moderate pain

Grade 3- Severe pain

**4. Prasaran akkunchanaana pravriti savedana (pain during flexion and extension)**

Grade 0 - No pain

Grade 1- Pain without winching of face

Grade 2- Pain with winching of face

Grade 3- Prevent compere flexion

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)

**2. 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

**3. Co – existing Illness** – Co- existing illness is present.

**4.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.

1. 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. 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.

**VIEW OF LITRATURE - ( Obesity and Knee Osteoarthritis )**

**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 .

**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)

1. **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.

**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**.

* **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 .

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

***Assessing the benefits of participation in structured weight reduction program based upon Ayurvedic principle and focusing upon obese knee Osteoarthritis: An observational study***

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

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

## 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