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A PHASE III, OPEN-LABEL, SINGLE-ARM, SINGLE-CENTERED CLINICAL STUDY TO EVALUATE THE SAFETY AND EFFICACY OF COMBINATION THERAPY OF BOSWELLIA CURCUMIN AND JOINT AID PLUS IN SUBJECTS WITH JOINT PAIN

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ABSTRACT

Background: Joint pain, particularly associated with osteoarthritis (OA), is a leading cause of disability and reduced quality of life globally. Planet Ayurveda developed the combination therapy of Boswellia Curcumin and Joint Aid Plus to support joint health, alleviate pain, and improve physical function and quality of life. Objective: To evaluate the efficacy and safety of the combination therapy of Boswellia Curcumin and Joint Aid Plus in participants diagnosed with knee osteoarthritis-associated joint pain. Materials and Methods: A Phase III, prospective, open-label, single-arm, single-centre study was conducted in participants with knee osteoarthritis-associated joint pain. Participants were instructed to use Boswellia Curcumin and Joint Aid Plus for 90 days. The primary objective was to assess change in total WOMAC score. Secondary objectives included assessment of VAS for pain, SF-36 for quality of life, safety, and tolerability. Results: Out of 60 participants, 58 completed the study. The combination therapy demonstrated a progressive improvement in joint pain and functional outcomes over the 90-day treatment period. The mean total WOMAC score decreased from 38.16±4.66 at baseline to 22.31±3.82 at Day 90, while the mean VAS score decreased from 6.55±0.95 to 4.70±0.65. The mean SF-36 score improved from 80.82 at baseline to 99.83 at Day 90. The treatment was well tolerated, with no serious adverse events reported; reported adverse events were mild and transient. Overall compliance was 96.7%. Conclusion: The combination therapy of Boswellia Curcumin and Joint Aid Plus demonstrated favourable effects on joint pain, osteoarthritis symptoms, and quality of life, with a favourable safety and tolerability profile.

Keywords: Boswellia Curcumin, Joint Aid Plus, Joint Pain, Osteoarthritis.

INTRODUCTION

Joint pain, particularly resulting from osteoarthritis (OA), is a leading cause of disability and reduced quality of life in the aging population globally. OA is characterised by progressive degeneration of articular cartilage, subchondral bone remodelling, synovial inflammation, and chronic pain, especially affecting the knees, hips, and hands. According to the World Health Organisation (WHO), approximately 10% of men and 18% of women over 60 years of age experience symptomatic OA worldwide, with the burden rising due to increased life expectancy and sedentary lifestyles.[1]

In India, the prevalence of knee osteoarthritis is notably high, particularly in women above 50 years of age, where it may be as much as 2.5 times higher than in Western countries.[2] Standard pharmacological interventions include non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids, and, in severe cases, surgical interventions such as joint replacement. However, long-term use of NSAIDs is associated with adverse gastrointestinal, cardiovascular, and renal effects.[3] This has led to increasing interest in herbal and alternative treatments that provide symptom relief with fewer side effects.

Boswellia serrata is traditionally used in Ayurvedic medicine for its anti-inflammatory and analgesic properties. Boswellic acids inhibit 5-lipoxygenase, an enzyme involved in leukotriene synthesis, thereby reducing inflammation in OA.[4] Clinical studies have shown that Boswellia extracts can significantly reduce pain and improve joint function in OA Subjects.[5]

Curcumin, the principal bioactive polyphenol of *Curcuma longa*, possesses anti-inflammatory and antioxidant properties. It has been reported to modulate inflammatory pathways involving nuclear factor-kappa B (NF-κB), tumour necrosis factor-alpha (TNF-α), and interleukins.[6] Clinical evidence suggests that curcumin may help reduce joint pain and stiffness and improve physical function in individuals with OA.[7, 8]

Joint Aid Plus is a proprietary polyherbal Ayurvedic formulation containing herbs such as Shallaki (*Boswellia serrata*), Haridra (*Curcumin longa*), Nirgundi (*Vitex negundo*), and Ashwagandha (*Withania somnifera*), among other ingredients, traditionally used to support joint health and manage musculoskeletal discomfort.[9-13] The combination of Boswellia Curcumin and Joint Aid Plus may provide complementary benefits in the management of joint pain and associated functional limitations. Therefore, we conducted this Phase III clinical study to evaluate the efficacy and safety of this combination therapy in participants with knee osteoarthritis-associated joint pain. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) assessed osteoarthritis-related pain, stiffness, and physical function.[14] The Visual Analogue Scale (VAS) was used to assess the intensity of joint pain[15], while the Short Form-36 (SF-36) questionnaire was used to evaluate health-related quality of life and overall functional well-being.[16] Safety and tolerability were assessed through monitoring of adverse events, physical examination findings, and vital signs.

MATERIALS AND METHODS

Study Design and Setting

This Phase III, prospective, open-label, single-arm, single-centre interventional study evaluated the safety and efficacy of Boswellia Curcumin and Joint Aid Plus combination therapy in participants with knee osteoarthritis-associated joint pain. Participants received the combination therapy for 90 days. The primary efficacy assessment was to assess the change in total WOMAC score. Secondary assessments included evaluation of joint pain using the VAS, quality of life using the SF-36 questionnaire, and safety and tolerability through monitoring of adverse events, physical examination findings, and vital signs.

Study Setting

Qualified healthcare professionals supervised the study at RVS Ayurvedic Hospital, Srigandhada Kaval, Chandana Layout, Sunkadakatte, Bengaluru, Karnataka, India-560091. The site functioned as the sole investigative centre for participant recruitment, intervention intake, and follow-up assessments. Ethical approval for the study was obtained from the Pranav Diabetes Centre Ethics Committee, Bengaluru. The Ethics Committee's role was limited to independent ethical review and approval. It was not involved in participant recruitment, clinical procedures, study conduct, data collection, or analysis. A No Objection Certificate (NOC) was obtained to confirm the absence of any conflict of interest.

Ethical Approval and Regulatory Compliance

Ethical clearance for the study was obtained from the Pranav Diabetes Centre Ethics Committee (PDCEC/SRS-CTSRS/2517/15 OCT 2025) prior to initiation of any study-related procedures.

- Name of Ethics Committee: Pranav Diabetes Centre Ethics Committee
- Ethics Committee Approval: Obtained prior to study initiation
- Type: Institutional Ethics Committee

Although the study was conducted at RVS Ayurvedic Hospital, we obtained ethical approval from the Pranav Diabetes Centre Ethics Committee because the study site does not have a formally constituted and registered Institutional Ethics Committee. The approving Ethics Committee is an accredited and competent body authorised to review and approve clinical research protocols and provide ethical oversight for the conduct of the study at the specified site.

The Ethics Committee reviewed the complete study Protocol, Informed Consent Form, and all relevant study documents, and approved the study at RVS Ayurvedic Hospital. Written informed consent was obtained from all the participants prior to enrolment.

The study was conducted in accordance with the ethical principles of the Declaration of Helsinki (2013)[17], ICH-GCP E6 (R3) guidelines[18] and applicable national regulatory requirements, including Ministry of AYUSH and Central Drugs Standard Control Organisation regulations[19, 20]. The study maintained participant confidentiality and safety throughout the study duration.

Study Population

A total of 60 participants were screened and enrolled after meeting predefined inclusion and exclusion criteria. The study population consisted of male and female adults aged 40-70 years diagnosed with unilateral or bilateral knee osteoarthritis for more than 3 months, as determined by the Investigator based on clinical symptoms and physical examination. The inclusion criteria required participants to have a stable health condition and be able to comply with the study protocol and procedures.[21]

Eligibility Criteria

Inclusion Criteria

- Age between 40 and 70 years (inclusive), of either sex.
- Written informed consent obtained voluntarily prior to initiation of study-related procedures.
- Clinical diagnosis of unilateral or bilateral knee osteoarthritis for more than 3 months, as determined by a physician based on clinical symptoms and physical examination.
- Willingness and ability to comply with all scheduled visits, treatment regimen, study procedures, and completion of questionnaires (WOMAC, VAS, SF-36).
- Stable general health condition with no major planned changes to existing medications during the study period.

Exclusion Criteria

- History of knee or hip joint replacement surgery, or significant hip or lower back pain that interferes with ambulation or could confound study assessments.
- Anticipated requirement for orthopaedic surgery during the 90-day treatment period.
- Pregnant or lactating women, or women planning to conceive during the study period.
- Participation in another clinical trial or use of any investigational drug within 30 days prior to screening.
- Uncontrolled diabetes mellitus, defined as fasting blood glucose >140 mg/dL or HbA1c >7.5% at last available assessment.
- Chronic respiratory illnesses such as chronic obstructive pulmonary disease (COPD), or history of breathing disorders that may impact physical activity tolerance.
- Current or recent (within 6 months) use of immunosuppressive medications, or diagnosis of an autoimmune disorder (e.g., rheumatoid arthritis, lupus).
- Known allergy or hypersensitivity to Boswellia, Curcumin, Joint Aid Plus, or any herbal ingredients in the investigational products.
- Any other medical or psychiatric condition which, in the opinion of the investigator, may compromise Subject Safety or interfere with the objectives of the study.

Intervention and Dosage

Participants received a combination therapy comprising Boswellia Curcumin and Joint Aid Plus for 90 consecutive days. Participants were instructed to take one capsule of Boswellia Curcumin and one capsule of Joint Aid Plus orally, twice daily, once in the morning and once in the evening, after meals, with lukewarm water. Both formulations were administered concurrently. Thus, each participant received a total of four capsules daily, comprising two Boswellia Curcumin capsules and two Joint Aid Plus capsules. Treatment compliance was assessed by pill count of returned medications, participant self-report of adherence, and investigational product (IP) accountability records.

Intervention Product Composition and Quality Control

The investigational products, Boswellia Curcumin and Joint Aid Plus, are proprietary Ayurvedic formulations developed to support the management of joint pain and musculoskeletal symptoms. Boswellia Curcumin comprises extracts of *Boswellia serrata* and *Curcuma longa*, while Joint Aid Plus is a polyherbal

formulation containing *Withania somnifera*, *Commiphora mukul*, *Zingiber officinale*, *Vitex negundo*, and other standardised herbal ingredients.

The formulation used raw materials procured from approved sources and subjected them to appropriate quality-control procedures. Relevant quality parameters, including botanical identity, organoleptic characteristics, purity, and physicochemical specifications, were assessed in accordance with applicable Ayurvedic Pharmacopoeial standards.[22] Certificates of Analysis were maintained, where applicable.

The investigational products were manufactured under appropriate Good Manufacturing Practice (GMP) conditions to ensure quality, uniformity, and batch-to-batch consistency.[23] The finished products were subjected to relevant physical, physicochemical, and microbiological quality-control testing as applicable. Packaging and storage conditions were maintained in accordance with established product specifications to preserve product integrity and stability throughout the study period.

Study Procedures and Visit Schedule

Participants were assessed at scheduled study visits over the 90-day treatment period:

Visit	Day	Key Assessments
Visit 1	Day 0	Screening; Informed consent; Eligibility assessment; Collection of demographics and medical history; Vital signs; Physical examination; Baseline assessments (WOMAC, VAS, SF-36); IP dispensation and accountability.
Visit 2	Day 30 ±3 days	Vital signs; Physical examination; Efficacy assessments (WOMAC, VAS); Safety monitoring; IP dispensation and accountability.
Visit 3	Day 60 ±3 days	Vital signs; Physical examination; Efficacy assessments (WOMAC, VAS); Safety monitoring; IP dispensation and accountability.
Visit 4	Day 90 ±3 days	Vital signs; Physical examination; End-of-Treatment visit with final assessments (WOMAC, VAS, SF-36); Safety monitoring; Final IP accountability.

All outcomes were assessed using standardised clinical and patient-reported measures. Safety monitoring was conducted in accordance with established regulatory guidelines. [17, 19]

Outcome Measures

Primary Efficacy Endpoint

The primary efficacy endpoint of this study was:

- Change in the Total WOMAC Score from Baseline to Day 30±3 days, Day 60±3 days, and Day 90±3 days.

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) was used to assess pain, stiffness, and physical function in participants with knee osteoarthritis-associated joint pain.

Secondary Efficacy Endpoints

The secondary efficacy endpoints of this study were:

- Change in VAS Score from Baseline to Day 30 ± 3 days, Day 60 ± 3 days, and Day 90 ± 3 days.

The Visual Analogue Scale (VAS) was used to assess the intensity of joint pain.

- Change in SF-36 Score from Baseline to Day 90 ± 3 days.

The Short Form-36 (SF-36) questionnaire was used to assess health-related quality of life in participants.

- Treatment Compliance - Treatment compliance was assessed throughout the study based on pill count of returned medications, participant self-reported adherence, and investigational product (IP) accountability records.

Safety and Tolerability Endpoints

- Adverse Events (AEs) - Incidence, severity, and causality of adverse events and serious adverse events were recorded and evaluated.
- Treatment Tolerability - Assessed based on reported symptoms, systemic adverse effects, and overall tolerability of the investigational products throughout the study.
- Changes in physical examination findings and vital signs (blood pressure, heart rate, temperature) were evaluated across visits to monitor general health and detect any adverse physiological trends potentially linked to the intervention.

Statistical Analysis

Data were analysed using validated statistical methods. Continuous variables were summarised using descriptive statistics, and changes from Baseline to the End-of-Treatment were evaluated using appropriate paired statistical tests. Categorical variables were presented as frequencies and percentages. A significance threshold of $p < 0.05$ was used for all statistical tests. Missing data were imputed using the Last Observation Carried Forward (LOCF) method.[24,25] Both intention-to-treat (ITT) and per-protocol (PP) analyses were performed, with sensitivity analyses using complete-case analyses to assess the robustness of the findings.

Quality Control and Monitoring

The study team conducted all procedures in accordance with the approved protocol and standardised study procedures. The study team reviewed and documented source data, protocol compliance, treatment compliance, safety information, and adverse events. Participant confidentiality and data integrity were maintained throughout the study. No protocol deviations were recorded.

RESULTS

Participant Disposition

The study screened 60 participants for eligibility; all met the inclusion criteria and were enrolled. Of the 60 enrolled participants, 58 (96%) completed the study, while 2 (4%) were lost to follow-up (Table 1).

Demographic Characteristics

Baseline demographic characteristics were collected for all enrolled participants during the baseline visit. The study included 37 female and 23 male participants (Figure 1). The overall mean (SD) age was 55.75 (8.37) years (Figure 2), and the mean (SD) BMI was 36.93 (7.41) kg/m².

Primary Efficacy Outcome

Change in Total WOMAC Score: The primary efficacy endpoint was the change in total Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score from baseline to Day 30 ± 3 days, Day 60 ± 3 days, and Day 90 ± 3 days. The WOMAC assesses pain, stiffness, and physical function, with higher scores indicating greater symptom severity. The mean WOMAC score progressively decreased from 38.16 ± 4.66 at baseline to 36.14 ± 5.20 at Day 30, 29.25 ± 4.14 at Day 60, and 22.30 ± 3.82 at Day 90. The mean reduction of 15.86 points from baseline to Day 90 indicated improved osteoarthritis symptoms

and joint function. The results are presented in Table 2 and Figure 3.

Secondary Efficacy Outcomes

Change in Visual Analogue Scale (VAS) Score for Joint Pain: The Visual Analogue Scale (VAS) was used to assess the intensity of joint pain, with scores ranging from 0 (no pain) to 10 (worst imaginable pain). The mean VAS score decreased progressively from 6.55 ± 0.95 at baseline to 5.68 ± 0.85 at Day 30, 5.07 ± 0.73 at Day 60, and 4.70 ± 0.65 at Day 90, indicating a reduction in joint pain over the 90-day treatment period. The mean reduction of 1.85 points from baseline to Day 90 indicated an improvement in pain intensity. The results are presented in Table 3 and Figure 4.

Change in Quality of Life (SF-36 Score): Health-related quality of life was evaluated using the Short Form-36 (SF-36) questionnaire by comparing mean scores at baseline and Day 90. The mean SF-36 score increased from 80.82 at baseline to 99.83 at Day 90, indicating improved health-related quality of life. This increase suggests improved physical well-being, functional capacity, and overall health perception following treatment. The results are presented in Table 4 and Figure 5.

Treatment Compliance: Overall treatment compliance was 96.7%, with 58 participants meeting the predefined compliance criterion of ≥80%. Treatment compliance was assessed based on pill count of returned medications, participant self-reported adherence, and investigational product (IP) accountability records (Table 5).

Safety and Tolerability

Incidence and Nature of Adverse Events (AEs): Safety and tolerability were evaluated throughout the 90-day treatment period. No serious adverse events (SAEs) were reported during the study. Mild adverse events, including dizziness, headache, and nausea, were reported in some participants. These events were transient, resolved without medical intervention, and were not considered related to the investigational products. No participant discontinued the study due to adverse events.

No clinically significant abnormalities were observed during the study period. Overall, the investigational products were well tolerated throughout the 90-day treatment period, with no major safety concerns identified.

Physical Examination, BMI and Vital Signs Monitoring: Physical examination findings, anthropometric parameters, and vital signs were evaluated from baseline to Day 90 to monitor participants' general health and identify any clinically relevant changes during the study. Descriptive statistics, including mean and standard deviation (SD), were calculated for the assessed parameters. BMI showed a minimal change from 36.93 ± 7.41 kg/m² at baseline to 37.08 ± 7.35 kg/m² at Visit 3. Respiratory rate and pulse rate remained stable, changing from 15.93 ± 1.60 to 15.98 ± 1.67 breaths/min and 73.73 ± 2.67 to 73.62 ± 2.98 bpm, respectively. Body temperature remained stable from 96.08 ± 0.94 to 96.03 ± 0.84 °F. Similarly, systolic and diastolic blood pressure changed minimally from 134.83 ± 10.00 to 134.08 ± 9.59 mmHg and from 86.37 ± 5.48 to 86.35 ± 5.71 mmHg, respectively. Overall, the assessed parameters showed no clinically significant changes during the study period, supporting the intervention's favourable tolerability. The results are presented in Table 6 and Figure 6.

Table 1: Participant Disposition

Category	Number of Participants (n)	Percentage (%)
Screened	60	100
Enrolled	60	100
Completed	58	96
Withdrawn	02	4
Reason for Withdrawal	Lost to follow up	NA
Serious Adverse events	NA	NA

Table 2: Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

Visit	Mean	SD
V1	38.16	4.66
V2	36.14	5.20
V3	29.25	4.14
V4	22.30	3.82

Table 3: Visual Analogue Scale (VAS) Score

Visit	Mean	SD
V1	6.55	0.95
V2	5.68	0.85
V3	5.07	0.73
V4	4.7	0.65

Table 4: Short Form-36 (SF-36) Questionnaire

Visit	Mean	SD
V1	80.82	3.34
V4	99.83	4.64

Table 5: Treatment Compliance

Compliance Category	Number of Participants (n)	Percentage (%)
Fully Compliant (≥80%)	58	96.7%

Table 6: Physical Examination, Anthropometric Parameters, and Vital Signs Monitoring

Parameter	BV (Baseline visit) Mean	BV (Baseline visit) SD	V3 (Visit-3) Mean	V3 (Visit-3) SD
BMI (kg/m^2)	36.93	7.41	37.08	7.35
Respiratory Rate (bpm)	15.93	1.6	15.98	1.67
Pulse Rate (bpm)	73.73	2.67	73.62	2.98
Body Temperature (°F)	96.08	0.94	96.03	0.84
Systolic Blood Pressure (mmHg)	134.83	10	134.08	9.59
Diastolic Blood Pressure (mmHg)	86.37	5.48	86.35	5.71

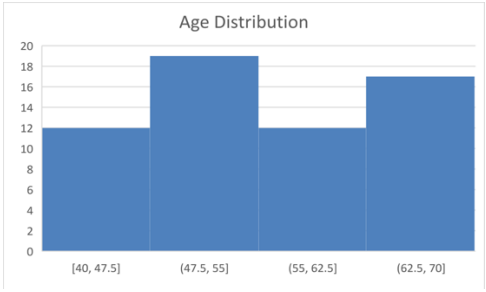

Figure 1: Age Distribution

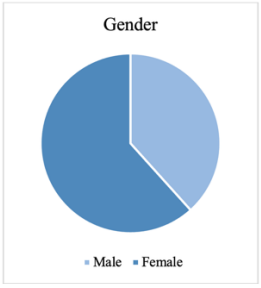

Figure 2: Gender Distribution

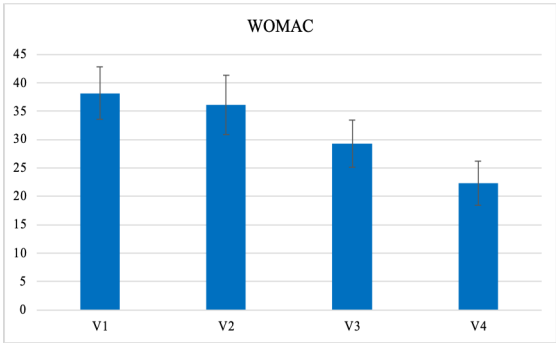

Figure 3: Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

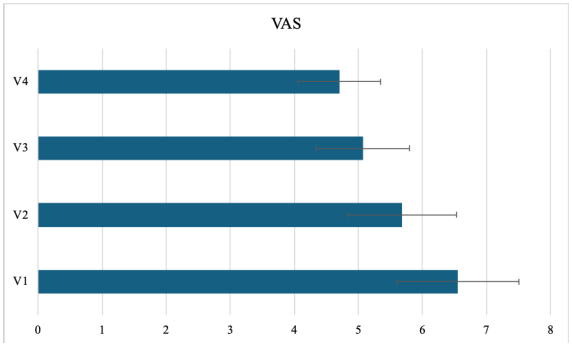

Figure 4: Visual Analogue Scale (VAS) Score

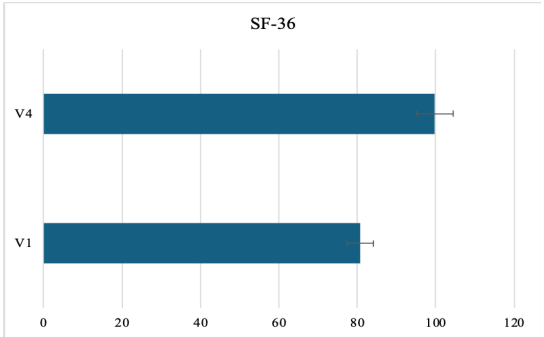

Figure 5: Short Form-36 (SF-36) Questionnaire

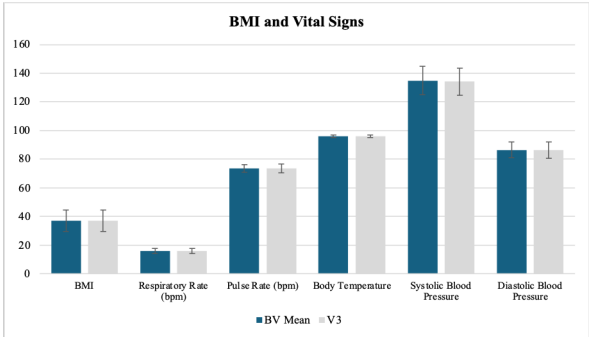

Figure 6: BMI and Vital Signs

DISCUSSION

The findings of this Phase III clinical study provide supportive evidence regarding the efficacy, safety, and tolerability of the combination therapy comprising Boswellia Curcumin and Joint Aid Plus in participants with knee osteoarthritis-associated joint pain. Over the 90-day treatment period, osteoarthritis symptoms, joint pain, and health-related quality of life improved progressively. The findings across the primary and secondary efficacy outcomes indicate an overall favourable response to the intervention during the study period.

The primary efficacy outcome demonstrated a progressive reduction in the total Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score. The mean WOMAC score decreased from 38.16 ± 4.66 at baseline to 22.30 ± 3.82 at Day 90, representing a mean reduction of 15.86 points. The reduction in WOMAC score indicates improvement across the domains of pain, stiffness, and physical function. The consistent decline observed across the assessment period suggests an overall improvement in osteoarthritis-related symptom burden and functional limitations following treatment.

The secondary endpoint assessing joint pain using the Visual Analogue Scale (VAS) also showed a favourable change. The mean VAS score decreased progressively from 6.55 ± 0.95 at baseline to 4.70 ± 0.65 at Day 90, corresponding to a mean reduction of 1.85 points. This reduction indicates improved perceived joint pain intensity over the treatment period and is consistent with the improvement observed in the WOMAC assessment.

Health-related quality of life was assessed using the Short Form-36 (SF-36) questionnaire. The mean SF-36 score increased from 80.82 at baseline to 99.83 at Day 90, indicating a favourable change in participants' overall health-related quality of life. The improvement in SF-36 scores, together with reductions in WOMAC and VAS scores, suggests that the observed clinical benefits extended beyond symptom reduction to physical well-being and daily functioning.

Treatment compliance was also favourable, with an overall compliance rate of 96.7%, as assessed through pill count of returned medications, participant self-reported adherence, and investigational product accountability records. The high compliance rate supports the feasibility and acceptability of the prescribed twice-daily combination regimen during the study period.

Safety Considerations

The combination therapy demonstrated a favourable overall safety profile during the 90-day study period. No serious adverse events were reported. Mild adverse events, including dizziness, headache, and nausea, were reported in some participants. These events were transient, resolved without medical intervention, and were not considered related to the investigational products. No clinically significant changes were observed in the assessed vital signs or physical examination findings. BMI, respiratory rate, pulse rate, body temperature, systolic blood pressure, and diastolic blood pressure remained generally stable throughout the study

CONCLUSION

The combination therapy comprising Boswellia Curcumin and Joint Aid Plus demonstrated favourable clinical outcomes and a good tolerability profile over the 90-day treatment period in participants with knee osteoarthritis-associated joint pain. Treatment was associated with progressive improvements in WOMAC and VAS scores, along with improved health-related quality of life as assessed by the SF-36 questionnaire.

The high treatment compliance rate of 96.7%, absence of serious adverse events, and favourable tolerability profile support the acceptability of the combination therapy during the study period. Overall, these findings suggest that the combination of Boswellia Curcumin and Joint Aid Plus may be a supportive approach for managing knee osteoarthritis-associated joint pain.

Although the findings are encouraging, they should be interpreted in the context of the open-label, single-arm study design and absence of a concurrent control group. Further randomised controlled studies with larger sample sizes and longer follow-up are warranted to confirm these findings, establish the durability of the observed effects, and provide more robust evidence of the efficacy and long-term safety of the combination therapy.

Study Strengths and Limitations

This study's strength lies in assessing both osteoarthritis-specific clinical outcomes and patient-reported outcomes using validated instruments. The WOMAC, VAS, and SF-36 assessments provided a comprehensive evaluation of changes in osteoarthritis symptoms, joint pain, physical function, and health-related quality of life over the 90-day treatment period. Additionally, the high treatment compliance and favourable safety and tolerability profile support the acceptability and feasibility of the combination therapy.

The study has certain limitations. The open-label, single-arm design and absence of a concurrent control group limit the ability to attribute the observed changes exclusively to the intervention. Subjective outcomes such as WOMAC, VAS, and SF-36 may also have been influenced by participant or investigator expectations. Further controlled studies with larger sample sizes and longer follow-up are warranted to confirm the observed findings.

Summary of Key Findings

- Progressive improvement in osteoarthritis symptoms, as demonstrated by a reduction in the mean total WOMAC score from Baseline to the End-of-Treatment.
- Reduction in joint pain intensity, as demonstrated by a progressive decrease in mean VAS scores from Baseline to the End-of-Treatment.
- Improvement in health-related quality of life, as demonstrated by an increase in the mean SF-36 score from Baseline to the End-of-Treatment.
- High treatment compliance, with the majority of participants meeting the predefined compliance criterion of ≥80%.
- Favourable safety and tolerability profile, with no serious adverse events reported during the treatment period.
- Some participants reported mild adverse events, including dizziness, headache, and nausea; these were transient, resolved without medical intervention, and were not considered related to the investigational products.

Public Health Relevance and Future Perspectives

From a clinical and public health perspective, the combination therapy of Boswellia Curcumin and Joint Aid Plus may represent a potential supportive approach for individuals with knee osteoarthritis-associated joint pain. The observed improvements in osteoarthritis symptoms, joint pain, and health-related quality of life, together with high treatment compliance and favourable tolerability, indicate potential clinical relevance of the intervention. Further randomised, controlled studies with larger sample sizes and longer follow-up periods are warranted to confirm these findings, assess the durability of treatment effects, and establish the long-term safety and efficacy of the combination therapy.

Ethics Approval and Consent to Participate

The study Protocol, Informed Consent Form, and related documents were reviewed and approved by the Pranav Diabetes Center Ethics Committee prior to initiation of the study. Written informed consent was obtained from all participants before enrollment. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki (2013) and Good Clinical Practice guidelines.

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REFERENCES

1. World Health Organization. The burden of musculoskeletal conditions at the start of the new millennium. WHO Technical Report Series 919. Geneva: World Health Organization; 2003.
2. Pal CP, Singh P, Chaturvedi S, Pruthi S, Vij A, Kumar D, *et al*. Epidemiology of knee osteoarthritis in India and related factors. Indian J Orthop 2016; 50(5):518-22.
3. Bjordal JM, Ljunggren AE, Klovning A, Slørdal L. Non-steroidal anti-inflammatory drugs, including cyclo-oxygenase-2 inhibitors, in osteoarthritic knee pain: meta-analysis of randomised placebo-controlled trials. Bmj. 2004 Dec 4;329(7478):1317.
4. Safayhi HA, Mack TH, Sabieraj JO, Anazodo MI, Subramanian LR, Ammon HP. Boswellic acids: novel, specific, nonredox inhibitors of 5-lipoxygenase. The Journal of pharmacology and experimental therapeutics. 1992 Jun 1;261(3):1143-6.
5. Kimmatkar N, Thawani V, Hingorani L, Khiyani R. Efficacy and tolerability of *Boswellia serrata* extract in treatment of osteoarthritis of knee–a randomized double blind placebo controlled trial. Phytomedicine. 2003 Jan 1;10(1):3-7.
6. Gupta SC, Patchva S, Aggarwal BB. Therapeutic roles of curcumin: lessons learned from clinical trials. The AAPS journal. 2013 Jan;15(1):195-218.
7. Belcaro G, Cesarone MR, Dugall M, Pellegrini L, Ledda A, Grossi MG, Togni S, Appendino G. Efficacy and safety of Meriva®, a curcumin-phosphatidylcholine complex, during extended administration in osteoarthritis patients. Altern Med Rev. 2010 Dec 1;15(4):337-44.
8. Bideshki MV, Jourabchi-Ghadim N, Radkhah N, Behzadi M, Asemani S, Jamilian P, Zarezadeh M. The efficacy of curcumin in relieving osteoarthritis: A meta-analysis of meta-analyses. Phytotherapy Research. 2024 Jun;38(6):2875-91.
9. Dubey V, Kheni D, Sureja V. Efficacy evaluation of standardized *Boswellia serrata* extract (Aflapin®) in osteoarthritis: A systematic review and sub-group meta-analysis study. Explore. 2024 Sep 1;20(5):102983.
10. Hidayat R, Parlindungan F, Nisa JI, Mahendra AI, Indika MI, Efendi C. Efficacy of *Curcuma longa* in relieving pain symptoms of knee osteoarthritis patients: a systematic review and meta-analysis of clinical trials. Journal of Rheumatic Diseases. 2025 Jan 1;32(1):17-29.
11. Raut SS, Tambe VN, Zoman D, Bedse AP. Review of Osteoarthritis-related Medicinal Herbs. Current Traditional Medicine. 2023 Apr 1;9(2):133-40.
12. Mundada P, Kuchewar V, Raut M, Garg D, Bharti. Evaluation of the efficacy of Ashwagandha in chronic knee pain among older adults with knee osteoarthritis–Protocol of a double-blind randomized controlled trial. medRxiv. 2026 Jun 25:2026-06.
13. Sunita, Kalsi V, Mukhtar HM, Dubey S. Medicinal properties and health benefits of guggul-*Commiphora mukul*. In AIP conference proceedings 2023 Sep 8 (Vol. 2800, No. 1, p. 020158). AIP Publishing LLC.
14. Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, Stitt LW. Validation study of WOMAC: a health status instrument for measuring clinically important Subject-relevant outcomes. J Rheumatol. 1988;15(12):1833–1840.
15. Huskisson EC. Measurement of pain. The Lancet. 1974 Nov 9;304(7889):1127-31.
16. Instrument Ware Jr J, Sherbourne CD. The MOS 36-item short-form health survey (SF-36): I. Conceptual framework and item selection. Med Care. 1992 Jun;30(6):473-83.
17. World Medical Association. Declaration of Helsinki: ethical principles for medical research involving human subjects [Internet]. Ferney-Voltaire: World Medical Association; 2013 [cited 2026 Jul 27]. Available from: https://www.wma.net/policies-post/wma-declaration-of-helsinki/
18. International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH E6(R3) guideline for good clinical practice [Internet]. Geneva: ICH; 2025 [cited 2026 Jul 27].
19. Ministry of AYUSH. Guidelines for AYUSH clinical trials. New Delhi: Government of India; 2018.
20. Central Drugs Standard Control Organization. New Drugs and Clinical Trials Rules, 2019 [Internet]. New Delhi: Government of India; 2019 [cited 2026 Jul 27]. Available from: https://cdsco.gov.in
21. Samahitha Research Solutions. Clinical Study Protocol CTSRS/2517, Version 1.0.
22. Government of India. The Ayurvedic Pharmacopoeia of India. Part I. Vol I–IX. New Delhi: Ministry of AYUSH; latest edition.
23. World Health Organization. WHO guidelines on good manufacturing practices (GMP) for herbal medicines. Geneva: World Health Organization; 2007.
24. Rubin DB. Multiple imputation for nonresponse in surveys. New York: John Wiley & Sons; 1987.
25. Lachin JM. Fallacies of last observation carried forward analyses. Clin Trials 2016; 13(2):161-8.

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