



Original Research Article



Evaluation of Yograj Guggulu, Ashwagandha Churna and Narayana Taila in management of Osteoarthritis Knee: A study in tribal dominant community

Kalpana Kachare^{a,*}, Deepa Makhija^a, Abha Sharma^a, Sunita^a, N. Srikanth^a, B.S. Sharma^a, Rakesh Rana^a, Arunabh Tripathi^a, B.C.S. Rao^a, Purnendu Panda^b, Ekta^c, Raghavendra Naik^d, K. Nishanth^e, U.R. Shekhar Namburi^f, Vimal Tiwari^g, S.B. Singh^h, Monikaⁱ, P. Srinivas^j, Vipin Sharma^k, Anil Avhad^l, Ashok Sinha^m, Rohit Ravteⁿ, Akash Lal^o, Krishna Rao^b, Pravin Mashram^c, S.H. Doddamani^d, Savita Gopad^e, Priya^f, Deepika Tiwari^g, Anil Mangal^h, V.B. Kumawatⁱ, K. Prameela^j, Subhash^k, Jaiprakash Ram^l, S.K. Sahu^m, Sojeetra Niraliⁿ, Abhaydev^o

^a Central Council for Research in Ayurvedic Sciences (CCRAS), New Delhi, Ministry of AYUSH, Govt. of India, India

^b Central Ayurveda Research Institute (CARI), Bhubaneswar (CARI), CCRAS, Ministry of AYUSH, Govt. of India, India

^c Central Ayurveda Research Institute (CARI), Guwahati, CCRAS, Ministry of AYUSH, Govt. of India, India

^d Central Ayurveda Research Institute (CARI), Bangalore, CCRAS, Ministry of AYUSH, Govt. of India, India

^e Regional Ayurveda Research Institute (RARI), Vijaywada, CCRAS, Ministry of AYUSH, Govt. of India, India

^f Regional Ayurveda Research Institute (RARI), Nagpur, CCRAS, Ministry of AYUSH, Govt. of India, India

^g Regional Ayurveda Research Institute (RARI), Patna, CCRAS, Ministry of AYUSH, Govt. of India, India

^h Regional Ayurveda Research Institute (RARI), Gwalior, CCRAS, Ministry of AYUSH, Govt. of India, India

ⁱ Regional Ayurveda Research Institute (RARI), Jaipur, CCRAS, Ministry of AYUSH, Govt. of India, India

^j Dr. Achanta Lakshmi Prathi Regional Ayurveda Research Institute (ALRARI), Chennai, CCRAS, Ministry of AYUSH, Govt. of India, India

^k Regional Ayurveda Research Institute (RARI), Jammu, CCRAS, Ministry of AYUSH, Govt. of India, India

^l Regional Ayurveda Research Institute (RARI), Ahmedabad, CCRAS, Ministry of AYUSH, Govt. of India, India

^m Regional Ayurveda Research Institute (RARI), Gangtok, CCRAS, Ministry of AYUSH, Govt. of India, India

ⁿ Regional Ayurveda Research Centre (RARC), Tripura, CCRAS, Ministry of AYUSH, Govt. of India, India

^o Regional Ayurveda Research Institute (RARI), Port Blair, CCRAS, Ministry of AYUSH, Govt. of India, India

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ABSTRACT

Background: Osteoarthritis (OA) is the most prevalent joint disease and a major cause of joint impairment and physical debility, common in elderly, women and laborious workers. The available non-steroidal anti-inflammatory drugs (NSAID) are being prescribed to manage the condition; however, newly discovered alternatives are looked upon by the practitioners. Thus, the study was aimed to provide an effective and safer alternative through Ayurveda for the management of OA.

Objective: To document the role of the selected Ayurveda formulations in the management of OA and to assess the tolerability of the formulations.

Material and methods: It was an open-label, multicentric, single-arm, prospective, study conducted at 14 peripheral institutes of the Central Council for Research in Ayurvedic Sciences, New Delhi. 483 participants of any gender between the age 40 to 65 years diagnosed with OA knee as per the ACR diagnostic criteria (2012) and willing to provide consent were enrolled in the study. Oral administration of Ayurvedic formulations Yograj Guggulu, Ashwagandha Churna and the local application of Narayana Taila was given for 12 weeks and assessment was done by means of Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Modified-CRD, Pune version Score, Visual Analogue Scale score and disease-specific symptoms on 28th, 56th, 84th and 112th day.

Results: Significant change ($P < 0.001$) was observed in WOMAC score, VAS score and cardinal symptoms of OA knee. No adverse events reported in the study and the study drugs were well tolerated by the participants.

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* Corresponding author.

E-mail address: kachare.kalpana@gmail.com (K. Kachare).

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Conclusion: The study substantiates that administration of Yograj guggulu, Ashwagandha Churna and Narayana Taila, is well acceptable and tolerable. The interventions effectively alleviate the cardinal symptoms of OA knee.

Introduction

Osteoarthritis (OA) is a degenerative disease of joints that impacts hundreds of millions of individuals worldwide, emerging as a leading cause of extreme long-term pain and physical disability [1]. OA is significantly correlated with aging, and jobs demanding physical work. In India, around 23.46 million individuals had OA in 1990 which reached 62.35 million in 2019 [2]. It is most commonly reported in the hip, knee, and the joints of the hand, foot, and spine [3]. The knee is the most common joint affected by OA, which is characterized by irreversible degeneration of the articular cartilage at the ends of the bones such as femoral, tibial, and patella cartilages [4]. The clinical manifestations of the condition comprise joint discomfort, soreness, mobility restriction, crepitus, sporadic effusion, and varying degrees of local inflammation. A community-based study exhibited the prevalence of knee OA in India to be 28.7% [5]. Therefore, considering the state of emerging knee OA cases, the present tribal-dominant community-based study was planned.

The goals of the treatment of OA are to alleviate pain and mitigate loss of physical function. For the pharmaceutical management of OA, practitioners are only left with an array of analgesic choices as there are no preventive or curative medicinal treatments available. The most popular "over the counter" medications for any indication are non-steroidal anti-inflammatory drugs (NSAID) [6] which may cause potentially fatal drug toxicity (especially to the gastrointestinal, renal, and cardiovascular systems) [7]. Due to worries about such adverse effects people with OA now frequently use complementary and traditional medicines either in addition to or as a substitute for modern analgesics.

In Ayurveda, OA can be correlated to *Sandhigata Vata* (vitiated *Vata* in joints), *Sandhi* means joint and *Vata* is one of the three humours of the body. Since *Vata* is considered a governing factor in the maintenance of equilibrium in the universe as well as in the body, its vitiation results in the process of gradual degeneration of the body as age progresses, manifesting into *Sandhigata Vata* [8]. Various formulations along with therapeutic procedures have been elaborated in Ayurveda including *Yograj guggulu* [9], *Ashwagandha Churna* [10] and *Narayana Taila* [11] which have been earlier reported to be beneficial in the management of *Janugata Sandhivata* [12,13]. Therefore, given escalating incidences and desired safer alternatives, the study was planned to assess the effectiveness of Ayurvedic formulations and the tolerability of these formulations in the management of OA knee.

1.1. Objectives

Primary objective of the study was to assess the role of Ayurvedic formulations *Yograj Guggulu*, *Ashwagandha Churna* and *Narayana Taila* in attaining the subjective outcomes of OA knee. The secondary objectives comprised of the assessment of role of the intervention in disease specific symptoms as well as evaluation of the tolerability of Ayurvedic formulations in the management of OA knee.

2. Materials and methods

2.1. Study design

It was an open-label, single-arm, interventional, multicentric, prospective study conducted at 14 peripheral institutes of the Central Council for Research in Ayurvedic Sciences, New Delhi from July 2021 to March 2022.

2.2. Participants

2.2.1. Inclusion criteria

Participants of any gender in the age group 40–65 years belonging to the Scheduled Tribe (ST) community, who were willing to provide written informed consent and diagnosed with primary OA knee (Unilateral/bilateral) as per the ACR diagnostic criteria were selected for the study [1].

2.2.2. Exclusion criteria

Participants diagnosed with Rheumatoid arthritis or other types of inflammatory arthritis or those who reported to have been under anti-arthritis medication for RA or inflammatory arthritis, participants prescribed joint replacement surgery, having a history of trauma to the afflicted joint were excluded. Participants with ambulatory aids such as wheelchairs, walkers, etc., participants with BMI ≥ 32 kg/m² at the screening visit, co-morbid conditions such as a past history of Cardiac Arrhythmia, Acute Coronary Syndrome, Myocardial Infarction, Stroke, or Severe Arrhythmia in the last 6 months, known case of Renal/Hepatic/Pulmonary Dysfunction (Asthmatic and Chronic Obstructive Pulmonary Disease patients) or other concurrent severe diseases, uncontrolled Diabetes Mellitus or hypertension, pregnant women/women who are planning for conception/lactating women, patient taking participation in any other clinical study or any other condition which might have been perceived by Principal Investigator to jeopardize the study were identified and were also excluded from the study.

2.3. Study Intervention

A dose of 1 gm of *Yograj Guggulu* (tablet) and 3 gm of *Ashwagandha Churna* (powder) were administered orally after meals twice a day with lukewarm water along with the local application of *Narayana Taila* (twice daily) for 12 weeks. These study drugs were procured from Good Manufacturing Practice (GMP) certified company, "The Indian Medicines Pharmaceutical Corporation Ltd. (IMPCL)".

2.4. Primary and secondary outcome measures

The primary outcome measure of the study was to evaluate change in WOMAC score from baseline to end of treatment [Indian WOMAC (Modified –CRD Pune Version)]. The secondary outcome measures were to evaluate any change in the Visual Analog Scale (VAS) score for pain from baseline to end of treatment, any change in the Ayurvedic disease-specific symptoms of *sandhi vata* (vitiated *vata* in joints) viz *sandhishula* (joint pain), *sandhishotha* (swelling in the joints), *akunchana prasar-anayoh vedana* (flexion and extension of joint with pain), *stambha* (stiffness), *sandhisphutana* (crepitus), frequency of use of number of NSAID/analgesic medication, change in WOMAC sub-score (Pain, Stiffness, Physical activity), assessment of tolerability based on proportion of recruited participants completing the study.

2.5. Sample size

Based on the assumption of detecting relevant change of 20 points in the WOMAC Score, pre and post-test, based on the results of the previous studies and the standard deviation of 35 points with 95% Confidence Level ($\alpha = 0.05$) and 80% power and expecting a dropout rate of 25% the number of patients to be enrolled in the study was calculated as below:

Here,

$$\alpha = 0.05 \text{ Hence } Z_{1-\alpha/2} = 1.96; 1-\beta = 80\%; \text{ hence } Z_{1-\beta} = 0.8416, \sigma =$$

15 points, $\delta = 5$ points

$$n = \frac{(Z_{1-\alpha/2} + Z_{1-\beta})^2 \sigma^2}{\delta^2}; n = 28.33$$

$n = 28.33 + 7.08 = 35.41$ (Assuming a dropout rate of 25 %)

Approximately 35 patients were to be included in the trial at each centre. The study was executed through 14 peripheral institutes with 35 participants at each institute, therefore, the total sample size of the study was 490.

2.6. Withdrawal criteria

The participant willing to withdraw from the study, the participant with a condition worsened, or any participant who developed any other ailments mentioned in the exclusion criteria during the study were free to withdraw from the study.

2.7. Study procedure

The participants were screened from the outreach OPDs/camps/door to door visits conducted in identified ST dominant areas/villages under Tribal Health Care Research Program through 14 research institutes of CCRAS. Before initiation of the study, the head of the village or local administrative authority was informed about the study and permission was obtained prior to commencement. The study was conducted in accordance with ICMR ethical guidelines involving human participants (2006), ICH Good Clinical Practice (GCP) guidelines and Ayush GCP guidelines (2013). The Institutional Ethics Committee (IEC) at each institute thoroughly reviewed the study protocol and related documents and granted approval. The study was prospectively registered with the Clinical Trial Registry of India (CTRI/2021/07/034964). Participants with OA Knee were selected based on the defined inclusion and exclusion criteria. Participants were explained about the study in detail (in their regional language) and were asked for providing consent in writing regarding their participation in the study (Fig. 1). The participants underwent a general and systematic examination and were also evaluated for their WOMAC and VAS scores.

The data obtained from the participants was documented in a specifically designed Case Record Form (CRF). Study interventions were provided to the enrolled participants either at their door steps or through home visits. The assessment was done on 28th day, 56th day and 84th day. One follow-up without medication was performed on 112th day (Fig. 2).

2.8. Statistical analysis

The categorical/qualitative data have been reported as n (%). The continuous/quantitative data on outcome measures and safety parameters have been reported as mean (SD). The categorical/qualitative data

were compared using Cochrane Q-test/Mac-Nemar chi-square test. The continuous/quantitative data were compared using rANOVA/ Paired sample t-test. The level of significance was taken at 5%. The study data was analyzed using STATA software version 16 (Copyright 1985–2019, Stata Corp LLC, Stata Corp, 4905 Lakeway Drive College Station, Texas 77845 USA).

3. Observations & result

Total sample size of the study was 490 for which 714 cases were screened, 224 cases failed in the screening attributed to not fulfilling the eligibility criteria. A total of 7 participants were dropped out from the study among them, 4 participants were unable to contact, the drug was not palatable for 2 participants and 1 participant was not willing to continue in the study. Therefore, data of total 483 participants has been analyzed in the study (Fig. 3).

3.1. Demographic Profile

The demographic data of the participants, summarized in Table 1, suggests that OA knee is prevalent more in females (56.3%) than males (43.7%). The majority of the participants were found to be above 50 years of age (61.4%). The occupation of the maximum number of participants was fieldwork with physical labour (40.0%). The majority of participants had normal BMI (61.02%).

3.2. Effect of therapy on total WOMAC score

The total WOMAC Score was reduced significantly ($p < 0.001$) from Baseline (52.26 ± 14.177) to subsequent visits on 28th day (44.65 ± 13.180), 56th day (36.41 ± 13.578), 84th day (28.83 ± 13.569) and 112th day (23.76 ± 14.310). The effect of treatment on total WOMAC score was assessed by using a paired sample t-test (Table 2).

3.3. Effect of therapy on WOMAC sub score

The WOMAC sub-score for pain was reduced from baseline to subsequent visits. A significant reduction ($p < 0.001$) in mean WOMAC score for pain was observed from baseline (10.31 ± 2.976) to the completion of treatment (5.09 ± 2.814) and 112th day (4.21 ± 2.804). A significant reduction ($p < 0.001$) in the mean WOMAC sub-score for stiffness was observed at the end of treatment (2.05 ± 1.714) and on 112th day (1.53 ± 1.504) from baseline (4.36 ± 1.782). The WOMAC sub-score for physical activity was reduced significantly ($p < 0.001$) from baseline (37.67 ± 10.703) to 84th day (21.69 ± 10.318) and 112th day (18.06 ± 10.885). The effect of treatment on total WOMAC score was assessed by using a paired sample t-test (Table 2).

3.4. Effect of therapy on VAS score for pain

The pain score assessed on VAS reduced significantly ($p < 0.001$) at the end of treatment (3.91 ± 1.754) and 112th day (3.30 ± 1.773) from baseline (6.71 ± 1.432). The median of the distribution of the VAS score was 4 in the last follow-up. The distribution was negatively skewed, representing that most of the data lies below 4 (Table 2).

3.5. Effect of therapy on Ayurvedic disease-specific symptoms

Significant improvement ($p < 0.001$) was observed in Ayurvedic disease-specific symptoms of OA knee i.e., joint pain on flexion & extension (Prasarana – Akunchana Vedana), restricted movements of joints (Apravritti), crepitus (Sandhisphutana), swollen joints (Sandhishoth), and joint pain at rest (Sandhishul). The effect of treatment was assessed by using Cochrane Q – test (Table 3).

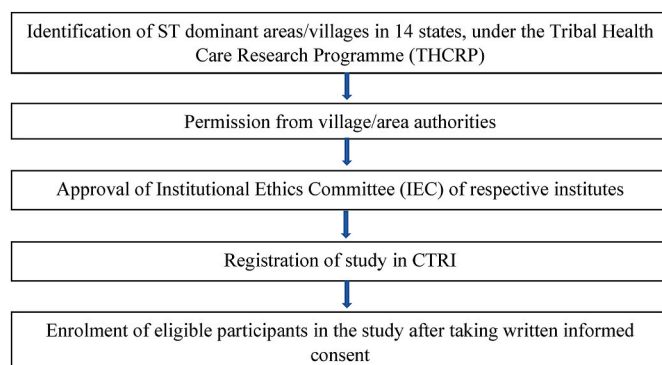


Fig. 1. Flow diagram depicting the procedure of the study.

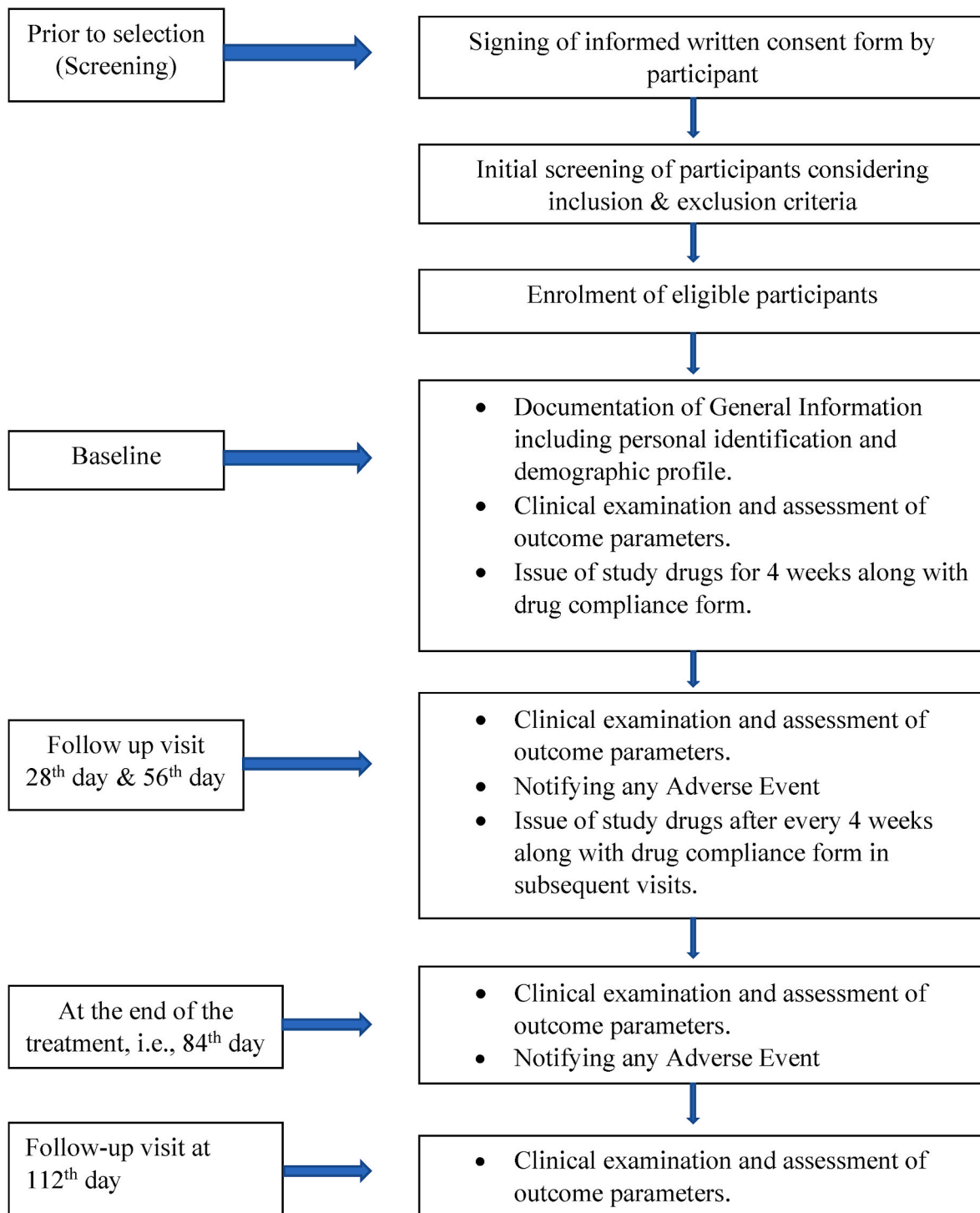


Fig. 2. Flow diagram depicting the study schedule for evaluation of the interventions in knee OA.

3.6. Effect of therapy on frequency of use of number of NSAIDs/analgesics

The requirement of NSAID or analgesics reduced significantly from baseline (10.61%) to 28th day (1.42%), 56th day (0.40%), and at the end of the treatment on 84th day (0.0%).

3.7. Adverse events and tolerability

As such no adverse events were reported in the study and the

interventional drugs were well tolerated by the participants.

3.8. Concomitant and rescue medicines

In one participant with hypertension, the existing medication was continued, while three other participants were prescribed concomitant medication for constipation, transient burning micturition, and hyperacidity for a few days (as per requirement) during the study period. In one case, rescue medication was needed for fever and cough, which were not related to the study drug.

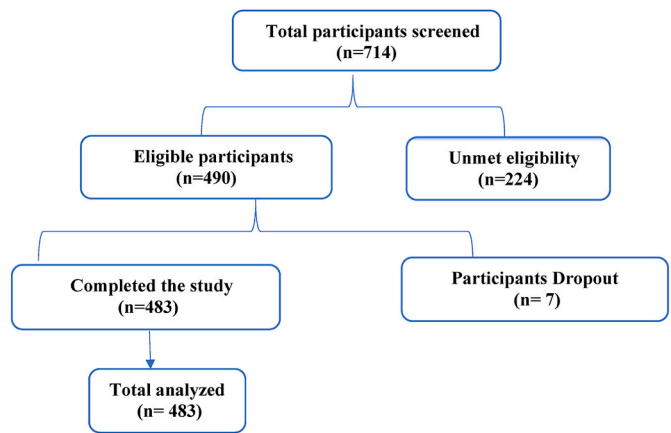


Fig. 3. Diagram depicting the participant flow in the study from screening to enrolment, assessment, and analysis.

Table 1
Socio-economic and demographic Profile of the study participants(N = 483).

Variables		n (%)
Age <50	Male	140 (28.58)
	Female	161 (32.86)
Age >50	Male	74 (15.10)
	Female	115 (23.47)
Gender:	Male	211 (43.7%)
	Female	272 (56.3%)
Marital Status:	Married	439 (90.9%)
	Unmarried	6 (1.2%)
	Widow	36 (7.5%)
	Divorced	1 (0.2%)
	Any other	1 (0.2%)
Educational status:	No formal schooling	212 (44.0%)
	Less than primary school	81 (16.8%)
	Primary School (5th)	96 (19.9%)
	Middle School (8th)	41 (8.5%)
	High School (10th)	29 (6.0%)
	Intermediate (12th/diploma)	13 (2.7%)
Occupation:	Graduate &above	10 (2.1%)
	Desk work	19 (3.9%)
	Field work with physical labour	193 (40.0%)
	Field work	90 (18.7%)
	Household work	180 (37.3%)
Socio-economic status:	Above poverty line	83 (17.3%)
	Below poverty line	398 (82.7%)
Habitat:	Urban	20 (4.1%)
	Semi-urban	9 (1.9%)
	Rural	453 (94.0%)
Religion	Hindu	407 (84.3%)
	Muslim	35 (7.2%)
	Sikh	3 (0.6%)
	Christian	38 (7.9%)
Dietary Habits	Vegetarian	59 (12.2%)
	Non-vegetarian	423 (87.8%)
Addictions	Tobacco	67 (13.9%)
	Gutakha/Pan masala	55 (11.4%)
	Alcohol	47 (9.8%)
	Smoking	10 (2.1%)
	Snuff	1 (0.2%)
	Bhang	1 (0.2%)
	None	301 (62.4%)

Table 2
Showing WOMAC& VAS Score for pain.

Visit Day	Baseline	28th day	56th day	84th day	112th day
Womac Sub Score for Pain	10.31 ± 2.97	8.66±	6.78	5.09 ± 2.81	4.21 ± 2.804
Womac Sub Score for Stiffness	4.36 ± 1.78	3.5	2.02	2.05 ± 1.714	1.53 ± 1.50
Womac Sub Score for physical activity	37.67 ± 10.703	32.47	26.98	21.69 ± 10.318	18.06 ± 10.885
Total Womac Score	52.26 ± 14.17	44.65 ± 13.18	36.41 ± 13.57	28.83 ± 13.59	23.76 ± 14.31
VAS score	6.71 ± 1.432	6	5	3.91 ± 1.754	3.30 ± 1.77

4. Discussion

The analysis of the data supports the relation of gender, age, and occupation with OA. Females were observed to be more susceptible to OA attributing to the common causes as hormonal imbalances or the level of osteoporosis [14]. A higher number of participants aged above 50 years was found in the study. The finding is in congruence with the risk factors mentioned in the texts [15]. Age is the strongest predictor of the development and progression of OA. In higher age group, increased catabolic activity over anabolic activity results in cell death causing joint tissue degeneration and matrix loss [16]. A recent retrospective study conducted on patients aged above 50 years having knee pain, reported Knee OA in majority of radiographs and MRI [17]. As per the *ayurvedic* perspective, *Vata* vitiation (*Vataprakopa*) due to advanced age causes tissue degradation (*Dhatukshaya*), which in turn causes *sandhigata Vata* [18].

Most of the participants were involved in fieldwork with physical labour. Occupation comprising physical labour is also considered as a risk factor as there are more chances of wear and tear to the joint capsule leading to further fibrosis and the development of OA [19]. Excess of physical exercise (*Ativiyayama*) is one of the causes of *Sandhivata* as mentioned in *ayurveda* and is also supported by this finding. Though there is a recognized association between obesity and knee OA [20], the present study exhibits normal BMI in the majority of the participants which may be on account of low socio-economic status and indulgence in physical labour.

The study showed significant improvement in the cardinal features of OA such as joint pain on movement, joint pain at rest, joint stiffness, crepitus, restricted movements, and swelling. Significant improvement was observed in VAS score, total WOMAC score, and WOMAC sub-score. A significant decline in the frequency of use of NSAID/analgesic medication was also observed in the study. No aggravation of symptoms was found in the follow-up visit without intervention, indicating a sustained effect of the drug.

Changes in the capsule of the knee joint and bone structure are responsible for the pathogenesis of OA knee. In a healthy joint, the synthesis and breakdown of the cartilaginous matrix are balanced by the chondrocytes to provide appropriate load distribution across the joint and minimize friction [21]. The failure of the repair process of damaged cartilage due to biomechanical and biochemical changes in the joint increases apoptotic death of chondrocytes and results in degeneration of bones and fibrosis of the joint capsule [22]. The synovial fluid present in the joint negatively affects the balance of cartilage matrix degradation and repair due to inflammation, resulting in pain [23]. The synovial fluid resembles the *shleshak kapha* (a type of humor of body) which holds the joint together and provides lubrication to the joint [24]. The *vata* vitiated due to tissue degeneration (*dhatu kshaya*) affects the *shleshak kapha* resulting in characteristic features such as pain (*Shoola*), stiffness (*Stambha*), crepitus (*Sandhisphutana*) etc. of the joint [25]. Therefore, the intervention was planned to delineate the progression of degenerative pathology by balancing the deranged *vata* as well as

Table 3

Showing pattern of Changes in the cardinal symptoms of OA Knee.

Cardinal Symptoms	Baseline n (%)	28th day n (%)	56th day n (%)	84th day n (%)	112th day n (%)	p-value [#]
Joint pain on movement (<i>Prasarana – kunchanavedana</i>)	482 (99.8%)	467 (96.7%)	435 (90.1%)	378 (78.3%)	378 (78.3%)	<0.001 (*)
Restricted movement of joints (<i>Apravritti</i>)	369 (76.4%)	347 (71.8%)	284 (58.8%)	173 (35.8%)	173 (35.8%)	<0.001 (*)
Crepitus/crunching in the joint(s)	417 (86.3%)	425 (88.0%)	361 (74.7%)	242 (50.1%)	242 (50.1%)	<0.001 (*)
Swollen joints (<i>Sandhishoth</i>)	266 (55.1%)	252 (52.2%)	168 (34.8%)	72 (14.9%)	72 (14.9%)	<0.001 (*)
Joint pain at rest (<i>Sandhishul</i>)	253 (52.4%)	179 (37.1%)	141 (29.2%)	70 (14.5%)	70 (14.5%)	<0.001 (*)

•The symbol "#" typically denotes statistical significance (p-value) & The asterisk (*) accompanying "<0.001" indicates that the p-values for all changes observed are highly statistically significant.

providing nourishment to the muscles and bones of the joint by stabilizing the shleshaka kapha.

Yograj guggulu is the most frequently used medication for arthritis and myalgia indicating the potency and tolerability of the formulation [26]. It possesses analgesic (*vedanasthapana*) & anti-inflammatory (*shothahara*) properties and maintains the equilibrium of the deranged doshas (*vata*, *pitta* and *kapha*) [27]. As the age advances, immunity is compromised owing to declining metabolism. *Yograj guggulu* enhances metabolism (*agni*) and physical strength (*bala*) by its appetizing (*deepana*), digesting (*pachana*) & rejuvenative (*rasayana*) properties and thereby improves general condition [28]. A preclinical study on guggulu demonstrated its anti-arthritis activity in formaldehyde-induced albino rats [29]. Apart from that, guggulu reduces inflammation and stiffness of the joint and increases joint mobility. Oleo-gum resin has been shown to have significant anti-inflammatory and anti-arthritis properties against carrageenan-induced rat paw edema, granuloma pouch, and adjuvant arthritis, which aids in the prevention of degenerative changes that may happen in the bones and joints as a result of arthritis [30].

Ashwagandha (*Withania somnifera*) or "Indian ginseng" used in the intervention exhibits *vata* pacifying (*vatahara*), anti-inflammatory (*shothahara*), pain-relieving (*vedanasthapana*) and rejuvenative (*rasayana*) actions [31]. Also, ashwagandha nourishes the bone and muscles attributing to its brumhana (*dhatupushthikar*) property [32]. *Ashwagandha* has demonstrated various biological actions including anti-arthritis activity [33] and it exhibits the ability to control mitochondrial function, reduce oxidative stress and inflammation, control apoptosis, and enhance endothelial function [34]. In accordance to a study, 50% of the patients evaluated had a chondroprotective impact on their damaged osteoarthritic cartilage matrix after taking an extract of *withania somnifera*'s root in powdered form [35].

Narayana taila is an effective cure for *vata* imbalance owing to its hot potency (*ushna veerya*) and *vata* pacifying properties [36,37]. Due to pungent (*tikshna*), fine (*sukhma*) properties, it may penetrate the cartilage and provide nourishment to the joint by its unctuous (*snigdha*) & heavy (*guru*) qualities. Recent studies have shown that massage (*abhyanga*) increases waste disposal from the body by stimulating blood flow and supporting the lymphatic system. Due to the oleaginous form, absorption of the formulation through the skin is increased when used topically [38]. *Snigdha*, *guru*, and *mridu* (soft) qualities of *taila* (oil) are opposites of the *ruksha*, *laghu* and *khara* traits of *vata*. Application of oil restores the degeneration of the tissues (*dhatu*) and pacifies the symptoms like pain and stiffness by balancing the vitiated *vata*.

A recent study acknowledges that evaluating the effectiveness of traditional medical systems like Ayurveda can be challenging. These challenges arise from differences in nomenclature (terminology), approaches to treatment, and overall paradigms (underlying philosophies and principles) [32]. Despite this, the CCRAS is implementing this study as part of a health care program for the ST community. The current study results demonstrated the effectiveness of Ayurvedic formulations in treating OA with significant improvement in its cardinal symptoms.

The study was conducted during the COVID-19 pandemic period. However, all the study areas were in remote locations where COVID-19 was less prevalent at the time of execution of the study. Moreover, containment zones had already been isolated by government

authorities. Additionally, due to the rigorous selection criteria, the investigators were able to control most confounding factors at the design stage.

The study focused on a tribal group that shared similar habits, cultural traditions, and behavioral practices, which reduced the chances of confounding factors influencing the results. Furthermore, the study employed a pretest-posttest design, which offers several advantages. This design provides a direct measure of the effect of intervention by comparing outcomes before and after the intervention. It also enhances the study's internal validity by reducing potential threats such as age, gender & other biological factors, socio-economic status, history, regression, and selection biases. In the context of co-morbidities, patients having concurrent severe diseases were excluded from the study. There was just one participant with hypertension. No adverse events were reported in the study and interventional drugs were well tolerated by the participants.

The study also had certain limitations. The comparable results of the intervention could not be attained as a control group was requisite for the Randomized Control Trial (RCT), and the present study was designed as a single arm. The study participants were diagnosed based on their clinical presentation and ACR criteria. Baseline tests/investigations/x-rays were not carried out or outsourced due to limited access to laboratory and radiological services in the selected tribal areas which were over 50 km from the nearest laboratory/Diagnostic facilities. Furthermore, logistical challenges with sample transportation for laboratory investigations, and patients' access to diagnostic services also contributed to this limitation.

Future studies may include detailed *Ayurvedic* parameters such as *Naadi* and *Prakriti* analysis with conventional diagnostic criteria, to provide a more comprehensive evaluation of participants' health status and treatment outcomes. Further, the efficacy of these *Ayurvedic* interventions should also be explored through a Randomized Controlled Study (RCT) design.

5. Conclusion

The study substantiates that combination of *Ayurvedic* interventions *yograj guggulu*, *ashwagandha churna* and *narayana taila* are well accepted and tolerable in the management of OA knee. The intervention is effective in managing the cardinal symptoms of OA knee.

Author contribution

Dr. Kalpana Kachare, R.O. (Ayu.), CCRAS-Hq, New Delhi: Conceptualization, Project administration, Methodology, Supervision & Editing of draft article.

Dr. Deepa Makhija, A.D.(Ayu.), CCRAS-Hq, New Delhi: Conceptualization, Project administration, Methodology, Supervision, Review & Editing of draft article.

Dr. Abha Sharma, Consult. (Ayu.), CCRAS-Hq, New Delhi: Writing - Original Draft.

Dr. Sunita, R.O (Ayu.), CCRAS-Hq, New Delhi: Conceptualization, Supervision, Methodology, Review & Editing of draft article.

Dr.N.Srikanth, DDG, CCRAS-Hq, New Delhi: Conceptualization,

Methodology.

Dr. B.S. Sharma, R.O(Ayu.), CCRAS-Hq, New Delhi: Methodology.
 Dr. Rakesh Rana, Stat Officer, CCRAS-Hq, New Delhi: Methodology,
 Data analysis.
 Dr. Arunabha Tripathi, Stat Officer, CCRAS-Hq, New Delhi: Methodology, Data analysis.
 Dr. BCS Rao, A.D.(Ayu.), CCRAS-Hq, New Delhi: Conceptualization, Methodology.
 Dr. Purnendu Panda R.O(Ayu.), CARI, Bhubaneswar: Investigator.
 Dr. Ekta, R.O(Ayu.), CARI, Guwahati: Investigator.
 Dr. Raghavendra Naik, R.O(Ayu.), CARI, Bangalore: Investigator.
 Dr. Nishant K, R.O(Ayu.), RARI, Vijayawada: Investigator.
 Dr. UR Shekhar Namburi, R.O(Ayu.), RARI Nagpur: Investigator.
 Dr. Vimal Tiwari, R.O(Ayu.), RARI, Patna: Investigator.
 Dr. S.B. Singh, R.O(Ayu.), RARI, Gwalior: Investigator.
 Dr. Monika, R.O(Ayu.), RARI, Jaipur: Investigator.
 Dr. P. Srinivas, R.O(Ayu.), ALRARI, Chennai: Investigator.
 Dr. Vipin Sharma, R.O(Ayu.), RARI, Jammu: Investigator.
 Dr. Anil Avhad, R.O(Ayu.), RARI, Ahmedabad: Investigator.
 Dr. Ashok Sinha, R.O(Ayu.), RARI, Gangtok: Investigator.
 Dr. Rohit Rawate, R.O(Ayu.), RARC, Tripura: Investigator.
 Dr. Akash Lal, R.O(Ayu.), RARI, Port Blair: Investigator.
 Dr. Krishna Rao, R.O(Ayu.), Co-I, CARI, Bhubaneswar: Investigator.
 Dr. Pravin Mashram, R.O(Ayu.), Co-I, CARI, Guwahati: Investigator.
 Dr. S.H.Dodamani Co-I, CARI, Bangalore: Investigator.
 Dr. Savita Gopad, R.O(Ayu.), Co-I, RARI, Vijayawada: Investigator.
 Dr. Priya, R.O(Ayu.), Co-I, RARI Nagpur: Investigator.
 Dr. Deepika Tiwari, R.O(Ayu.), Co-I, RARI, Patna: Investigator.
 Dr. Anil Mangal, R.O(Ayu.), Co-I, RARI, Gwalior: Investigator.
 Dr. V.B. Kumawat, R.O(Ayu.), Co-I, RARI, Jaipur: Investigator.
 Dr. K.Pramila, R.O(Ayu.), Co-I, ALRARI, Chennai: Investigator.
 Dr. Subhash, R.O(Ayu.), Co-I, RARI, Jammu: Investigator.
 Dr. Jaiprakash Ram, R.O(Ayu.), Co-I, RARI, Ahmedabad: Investigator.
 Dr. S.K.Sahu, R.O(Ayu.), Co-I, RARI, Gangtok: Investigator.
 Dr. Sojitra Nirral, R.O(Ayu.), Co-I, RARC, Tripura: Investigator.
 Dr. Abhaydev, R.O(Ayu.), Co-I, RARI, Port Blair: Investigator.

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Declaration of generative AI in scientific writing

The authors have not used any generative AI or AI-assisted technologies in the writing process of this manuscript.

Conflict of Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

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