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COMPARATIVE CLINICAL EVALUATION OF AYURVEDIC AND SIDDHA FORMULATIONS IN THE MANAGEMENT OF CHRONIC JOINT PAIN

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ABSTRACT

Chronic joint pain—most commonly due to osteoarthritis and chronic inflammatory arthropathies—poses a major burden on function and quality of life worldwide. Traditional medical systems such as Ayurveda and Siddha offer multi-component herbal formulations that are widely used in South Asia for symptomatic relief and functional improvement. This randomized, open-label, parallel-group clinical trial compared the clinical effectiveness, safety, and patient-reported outcomes of a standardized Ayurvedic formulation (AF) versus a standardized Siddha formulation (SF) in adults with chronic knee joint pain (duration ≥ 6 months). One hundred fifty participants were randomized to receive AF (n = 75) or SF (n = 75) for 12 weeks in addition to standard advice on joint care and physiotherapy. Primary outcomes were change in pain intensity (Visual Analog Scale, VAS) and functional status (Western Ontario and McMaster Universities Osteoarthritis Index, WOMAC). Secondary outcomes included range of motion (ROM), sit-to-stand repetitions, inflammatory marker (CRP), patient global impression of change (PGIC), and adverse events. At 12 weeks, both groups showed significant improvement from baseline, with mean VAS reductions of 3.4 ± 1.2 (AF) and 3.1 ± 1.3 (SF) and mean WOMAC total score reductions of 28 ± 9 (AF) and 25 ± 10 (SF). Between-group differences favored AF on WOMAC pain subscore (mean difference −1.8, 95% CI −3.2 to −0.4, p = 0.011) but were not statistically significant for VAS (p = 0.12). CRP decreased modestly in both groups. Adverse events were mild and comparable. Both formulations are effective and well-tolerated; Ayurvedic formulation demonstrated a small advantage in functional pain reduction. Further multicenter, longer-term studies are warranted to confirm these findings and identify mechanisms.

INTRODUCTION

Chronic joint pain—most commonly attributable to osteoarthritis (OA), chronic low-grade inflammatory conditions, or post-traumatic degeneration—affects mobility, independence, and quality of life in adults worldwide. Conventional management includes analgesics (paracetamol, NSAIDs), physical therapy, weight management, and, in advanced cases, surgery. Long-term pharmacotherapy may lead to adverse effects, prompting patients and clinicians to explore complementary and traditional options.

Ayurveda and Siddha are classical Indian medical systems that use multi- herbal formulations, internal and external therapies, and lifestyle guidance. Ayurvedic formulations often combine anti-inflammatory, analgesic, and rejuvenative herbs (e.g., Boswellia serrata, Withania somnifera, Zingiber officinale), while Siddha formulations—rooted in Tamil tradition—employ similar herbal-mineral combinations with emphasis on digestive fire balance and rheumatologic protocols. Despite widespread use, direct comparative clinical data between

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standardized Ayurvedic and Siddha formulations for chronic joint pain are limited.

This study aims to compare the clinical efficacy, safety, and patient- centered outcomes of a standardized Ayurvedic formulation (AF) and a standardized Siddha formulation (SF) over 12 weeks in adults with chronic knee joint pain, using validated outcome measures (VAS, WOMAC), objective functional tests, and routine safety monitoring.

METHODOLOGY

Study design and setting

A randomized, open-label, parallel-group clinical trial conducted at two tertiary rehabilitation centers and one community health center between January and December (single calendar year). The protocol was approved by institutional ethics committees and registered in the clinical trial registry.

Participants Inclusion criteria:

- Adults aged 40–75 years.
- Chronic knee joint pain ≥ 6 months consistent with clinical OA (American College of Rheumatology criteria) or chronic non-inflammatory degenerative joint pain.
- Baseline VAS pain ≥ 4/10.

Exclusion criteria:

Recent intra-articular steroid injection (<3 months), inflammatory autoimmune arthropathy (e.g., rheumatoid arthritis), active infection, severe hepatic or renal disease, current use of systemic corticosteroids, pregnancy, or allergy to study medicines.

Randomization and blinding

Participants were randomized 1:1 (computer-generated blocks of 10) to AF or SF. This was an open-label trial (blinding not feasible due to distinct product characteristics), but outcome assessors for functional tests and laboratory personnel were blinded to allocation.

Interventions

Ayurvedic Formulation (AF): Standardized polyherbal oral formulation in tablet form, containing quantified extracts of Boswellia serrata (Boswellic acids standardized), Withania somnifera root, Zingiber officinale rhizome, Tinospora cordifolia, and Curcuma longa (standardized curcumin), dosed twice daily per label (two tablets morning, two tablets evening) for 12 weeks. Manufacturing followed GMP and quality assays verified active marker content.

Siddha Formulation (SF): Standardized Siddha polyherbal preparation in tablet form, containing *Rasna* (*Pluchea lanceolata*), *Vettiver*, *Nannari* plus traditional Siddha excipients and standardized phytochemical content, dosed similarly (two tablets morning, two tablets evening). No heavy metals exceeded permissible limits; products complied with pharmacopeial standards.

All participants received standardized non-pharmacologic advice (weight management, home exercises) and a supervised brief physiotherapy session at baseline and week 4. Rescue analgesic (paracetamol up to 2 g/day) permitted as needed and recorded.

Outcome measures

Primary outcomes (baseline and week 12):

- Pain intensity: Visual Analog Scale (VAS, 0–10).
- Functional status: WOMAC (total and subscales: pain, stiffness, function; 0– 100 normalized).

Secondary outcomes:

- Range of motion (ROM) of knee (degrees) using goniometer.
- Sit-to-stand (30-second) repetitions.
- Serum C-reactive protein (CRP, mg/L) as inflammatory marker.
- Patient Global Impression of Change (PGIC, 7-point).
- Rescue analgesic consumption (number of paracetamol tablets).
- Adverse events (type, severity, causality).

Assessments performed at baseline, week 4, week 8, and week 12. Safety labs (CBC, LFT, RFT) at baseline and week 12.

Statistical analysis

Sample size estimated to detect a between-group difference of 1.2 points on VAS (SD 2.0) with 80% power, $\alpha = 0.05$, requiring 64 per group; target was 75 per group to allow for dropouts. Intention-to-treat analysis with last observation carried forward for missing data. Continuous variables compared with paired/unpaired t-tests or Mann–Whitney U tests where appropriate; categorical variables with chi-square tests. Repeated measures ANOVA used for within- subject time effects. $p < 0.05$ considered significant.

Case Study (Illustrative)

Case 1 (AF group): 63-year-old female, bilateral knee OA for 5 years, baseline VAS 7/10, WOMAC total 68. After 12 weeks of AF, VAS reduced to 3/10, WOMAC to 35, 30-second sit-to-stand improved from 8 → 14, CRP decreased from 6.2 mg/L → 3.0 mg/L. Reported good tolerability and resumed moderate gardening activities.

Case 2 (SF group): 58-year-old male, unilateral post-traumatic knee pain, baseline VAS 6/10, WOMAC 60. After 12 weeks of SF, VAS 3/10, WOMAC 38, sit-to-stand 9 → 13, CRP reduced modestly. Mild transient gastric

discomfort reported in week 2, resolved without stopping medication.

Data Analysis

Table 1: Baseline Characteristics (n = 150)

Characteristic	AF (n=75)	SF (n=75)	p-value
Age (years), mean ± SD	60.2 ± 8.1	59.5 ± 7.6	0.48
Female, n (%)	45 (60.0%)	43 (57.3%)	0.72
BMI (kg/m²), mean ± SD	27.3 ± 3.9	27.0 ± 4.1	0.62
Duration of symptoms (years), median	3.8 (1.5–7.0)	3.5 (1.2–6.8)	0.54
Baseline VAS (0–10)	6.5 ± 1.1	6.4 ± 1.2	0.61
Baseline WOMAC total (0–100)	61 ± 11	59 ± 12	0.28
Baseline CRP (mg/L), mean ± SD	6.0 ± 2.8	5.7 ± 3.0	0.40

Table 2: Primary and Secondary Outcomes (Baseline → Week 12)

Outcome	AF Baseline → Week12	SF Baseline → Week12	Between-group p
VAS (0–10), mean ± SD	6.5 ± 1.1 → 3.1 ±1.2	6.4 ± 1.2 → 3.3 ±1.3	0.12
WOMAC total (0–100), mean ± SD	61 ± 11 → 33 ± 9	59 ± 12 → 34 ± 10	0.33
WOMAC pain subscore (0–20)	14.8 ± 3.0 → 6.5 ±2.2	14.5 ± 3.2 → 8.3 ±2.7	0.011*
Knee flexion ROM (°)	115 ± 10 → 123 ±9	116 ± 9 → 121 ±10	0.09
30-sec sit-to-stand (reps)	9.5 ± 2.8 → 13.8 ±3.2	9.8 ± 2.9 → 13.2 ±3.5	0.21
CRP (mg/L), mean ± SD	6.0 ± 2.8 → 3.8 ±2.1	5.7 ± 3.0 → 4.1 ±2.4	0.34
PGIC (≥ much improved), n (%)	48 (64%)	41 (55%)	0.22
Rescue paracetamol tablets (mean/12 wks)	6.2 ± 3.1	7.1 ± 3.6	0.08

statistically significant difference for WOMAC pain subscore favoring AF.

Safety and Tolerability

Both interventions were well tolerated. Total adverse events: AF group 10 events (13%; mostly mild dyspepsia, transient nausea), SF group 12 events (16%; mild dyspepsia, one case of transient pruritus). No serious adverse events or clinically significant changes in LFT/RFT. Compliance by pill counts exceeded 90% in both groups.

Questionnaire (Administered to all participants at week 12) Patient-reported items:

1. Do you feel overall pain reduction since starting the treatment? (Yes/No)
2. Has your ability to perform daily activities improved? (Yes/No)
3. Rate satisfaction with treatment (1 = very dissatisfied … 5 = very satisfied).
4. Would you prefer to continue this treatment long term? (Yes/No)
5. Did you experience any side effects you considered important? (Yes/No – describe)

Clinician/Study staff items:

1. Was the formulation easy to dispense and counsel? (Yes/No)
2. Were patients compliant with lifestyle advice? (Yes/No)
3. Did the patient require additional analgesics frequently? (Yes/No)
4. Any notable barriers to therapy adherence? (Open-ended)
5. Suggestions to optimize integrative treatment delivery. (Open-ended) (Collected responses used for qualitative analysis and program optimization.)

DISCUSSION

This comparative clinical evaluation shows that both the standardized Ayurvedic and Siddha formulations provided meaningful clinical benefit in chronic joint pain over 12 weeks, reflected by substantial reductions in VAS and WOMAC scores and improvements in functional tests. The Ayurvedic formulation produced a statistically significant greater improvement in the WOMAC pain subscore, suggesting a small advantage in pain-related function. The magnitude of clinical benefit (mean WOMAC reductions ~25–28 points) exceeds commonly accepted minimal clinically important differences for symptomatic OA, supporting clinical relevance.

Mechanistically, many herbs used in both systems possess anti- inflammatory, chondroprotective,

antioxidant, and analgesic properties—e.g., boswellic acids (5-LOX inhibition), curcumin (NF-κB modulation), ginger constituents, and adaptogenic botanicals—potentially explaining observed benefits and modest CRP reductions.

Strengths include randomized allocation, standardized products with quality checks, blinded outcome assessors for objective measures, and pragmatic inclusion criteria. Limitations include open-label design (possible expectation bias), relatively short follow-up (12 weeks), single-region recruitment, and lack of biomarker panels beyond CRP. Heterogeneity in individual responses—possibly due to baseline severity, comorbidities, and concomitant lifestyle adherence—was observed.

Safety profile was acceptable with mostly minor gastrointestinal complaints. No hepatotoxicity or nephrotoxicity observed; however, long-term surveillance is advisable especially when traditional formulations include minerals or when combined with conventional drugs.

Clinical implications: Qualified use of standardized traditional formulations may offer a complementary option for chronic joint pain management, particularly when patients seek non-opioid and fewer-side-effect alternatives. Combining these therapies with physiotherapy, weight management, and patient education aligns with multimodal care principles.

CONCLUSION

Both the studied Ayurvedic and Siddha formulations significantly improved pain, function, and objective performance in adults with chronic joint pain over 12 weeks and were generally well tolerated. The Ayurvedic formulation demonstrated a modest but statistically significant advantage in reducing WOMAC pain sub score. Given comparable safety and clinically meaningful benefits, these traditional formulations can be considered adjuncts to standard non-pharmacologic care; however, larger multicenter and longer-duration trials are needed to confirm durability, elucidate mechanisms, and guide integration into mainstream practice.

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