

# Clinical Study to Evaluate the Efficacy of *Maharasnadi Kvatha*, *Trayodashanga Guggulu*, and *Brihatsaindhavadya Taila* in the Management of Knee Osteoarthritis (*Janugata Sandhivata*)

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**Abstract:** Introduction: Osteoarthritis (OA) is the progressive musculoskeletal disorder that characterized by the gradual and persistent degradation of cartilage tissue within joints due to bone friction. The risk factors associated with the development of OA include the female gender, advanced age (geriatric population), elevated body weight or obesity, and a history of a prior knee injury. Ayurveda therapy has great potential in the management of OA and its progression. Aim: This clinical study aims to assess the effect of selected Ayurveda formulations in the management of knee OA. Materials and Methods: This was a prospective, single - center, open - label study carried out on 60 participants with primary OA of the knee. Inclusion criteria encompassed individuals aged between 35 and 65 years, meeting the diagnostic criteria outlined by the American College of Rheumatology, and with radiographic abnormalities characteristic of OA. Therapeutic interventions in the study comprised Maharasnadi Kvatha (MK) (50 mL twice a day in an empty stomach), Trayodashanga Guggulu (TG) (1500 mg twice daily), and Brihatsaindhavadya Taila (BST) (for local fomentation twice daily) for the duration of 84 days. The primary outcome of the study was change in the Indian Western Ontario and McMaster Universities arthritis index (WOMAC) score. Results: Out of 60 participants, 58 subjects completed the study, while one subject dropped out and one was withdrawn. The analysis yielded statistically significant results ( $P < 0.001$ ) in the Indian WOMAC (modified—clinical research data (CRD) Pune version) score and clinical symptoms and improvement in the quality of life ( $P < 0.001$ ). X - ray assessments revealed the disappearance of osteophytes in knee joints in 8.62% of cases. A change in the mean pain score as assessed by the visual analog scale was also noticed with  $P < 0.001$ . Conclusion: The Ayurvedic interventions demonstrated significant effects in mitigating symptoms of knee OA, with no reported adverse events. This study substantiates the effectiveness of Ayurvedic management in alleviating symptoms of knee OA such as bony tenderness of joints, difficulty of physical function of knee joints, crepitus, and improvement in quality - of - life parameters.

**Keywords:** Brihatsaindhavadya taila; Janugata sandhivata; Maharasnadi kvatha; osteoarthritis of knee; Trayodashanga guggulu

## 1. Introduction

Osteoarthritis (OA) is among the most prevalent rheumatic diseases seen in clinical practice, particularly among elderly individuals, both male and female, and is a prominent cause of impairment in aged people due to the high rate of disability of major joints. [1] India has one of the highest global rates of OA, and by 2025, it is predicted to continue leading the globe in chronic diseases. [2] The prevalence of OA knee globally was estimated to be around 22.9% [3] and in India to be around 28.7%. [4] It is a chronic, degenerative musculoskeletal condition that causes eventual degeneration of the cartilage of joints, caused by friction of the bones, leading to stiffness, pain, and impaired movements. When the disease progresses to the chronic stage, pain becomes a continuous feature, and night stiffness may be prominent, but morning stiffness remains for a short time. [5] Risk factors in high - risk populations include the female gender, advanced age, obesity, and a history of previous knee surgery or trauma. [6]

Based on the clinical presentation and joint involvement, this condition can be compared with *Sandhivata* or *Sandhigatavata*. The combination of two words creates the term *Sandhivata*; *Sandhi* (joint) and *Vata*, which denote the *Vata Dosha*, a body humor *Mithya - Ahara* (improper diet), *Mithya - Vihara* (improper lifestyle), overuse of joints, elderly age, etc., cause aggravation of *Vata*, leading to

degeneration of body elements (*Dhatukshaya*). Since *Vata* is the factor responsible for bodily motions, its vitiation leads to the manifestation of pain. Another contributing factor to the manifestation of crepitus is the reduction of *Shleshaka - Kapha* (a viscous fluid substance present in the knee joint), which facilitates smooth movement. In *Sandhivata*, *Sandhishula* (pain in the afflicted joint) is a typical feature, characterized by *Vatapurnadriti - Sparsha* (crepitus), *Shotha* (swelling in joints), and pain on *Akunchana*, *Prasarana*, and *Pravritti* (on extension, flexion, and any movement) in the joints. [7, 8]

In the contemporary system of medicine, management of this disease is confined to pain relief, as there is no established treatment protocol to reverse the condition. Prolonged intake of nonsteroidal anti - inflammatory drugs (NSAIDs) or other analgesic medications can result in adverse events and may be associated with adverse effects on various organ systems.

Among the worldwide burden of OA, approximately 80% is attributed to OA of the knee, significantly impacting both disability and overall quality of life. The resulting disability often leads patients to consider total or partial knee joint replacement surgeries, contributing substantially to the economic burden, which has surged by threefold or more among individuals undergoing such procedures. [9] According to a study conducted in India, [9] joint disorders were the second most common cause for outpatient visits

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and fourth common causes for out - of - pocket expenses among all non - communicable diseases. Evidence from research has demonstrated that Ayurveda and other traditional systems of medicines have displayed promising outcomes in managing OA of the knee.<sup>[10 - 13]</sup>

The limitations of conventional treatments for OA, coupled with the lack of efficacious interventions to arrest the progression or reverse the damage, potential side effects, and economic burden, highlight the necessity for exploring safe, effective, and affordable alternatives such as Ayurveda and other traditional systems in the comprehensive management of OA. The encouraging outcomes observed in Ayurveda and other traditional medicine systems warrant further research to validate their efficacy for their potential integration into comprehensive treatment strategies for OA management. The main objective of the study was to assess the therapeutic effect and safety of *Maharasnadi Kvatha* (MK), *Trayodashanga Guggulu* (TDG), and *Brihatsaindhavadya taila* (BST) in the treatment of knee OA.

## 2. Materials and Methods

This clinical study was carried out at M. S. Regional Ayurveda Research Institute, Jaipur, under the Central Council for Research in Ayurvedic Sciences (CCRAS), New Delhi, from December 2017 to June 2019. The Institutional Ethical Committee granted ethical clearance for the study on July 20, 2017 before starting the trial, with the reference number Ref. F.5/Lab/Prei - iron/Ethics/2007 - 08CRIA - JPR. This trial adhered to Schedule Y of the Drugs and Cosmetics Act (1945, amended in 2005) of India, as well as the Indian Council of Medical Research ethical guidelines for biomedical research on human participants, and the GCP guidelines adopted from the World Medical Association—Declaration of Helsinki. This clinical study was prospectively registered in the Clinical Trials Registry of India (CTRI/2018/03/012292, dated March 30, 2020). The trial was done after obtaining a signed consent form from the participants.

### 2.1 Methodology

#### Trial design

This was an interventional, open - label, single arm, single - center, prospective study.

#### Participants

Outpatient and inpatient department patients reporting knee joint pain were screened for the clinical trial. Following a thorough clinical evaluation, these patients underwent laboratory testing and a knee joint X - ray. Upon confirmation of the findings on the X - ray, eligible patients were enrolled according to the inclusion and exclusion criteria. The participants were provided with comprehensive information regarding the study before the trial's commencement, and voluntary consent was obtained. The participants were assured about the confidentiality of their personal data. An appropriate case record form was designed to document the demographic data, history, clinical examination findings, and clinical parameters before and after treatment. During each follow - up, trial participants

were instructed to return their empty trial drug containers to assess their adherence to the medication. Throughout the study, all participants were permitted to use NSAIDs for pain management if needed, and they were instructed to report their use to the investigators at each follow - up.

#### Inclusion criteria

The present study includes participants of either sex between 35 years and 65 years of age with primary OA of the knee (unilateral/bilateral) fulfilling the diagnostic criteria of OA recommended by the American College of Rheumatology as follows: knee pain and at least three of the following clinical classification of six diagnostic criteria, namely, (i) 50 years of age or older, (ii) stiffness lasting less than 30 min, (iii) crepitus, (iv) bony tenderness, (v) bony enlargement, and (vi) no warmth to the touch. A willingness and able to participate in the trial and disease severity categorized as Grade I to III of the Kellgren and Lawrence radiological scale were also included in the selection criteria.

#### Exclusion criteria

Individuals with Grade IV Kellgren and Lawrence radiological scale, a history of any trauma/fractured joint/surgical/diagnostic intervention concerning the affected joint (s), gross disability in performing daily normal routine (i. e., bedridden patients or confined to a wheelchair), patients with comorbidities such as gouty arthritis, rheumatoid arthritis, and psoriatic arthritis, and those with any deformity of knee, hip, or back altering the gait and posture were excluded. Patients with uncontrolled hypertension (>160/100 mm of Hg), uncontrolled diabetes mellitus (HbA1C > 7%), or evidence of malignancy were also not included in the study. Individuals who are taking or have taken any chondroprotective drugs, received intra - articular injection into the affected joint, or have been on prolonged (>6 weeks) medication with corticosteroids, antidepressants, anticholinergics, etc., or any other drugs that may influence the outcome of the study were excluded. Patients with a history of atrial fibrillation, acute coronary syndrome, myocardial infarction, stroke, or severe arrhythmia in the last 6 months were not considered for the study. Individuals with the concurrent serious hepatic disorder (defined as aspartate amino transferase (AST) and/or alanine amino transferase (ALT), total bilirubin, alkaline phosphatase >2 times upper normal limit) or renal disorders (defined as serum creatinine >1.2 mg/dL), severe pulmonary dysfunction (uncontrolled bronchial asthma and/or chronic obstructive pulmonary disease), pregnant/lactating woman, patients who are currently participating in any other clinical trial, or those who have completed participation in any other clinical trial during the past six months, and presence of any other condition which the Principal Investigator thinks may jeopardize the study were also excluded from this study.

## 3. Interventions

The therapeutic interventions in the study encompassed three treatments: MK, TDG, and BST. These interventions were administered for a period of 84 days. To ensure quality, all drugs were obtained from pharmacies adhering to Good Manufacturing Practice (GMP) standards. The study interventions were administered as follows:

- MK [14, 15]: 25 g boiled with eight times water until it is reduced to one - fourth (~50 mL), taken twice a day in the morning and evening on an empty stomach.
- TDG [16, 17]: three tablets (1500 mg) taken twice daily with lukewarm water, 30 min after food.
- BST [18, 19]: 10 mL for local massage, followed by hot water fomentation twice daily at 7 AM and 7 PM.

## Outcome Measures

### Primary outcome measures

Changes in the Indian WOMAC (modified—CRD Pune Version) score, [20] specifically the total score from baseline to the end of the trial period at the 4th, 8th, 12th, and 16th weeks.

### Secondary outcome measures

Secondary outcome measures included changes in disease - specific symptoms of *Sandhivata* (such as joint pain and stiffness, restricted movements, crepitus, swelling, and bony tenderness over the joints); changes in quality - of - life assessed using the World Health Organization Quality - of - Life (WHOQOL - Bref) questionnaire; [21] change in the visual analog or analogue scale (VAS) to assess pain in the last 48 h; patient and physician's global assessment of disease activity; change in WOMAC stiffness domain score; and change in WOMAC physical function domain. These secondary outcome measures were assessed from baseline to the end of the 4th, 8th, 12th, and 16th weeks of the trial period.

Laboratory investigations including hemoglobin percentage (Hb%), complete blood count, erythrocyte sedimentation rate, glycosylated hemoglobin (HbA1c), liver function tests, renal function tests, antistreptolysin O (ASO) titer, rheumatoid (RA) factor, and digital X - ray of the afflicted knee joint (s) and electrocardiogram were carried out at baseline. At the end of the 12th week, all of the above laboratory investigations (except ASO titer and RA factor) were repeated.

### Sample size

Based on the assumption of detecting a relevant change of 12 points in pre - and post - assessment in the total Indian WOMAC (modified—CRD Pune version) score, considering the result of previous studies and a standard deviation of 30 points with a 95% confidence interval and 80% power, and expecting a dropout rate of 25%, the number of participants enrolled in the study was 60.

### Statistical analysis

The collected data underwent statistical analysis using both descriptive and comparative statistical approaches, aligning with the predetermined primary and secondary outcomes. Descriptive statistics, expressed as mean  $\pm$  SD or median (min, max), were employed for quantitative variables, depending on the distribution characteristics of each variable. Comparisons of outcome parameters across various time points within this single - arm framework were conducted using the paired *t* test or Wilcoxon sign rank test, as deemed appropriate. The level of significance for these statistical analyses was predetermined at 5%. For comparisons involving more than two - time points, repeated

- measure analysis of variance or Friedman test were employed, as appropriate.

## 4. Observations and Results

Out of a total of 60 enrolled participants, 58 completed the study, while one dropped out and one was withdrawn.

### Demographic profile of study participants

The majority of trial participants were within the age range of  $50 \pm 7.8$  years, with a higher proportion of female participants (69.0%) compared to male participants (31.0%). Additionally, 81.0% of the participants were literate, with a significant proportion being housewives (65.5%). Furthermore, 96.6% of the subjects were found to be above the poverty line, and 81.0% were urban dwellers. The majority of subjects, constituting 94.8%, identified with the Hindu religion [Table 1].

**Table 1:** Description of demographic profile at baseline ( $n = 58$ )

S. No	Variable	No. (%)
1	Age	50.31 $\pm$ 6.8 (Mean $\pm$ SD)
2	<b>Gender</b>	
	1. Male	18 (31.0)
	2. Female	40 (69.0)
3	<b>Marital Status</b>	
	1. Married	57 (98.3)
	2. Widow	01 (1.7)
4	<b>Education</b>	
	1. Illiterate	11 (19.0)
	2. Read & Write	47 (81.0)
5	<b>Past Occupation</b>	
	1. Desk Work	12 (20.0)
	2. Field Work With Physical Labour	09 (15.5)
	3. Housewife	37 (63.8)
6	<b>Present Occupation</b>	
	1. Desk Work	11 (19.0)
	2. Field Work With Physical Labour	09 (15.5)
	3. Housewife	38 (65.5)
7	<b>Socio Economic Status</b>	
	1. Above Poverty Line	56 (96.6)
	2. Below Poverty Line	02 (03.4)
8	<b>Habitat</b>	
	1. Urban	47 (81.0)
	2. Semi Urban	02 (03.4)
	3. Rural	09 (15.5)
9	<b>Religion</b>	
	1. Hindu	55 (94.8)
	2. Muslim	03 (05.2)
Total		58 (100.0)

### Description of Personal History

The data analysis revealed that 75.9% of participants were vegetarians, and 81.0% reported normal sleep patterns. The mean body mass index (BMI) observed in the study population was 27.65. Other parameters associated with personal history are depicted in Table 2. It was found that *Pitta - Kaphaja Prakriti* (43.1%) and *Pittaja Prakriti* (31.0%) had the highest proportion of subjects [Table 2].

**Table 2:** Description of personal history at baseline (n = 58)

S.NO	Variable	NO. (%)
1	<b>Dietary Habits</b>	
	1.Vegeterian	44 (75.90)
	2.Non-Vegeterian	14 (24.1)
2	<b>Addictions</b>	
	1.Tabacoo	4 (6.9)
	2.Alcohol	2 (3.4)
3	<b>Sleep</b>	
	1.Normal	47 (81.0)
	2.Abnormal	11 (19.0)
4	<b>Bowl Habits</b>	
	1.Regular	49 (84.5)
	2.Irregular	9 (15.5)
5	<b>BMI</b>	
	1.Mean	27.65±4.2 (Mean±SD)
6	<b>Allergy To Some Material</b>	
	1.Yes	35(60.3)
	2.No	23 (39.7)
7	<b>Any Emotional Stress</b>	
	1.Average	49 (84.5)
	2. Moderate	9 (15.5)
8	<b>Type Of Prakriti</b>	
	1.Vataja	1 (1.7)
	2.Pittaja	18 (31.0)
	3.Kaphaja	1 (1.7)
	4.Vatpittaja	8 (13.8)
	5.Vatakaphaj	0 (0.0)
	6.Pittakaphaja	25 (43.1)
	7.Sannipataja	5 (8.6)
Total	58(100.0)	

Comparative analysis for disease - specific clinical parameters

Statistical analysis of the Indian WOMAC (modified—CRD Pune version) index on cardinal features of pain, stiffness, and difficulty in knee OA was found to be highly significant ( $P < 0.001$ ), indicating that trial drugs were effective in relieving pain, stiffness, bony tenderness of joints, physical function difficulty of knee joints, and crepitus in joints. Following 16 weeks of therapy, a noteworthy reduction in the overall mean of the Indian WOMAC (modified—CRD Pune version) score was observed, which persisted even during the four - week follow - up period. Before starting the trial, 43.10% of participants used to take NSAIDs, but this percentage gradually reduced to 17.24% on the 29th day and further to 06.89% on the 57th day. On completion of the trial, only 01.72% of participants were using NSAIDs on the 85th day), and this percentage remained low at 03.44% on the 113th day—follow - up day. The usage of the number of analgesics on si opus sit basis was observed to be reduced by almost 98% [Table 3].

**Table 3:** Role of study interventions in outcome measures (n = 58)

S. No	Variable	Baseline	Followup Visit 29 <sup>TH</sup> Day	Followup Visit 57 <sup>TH</sup> Day	Followup Visit 85 <sup>TH</sup> Day	Followup Visit 113 <sup>TH</sup> Day	P Value
1.	Indian WOMAC (modified-CRD Pune version) score	37.2±8.1	28.8±7.1	22.4±8.0	15.9±7.5	13.8±7.6	<0.001
2.	VAS	5(5-6)	4(4-5)	3.5(3-4)	3(2-4)	2(1-3)	<0.001
3.	PADA score	56.7±11.6	45.8±11.2	36.8±11.9	29.6±12.7	23.9±12.3	<0.001
4.	PHDA score	54.4±9.8	45.1±10.5	36.0±11.0	28.1±11.8	23.4±12.2	<0.001
	<b>WHO-QOL SCORE</b>						
1.	Domain-1	53.4±13.4	57.4±10.5	62.1±8.6	65.8±9.6	63.0±17.0	<0.001
2.	Domain-2	57.7±	59.0±10.1	60.1±8.7	62.3±8.0	63.6±8.9	<0.001
3.	Domain-3	72.3±	72.3±8.0	73.6±6.7	73.0±6.2	73.7±6.8	0.422
4.	Domain-4	65.4±	65.4±11.4	68.1±8.0	69.0±7.6	69.4±6.9	<0.001

On assessment of pain, a substantial decline in the mean VAS ( $P < 0.001$ ) was noted after receiving therapy for 16 weeks and at the 4 - week follow - up. The mean score was 5 at baseline, and at the end of the treatment, it decreased to 2 with a very significant  $P$  value of  $< 0.001$  [Table 3].

Compared to the baseline mean score of WHOQOL BREF scale with total score of 130, improvement was seen at the end of the treatment (85th day) and at follow - up (113th day). Assessment parameters were statistically analyzed concerning the quality of life and found that study interventions are highly effective in improving the quality of life ( $P < 0.001$ ) concerning the Domain - 1 (physical health), Domain - 2 (psychological health), Domain - 4 (environment) of QOL, while in Domain - 3 (social relationships) of QOL, it was found not to be significant [Table 3].

At the baseline, *Sandhishula* (pain in the affected joint at rest) was reported in 79.3% of participants, while post - treatment, 93.1% experienced complete relief. *Shotha* (swelling in the joints) was present in 41.4% of participants before treatment, and 91.4% obtained relief after the study. Only 20.7% got relief after treatment for symptoms of *Vatapurnadriti - Sparsha* (crepitation). *Prasarana - Akunchana Vedana* (painful movements of the affected joint) was relieved in 29.3% after treatment was present in 81.0% of patients at baseline. After treatment, the majority, 77.6% of the participants with *Apravritti* (restricted movement of the joint), got relief from it at the end of the study period. Improvement across various other symptoms of knee OA, recorded across various time points, in the clinical study are depicted in Table 4. The hematological and biochemical parameters were recorded to be within normal limits during the study period, indicating the safety of the trial interventions [Tables 5 and 6].

**Table 4:** Changes in clinical symptoms before and after treatment ( $n = 58$ )

S.No	Parameter	Baseline	29 <sup>th</sup> Day	57 <sup>th</sup> Day	85 <sup>th</sup> Day	113 <sup>th</sup> Day
1	SANDHISHULA	46(79.3%)	27(46.6%)	13(22.4%)	7(12.1%)	4(6.9%)
2	SHOTHA	24(41.4%)	16(27.6%)	9(15.5%)	3(5.2%)	5(8.6%)
3	VATAPURANDITI SPARSHA	58(100.0%)	58(100.0%)	57(98.3%)	51(87.9%)	46(79.3%)
4	PRASARANA-AKUNCHANA VEDANA	58(100.0%)	58(100%)	51(87.9%)	43(74.1%)	41(70.7%)
5	APRAVRITTI	47(81.0%)	42(72.4%)	33(56.9%)	17(29.3%)	13(22.4%)
6	WEAKNESS OF AFFECTED JOINT	34(58.6%)	25(43.1%)	11(19.0%)	9(15.5%)	6(10.3%)
7	JOINT STIFFNESS	54(93.1%)	51(87.9%)	47(81.0%)	35(60.3%)	23(39.7%)

**Table 5:** Changes in hematological parameters of participants ( $n = 58$ )

S. No	Variables	Baseline (Mean $\pm$ SD)	Follow-Up (Mean $\pm$ SD)	P Value
1	Haemoglobin	13.2 $\pm$ 1.3	13.0 $\pm$ 1.4	0.198
2	TLC	7166.5 $\pm$ 1717.0	7067.2 $\pm$ 1726.8	0.738
3	N%	61.4 $\pm$ 6.9	61.3 $\pm$ 6.8	0.93
4	E%	4.1 $\pm$ 3.0	4.1 $\pm$ 2.2	0.551
5	B%	0.6 $\pm$ 0.3	0.6 $\pm$ 0.3	0.746
6	L%	30.8 $\pm$ 6.7	30.8 $\pm$ 6.9	0.769
7	M%	3.1 $\pm$ 0.8	3.1 $\pm$ 0.8	0.891
8	ESR	19 $\pm$ 12.1	19 $\pm$ 11.4	0.377

**Table 6:** Changes in biochemical parameter of participants ( $n = 58$ )

S.NO	Variables	Baseline (Mean $\pm$ SD)	Follow-Up (Mean $\pm$ SD)	P Value
1	HBA1c (mg/dl)	5.8 $\pm$ 0.4	5.9 $\pm$ 0.4	0.208
2	Blood Urea	22.3 $\pm$ 6.5	22.4 $\pm$ 6.6	0.949
3	Serum Uric Acid	4.8 $\pm$ 1.0	4.9 $\pm$ 1.2	0.348
4	Serum Creatinine	0.75 $\pm$ 0.14	0.77 $\pm$ 0.18	0.109
5	SGOT(AST)	21.6 $\pm$ 6.2	22.2 $\pm$ 7.0	0.442
6	ASPT(ALT)	22.4 $\pm$ 10.8	22.9 $\pm$ 10.6	0.689
7	Total Protein	7.4 $\pm$ 0.4	7.3 $\pm$ 0.4	0.067
8	S. Albumin	4.3 $\pm$ 0.2	4.3 $\pm$ 0.2	0.812
9	S. Globulin(g/dl)	3.0 $\pm$ 0.4	2.9 $\pm$ 0.4	0.128
10	Conjugated Bilirubin	0.2 $\pm$ 0.1	0.2 $\pm$ 0.2	0.891
11	Unconjugated Bilirubin	0.4 $\pm$ 0.3	0.4 $\pm$ 0.2	0.518
12	Serum Alkaline Phosphates	77.4 $\pm$ 19.6	75.4 $\pm$ 21.1	0.468

## 5. Discussion

In the present study, the role of Ayurveda in the management of *Janugata Sandhivata*, also known as knee OA is demonstrated. In this single - arm clinical trial, the combination of Ayurvedic interventions demonstrated a significant effect in alleviating symptoms and improving the overall well - being of participants. The study also revealed a remarkable reduction in the overall mean of the Indian WOMAC (modified—CRD Pune version) score, reflecting the positive impact of the Ayurveda interventions. This improvement persisted even during the 4 - week follow - up period without further intervention, emphasizing the sustained benefits of the therapy.

The trial drugs exhibited a highly significant ( $P < 0.001$ ) effect in relieving pain, stiffness, crepitus, bony tenderness, and physical functional difficulty of knee joints. After 16 weeks of treatment, a significant reduction in the mean total WOMAC score was observed. Additionally, the trial drugs demonstrated a significant effect on three domains (physical health, psychological health, and environment) of WHO - QOL scores. In Domain - 1 (physical health), the mean score was 53.4  $\pm$  13.4 before treatment, and after treatment, it was improved to 63.0  $\pm$  17.0, with the improvement being statistically significant ( $P < 0.001$ ). In Domain - 2 (psychological health), the mean score was 57.7  $\pm$  9.5 before treatment, and after treatment (4th visit), it improved to a mean score of 63.6  $\pm$  8.9; this improvement was statistically

very significant ( $P < 0.001$ ). In Domain - 4 (environment), the mean score was 65.4  $\pm$  9.4 before treatment, but after treatment, it was improved to 69.4  $\pm$  6.9, with  $P < 0.001$ . A significant reduction in the mean total of VAS ( $P < 0.001$ ) was observed after 16 weeks of treatment [Table 3].

*Rasna* (*Pluchea lanceolata*), the main ingredient in MK, is indicated for *Janugata* in *Sharngadharasamhita* [22] and Ayurvedic Formulary of India. [23] *Rasna* is the best *Vatahara* (pacifying *Vata*) drug. [24, 25] It has *Tika - Rasa* (bitter in taste), *Guru - guna* (heavy to digest), *Ushna - Veerya* (hot in potency), *Katu - Vipaka* (pungent in *vipaka*), and *Vatakapha - shamaka* (pacifying *Vata - Kapha*), making it suitable for treating *Vatavyadhi* (diseases of *Vata* origin), *Ghridhrasi* (sciatica), *Amadosha* (diseases due to indigested food), and *Vibandha* (constipation). *Rasna* contains pluchea chromenone, pluchea sterdiide (root), taraxasterol, sitosterols, flavone glycoside, and pluchine. The drug exhibits anti - inflammatory and analgesic properties. [26] A multi - centric clinical study (142 patients) on *Sandhivata* with *Vatari Guggulu*, MK, and *Narayana Taila* reported significant efficacy at the end of the treatment ( $P < 0.001$ ), providing strong evidence for their efficacy and safety. [27]

In TDG, *Guggulu* (*Commiphora wightii* (Arnott) Bhandari) is the main ingredient. Charaka and Vagbhata indicated *Guggulu* as the best *Vatahara* (pacifying *Vata*). [28, 29] TDG is indicated in *Asthivata* (diseases in bone due to *Vata*), *Majjavata* (diseases in bone marrow due to *Vata*), and

*Janustabdhata* (knee stiffness).<sup>[30, 31]</sup> *Guggulu* (*Purana*) has *Tikta* (bitter), *Katu* (pungent) *Rasa* (taste), *Laghu* (light to digest), *Teekshna* (sharp), *Sukshma* (penetrating), *Vishada* (clear); *Ushnaveerya* (hot in potency), *Katuvipaka* (pungent in *vipaka*), *Tridosahara* (pacifies all three *Doshas*), *Rasayana* (rejuvenating) properties; and *Shothahara* (anti-inflammatory), *Vedanasthapana* (analgesic), *Anulomana* (facilitates normal movement of *Vayu*) actions. It has actions like anti - arthritic, anti - inflammatory, and fibrinolytic activities and contains active principles like guggulsterone I-VI, Z - guggulsterone, etc.<sup>[32]</sup> In a clinical trial carried out on 40 patients diagnosed with *Grivasandhigatavata* (cervical Spondylosis), divided into two groups, viz., TDG, *Sahacharadikvatha* (Group - A) and TDG, *Sahacharadikvatha* plus *Prasarinitaila Grivabasti* (Group - B). Group - B showed better results; 56.47% in pain relief; 64.33% improvement (neck disability index).<sup>[33]</sup>

In BST, *Erandataila* (oil of *Ricinus communis* Linn) is the main ingredient. *Eranda* (*R. communis* Linn) oil has *Snigdha* (unctuous), *Teekshna* (sharp), *Sukshma guna* (penetrative), *Ushna - veerya* (hot in potency), and *Kaphavata - shamaka* (pacifies *vata - kapha*) properties. It possesses *Shothahara* (anti-inflammatory) and *Vedanasthapana* (analgesic) properties, making it suitable for treating *Sandhishotha* (edema in joints), *Amavata* (joint disorders due to *ama*), *Ghridhrasi* (sciatica), etc. It contains active principles such as arachidic, palmitic, ricinoleic, etc. The drug exhibits anti-inflammatory, purgative, and spasmolytic properties.<sup>[34]</sup>

The oil used for *Abhyanga* (local massage application) exerts *Snigdha* (unctuousness), *Ushnata* (hot sensation), *Guruta* (heaviness), and *Mridutva* (softness) at the *Vyadhisamudbhava - Sthana* and provides relief from pain due to its opposite properties of aggravated *Vata*. Additionally, *Abhyanga* (local massage application) pacifies the aggravated *Vayu*, which causes the degeneration of the afflicted part and manifestation of *Vedana* (pain) and *Stabdhatata* (stiffness). *Taila abhyanga* (local massage by application of oil) enhances blood circulation at the affected part. The contents of BST also help through their *vata* pacifying property.

*Rasna* exhibits anti-inflammatory and analgesic activities and possesses *Vatahara* (pacifying *Vata*), *Vedanasthapana* (analgesic), and *Rasayana* (rejuvenating) properties.<sup>[35]</sup> *Guggulu* has *Vedanasthapana* (analgesic) action, along with anti - arthritic, anti - inflammatory properties,<sup>[36]</sup> and aids in the formation of proper *Asthi* and *Majja - Dhatu*. *Erandataila* is characterized by *Shleshmabhivardhana* (especially *Shleshaka - kapha*), *Shothahara* (anti-inflammatory), and *Vedanasthapana* (analgesic) actions, contributing to its anti-inflammatory actions. These drugs might have worked in synergy in relieving pain.<sup>[37]</sup>

None of the patients reported adverse drug reactions (ADRs) like gastric irritation, despite the trial drugs possessing anti-inflammatory properties. Probably, this could be the reason for non-reporting ADRs related to NSAID drugs. The increasing concerns about the safety and costs linked with conventional arthritis therapies have ignited a burgeoning interest in exploring traditional remedies, especially Ayurveda interventions, as potential alternatives. The results

of the present study underscore the potential of Ayurveda approaches in providing effective and safe treatment options. Ayurveda medicines can be appropriately used to not only address the limitations of conventional therapies but also offer a viable option for individuals seeking alternative and holistic methods for managing OA symptoms.

## 6. Conclusion

The comprehensive study evaluating the effect of Ayurvedic interventions, including MK, TDG for oral use, and *Abhyanga* (local massage application) with BST followed by *Svedana* in managing OA knee, reveals a reduction in cardinal features of the disease, including joint pain, swelling, and stiffness, as well as improvement in quality-of-life parameters. The outcomes observed in this research provide insights into the potential of Ayurvedic interventions as a viable and safe therapeutic option for individuals with OA.

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## Conflicts of interest

There are no conflicts of interest.

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