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Clinical efficacy and safety of Turmeric extracts (CurcXR and CurcIR) in osteoarthritis and patients with low back ache- A randomized double blind, parallel group, active and placebo controlled, comparative clinical study

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Abstract
Background: Osteoarthritis is a degenerative joint disorder commonly presenting with pain, swelling, stiffness, and restricted joint mobility. Curcuminoids has been extensively studied for its anti-inflammatory and therapeutic effects in chronic inflammatory disorders, including musculoskeletal conditions such as osteoarthritis and low back pain.
Methodology: This randomized, multicentric, double-blinded, four-arm clinical study evaluated the efficacy and safety of CurcIR (200mg of 95% curcuminoids – T1) and CurcXR (200mg of 20% curcuminoids – T2) formulations in comparison with standard Turmeric Extract (1000 mg of 95% curcuminoids - C) and placebo (P) for their anti-inflammatory effects and pain reduction. A total of 100 participants both male and female aged between 30 and 80 years with osteoarthritis and low back pain, classified under American College of Rheumatology (ACR) Osteoarthritis as Class III, were equally randomized into four treatment groups and followed for 8 weeks. Clinical outcomes included pain intensity assessed using the Visual Analog Scale (VAS); inflammation assessed using inflammatory markers, namely C-reactive protein and erythrocyte sedimentation rate; and quality-of-life parameters assessed using the SF-12, OMERACT-OARSI criteria, WOMAC index, and Patient Global Assessment.
Results: VAS scores showed statistically significant within-group pain reduction from week 4 onward in the CurcIR and Comparator groups, whereas the CurcXR and placebo groups showed significant improvement only at week 8. Between-group analysis demonstrated that both CurcIR and CurcXR achieved significantly greater pain reduction than placebo from week 4 onward, with sustained effects. The Comparator showed efficacy comparable to CurcIR and CurcXR. CRP levels showed mild reductions across all groups, with no statistically significant within- or between-group differences, and CurcIR and CurcXR showed inflammatory profiles comparable to the Comparator. ESR levels showed statistically significant within-group reductions in all four groups, including placebo; however, no significant between-group differences were observed, and the placebo effect was likely influenced by concomitant medication use. WOMAC pain, stiffness, and physical function scores improved significantly at week 8 in the CurcIR and CurcXR groups, with selective improvements in the Comparator group, while placebo showed no change. Between-group analysis favored CurcIR and CurcXR over placebo. OMERACT-OARSI and PGA scores showed significant and sustained improvements in CurcIR and CurcXR compared with placebo, with Comparator demonstrating comparable efficacy.
Conclusion: CurcIR and CurcXR demonstrated significant and sustained improvements in pain and functional outcomes compared with placebo, with earlier onset observed for CurcIR. Both formulations showed efficacy comparable to the active comparator across VAS, WOMAC, OMERACT-OARSI, and PGA assessments. Inflammatory markers showed no significant between-group differences, indicating that clinical benefits were independent of systemic inflammatory changes.

Keywords: CurcIR, CurcXR, osteoarthritis, sustained release curcumin, immediate release curcumin

Introduction

Arthritis and chronic lower back pain are chronic, progressive conditions that affect millions of people worldwide leading to significant pain, stiffness and impaired mobility. According to the Global Burden of Disease Study, the prevalence of musculoskeletal disorders such as arthritis and back pain continues to rise, posing a growing challenge for healthcare systems globally [1]. These conditions result from persistent inflammation and oxidative stress that accelerate joint degeneration and tissue damage over time [2]. If inadequately managed, they can lead to long-term disability and reduced quality of life.

The current standard of care includes pharmacological, non-pharmacological and surgical interventions. Pharmacological therapies such as nonsteroidal anti-inflammatory drugs (NSAIDs), acetaminophen and corticosteroids are widely used for pain management. However, these agents mainly provide symptomatic relief and are associated with safety issues when used long-term, including gastrointestinal, hepatic and cardiovascular side effects [1, 2]. Consequently, there is an increasing need for natural, safe and clinically validated interventions that can alleviate pain and inflammation while being suitable for chronic use.

Curcumin, the principal bioactive compound in turmeric (Curcuma longa), has been extensively studied for its anti-inflammatory, antioxidant and analgesic effects. It modulates various signaling pathways including NF-κB, COX-2, TNF-α and interleukins which are key mediators of inflammation and pain [2]. Several clinical studies and meta-

analyses have confirmed curcumin's ability to reduce pain, improve joint function and enhance overall physical well-being in patients with arthritis and related inflammatory disorders [3, 4]. Despite its therapeutic potential, curcumin's poor aqueous solubility, low absorption and rapid metabolism result in low systemic availability, necessitating large doses for efficacy [5, 6]. Frequent dosing and poor absorption limit its clinical application and patient adherence.

Multiple approaches such as piperine co-administration, phospholipid complexes, micellar encapsulation and nanoparticle-based forms have been explored to enhance curcumin's bioavailability. While these strategies have demonstrated varying degrees of improvement, most rely on synthetic surfactants or chemical excipients that compromise natural product integrity and clean-label appeal. Moreover, many of these technologies provide only short-term plasma elevation without sustained systemic retention, reducing overall efficacy [5, 6, 7]. To overcome the limitations of poor solubility and rapid metabolism, Makams Biotech Pvt. Ltd. developed two distinct delivery systems: CurcXR™ and CurcIR™. CurcXR™ is a patented sustained-release formulation powered by Citrap20™ Technology, which utilizes a matrix of soluble and insoluble natural fibers. This proprietary platform protects curcuminoids from gastric degradation, enabling a gradual absorption profile over 12 hours. Preclinical evaluations confirmed that CurcXR™ achieves a 57-fold higher bioavailability compared to standard turmeric extract of curcuminoids 95%, maintaining therapeutic plasma levels throughout the day with a low dose of only 80 mg of active curcuminoids.

Complementing this, CurcIR™ was developed as a fast-acting, immediate-release formulation. By employing advanced micronization techniques, the particle size of the curcuminoids is significantly reduced, exponentially increasing its surface area for rapid dissolution. This is combined with specific natural bioenhancers that inhibit the metabolic pathways typically responsible for the rapid elimination of curcuminoids. As a result, CurcIR™ provides a swift spike in plasma concentration with an extended 12-hour retention, making it ideal for the early-onset management of acute symptoms in inflammatory conditions. Both formulations were validated in a randomized, double-blind, controlled clinical trial involving subjects with osteoarthritis and chronic lower back pain. While the CurcIR™ group showed an earlier onset of pain relief significant as early as Week 4, the CurcXR™ group demonstrated more pronounced improvements in functional mobility and stiffness by Week 8. These results highlight a dual-action approach to joint health: CurcIR™ for rapid symptomatic relief and CurcXR™ for consistent, long-term therapeutic coverage. Together, these innovations represent a significant advancement in curcumin delivery, addressing the need for safe, efficient, and clinically proven management of degenerative joint disorders

The study objectives were

1. To study the efficacy of Curcuminoids in osteoarthritis and patients with Low back ache
2. To assess the safety and tolerability of Curcuminoids in osteoarthritis and patients with Low back ache, by monitoring the occurrence of any adverse effects by clinical and laboratory evaluation.

Methodology

Study Design and Study Centers

This, double-blind, randomized, multicenter, parallel-group, placebo and active-controlled trial included participants with osteoarthritis and chronic lower back pain. The study was conducted at two sites in Puducherry, India (DK Elite Health Care Centre, First Floor, 370 Cuddalore Road, Nainarmandapam, Puducherry – 605004 and Sri Ortho Care, No. 6, Opposite to KBSN Buvan Street, Karamanikuppam, Puducherry – 605004) between March 10, 2025, and August 05, 2025.

Ethical Approval and Trial Registration

The study protocol was approved by the Ethics Committee, Ethique De La Nature Association (registration no: ECR/376/Indt/PY/2023). The trial was registered prospectively in the Clinical Trials Registry of India (CTRI) on December 17, 2024 (registration no: CTRI/2024/12/078207).

This study was conducted in compliance with the International Council for Harmonization-Good Clinical Practice (ICH-GCP) gsuidelines E6 (R2), 2016; the Indian Council of Medical Research (ICMR) National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017; the Declaration of Helsinki, 2013; and all applicable local regulatory requirements and institutional policies. Written informed consent was obtained from each participant prior to study initiation.

Study Population

Men and women aged between 30 and 80 years, diagnosed with osteoarthritis of the knee or lower back pain were enrolled in the study. Participants were eligible if they had chronic pain for more than three months with a baseline pain intensity score of ≥30 mm on the Visual Analogue Scale (VAS). Those with osteoarthritis were diagnosed according to the American College of Rheumatology (ACR) criteria and Kellgren–Lawrence grade 3 or 4 disease confirmed by radiographic evaluation.

All participants were in good health as assessed by medical history, physical examination, and clinical judgment of the principal investigator and had provided written informed consent prior to study procedures.

Participants were excluded if they had secondary causes of arthritis, lumbar spondylosis, uncontrolled hypertension, uncontrolled diabetes mellitus, severe renal impairment, pregnancy or lactation, recent participation in another clinical study, or hypersensitivity to curcuminoids or any study ingredients. Subjects receiving corticosteroids, glucosamine, chondroitin, omega-3 fatty acids, or intra-articular injections of corticosteroids or hyaluronic acid within the previous three months were also excluded.

Study Procedure and Treatment Randomization

After obtaining written informed consent, participants underwent a detailed screening procedure. Screening included medical and treatment history, physical examination, assessment of vital signs, and evaluation of pain severity using the Visual Analogue Scale (VAS). Laboratory investigations included hematology, liver function, renal function, random blood glucose. A urine pregnancy test was conducted for women of childbearing potential. Participants with osteoarthritis of the knee were evaluated radiographically to confirm Kellgren–Lawrence

grade 3 or 4, and those with lower back pain were clinically confirmed by qualified orthopedic specialists.

Eligible participants were equally randomized into four groups.

T1 (n=25): CurcIR 95% (Immediate Release formulation)-200mg in 1 capsule equivalent to 190mg curcuminoids twice daily after food for 8 weeks

T2 (n=25): CurcXR 20% (Sustained Release formulation)-200mg in 1 capsule equivalent to 40mg curcuminoids twice daily after food for 8 weeks

C (n=25): Comparator Curcuminoids 95% - 2 capsules each containg 500mg curcuminoids twice daily after food for 8 weeks, total 2000mg of 95% curcuminoids

P (n=25): Placebo - 1 capsule twice daily after food for 8 weeks

Randomization was done using a computer-generated block randomization schedule prepared by a biostatistician. All study products were provided in identical capsule formulation, matched for color, size, and packaging to maintain blinding of participants, investigators, and site staff.

Study Endpoints

The primary efficacy endpoints included the evaluation and comparison of changes in pain intensity using the Visual Analogue Scale (VAS, 0–100 mm) and the WOMAC pain subscale. Changes in inflammatory biomarkers, including C-reactive protein (CRP) and erythrocyte sedimentation rate (ESR), were assessed from baseline to Week 8.

The secondary efficacy endpoints included changes in the Patient's Global Assessment (PGA) scores and the proportion of subjects achieving a clinically meaningful improvement as per the Outcome Measures in Rheumatology and Osteoarthritis Research Society International (OMERACT–OARSI) response criteria. Quality of life was assessed using the Short Form-12 (SF-12) questionnaire from baseline to week 8 to determine the overall physical and mental health impact of CurcXR™ and CurcIR supplementation.

Safety assessments were conducted throughout the study by monitoring adverse events. Each reported event was recorded with details on onset, duration, severity, causality, and outcome. Laboratory assessments including complete blood count (CBC), liver function tests (LFT), renal function tests (RFT), glycated hemoglobin (HbA1c), and random blood sugar (RBS) were performed at baseline and at the end of the study to assess systemic safety.

Statistics

All statistical analyses were performed using GraphPad Prism version 10.5.0. Baseline demographic characteristics were summarized using descriptive statistics, with categorical variables presented as counts and percentages. Participants were categorized into age groups (41–50, 51–60, 61–70, and 71–80 years), and comparisons across these groups were made using a one-way ANOVA. Other demographic data, including gender and BMI categories, were compared using Fisher's Exact Test. The primary and secondary outcome variables, including VAS pain score, WOMAC, OMERACT–OARSI, Patient's Global Assessment, Quality of Life (SF-12) questionnaire, and Overall Global Status of Improvement were treated as ordinal or non-normally distributed continuous variables. For within-group comparisons across multiple study visits (Baseline, Week 4, and Week 8), the Friedman test was used. Post-hoc pairwise comparisons were conducted following significant Friedman results. Between-group comparisons were performed using the Kruskal–Wallis test, with Dunn's multiple comparisons test as a post-hoc procedure. CRP, ESR and other blood parameters being continuous variables, were compared within groups using the paired Student's t-test and across groups using one-way ANOVA followed by Tukey's post-hoc test. All statistical tests were two-tailed, and a p-value < 0.05 was considered statistically significant.

Results

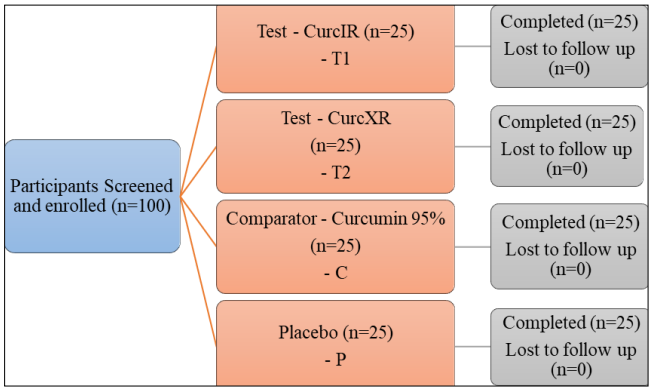

Fig 1: Participant flowchart

Demographic Details

A total of 100 participants were screened and successfully enrolled into the four study groups (CurcXR, CurcIR, comparator Curcuminoids 95% and placebo), with all participants completing the 8-week study without any dropouts (Fig.1). The gender distribution across groups showed a balanced representation of males and females, with no statistically significant differences ($p = 0.89$). Age distribution was also comparable among the groups, with most participants falling within the 41-80 years range and no significant differences between groups ($p = 0.72$). Body Mass Index (BMI) categories (healthy weight, overweight, and obese) were evenly distributed across all groups, and no statistically significant difference was observed ($p = 0.76$). Gender, age and BMI analyses confirmed that the study groups were demographically comparable at baseline, ensuring that outcomes were not influenced by population imbalance.

VAS scores (0 – No pain, 100 – Very high pain) showed a significant reduction from Week 4 onward in the CurcIR and Comparator groups, whereas the CurcXR and Placebo groups demonstrated significance only at Week 8, with the placebo effect likely influenced by concomitant medication use. Between-group analysis confirmed significantly greater pain reduction in the CurcIR and CurcXR groups compared to placebo (Table 1). ESR significantly decreased within all groups, reflecting improved inflammatory status. However, these differences were not significant between the groups. CRP showed a marginal decrease across groups without statistical significance. Overall, both CurcIR and CurcXR formulations demonstrated significant efficacy compared to standard formulations and placebo in reducing pain and maintaining a favorable inflammatory profile (Table 2).

Table 1: Pain Assessment by VAS Scale

Study visits	CurcIR (T1)	CurcXR (T2)	Comparator (C)	Placebo (P)	p-value among groups
Baseline	62 ± 10.8	57.2 ± 10.61	63.2 ± 12.49	62 ± 11.55	0.34
Week 4	*50.8 ± 11.52	*51.6 ± 11.43	55.6 ± 16.09	61.4 ± 12.03	0.02
Post study	*40 ± 17.56	*40 ± 15	*46.8 ± 20.96	58.4 ± 13.52	<0.0001
p-value (Baseline and Post study) within group	<0.0001	<0.0001	<0.0001	0.03	-

*These groups showed a statistically significant reduction in pain compared to placebo group

Table 2: Reduction in inflammatory biomarkers

Study groups	ESR (mm/hr)			CRP (mg/dL)		
	Baseline	Post study	P value (Baseline Vs. Post study)	Baseline	Post study	P value (Baseline Vs. Post study)
CurcIR	63.8±28.4	37.59±20.07	<0.0001	9.21±10.65	7.9±3.32	0.73
CurcXR	66.04±29.72	38.04±18.34	<0.0001	8.69±5.68	8.42±7.87	0.52
Comparator	66.08±28.81	42.28±21.16	0.0001	9.12±9.63	8.32±4.69	0.94
Placebo	61.24±21.3	49.88±16.44	0.04	8.03±3.27	7.34±2.64	0.49
P value (among the groups)	0.97	0.06	-	0.74	0.88	

Patient's Global Assessment (PGA) scores demonstrated a statistically significant reduction from Week 4 onwards in the CurcIR ($p = 0.009$) and Comparator ($p = 0.01$) groups, which was sustained through Week 8, while the CurcXR group showed a significant improvement only at Week 8 ($p < 0.0001$). Between-group analysis showed that both CurcXR ($p = 0.02$) and CurcIR ($p = 0.03$) formulations produced significantly greater improvement from Week 4 onwards compared to placebo, with sustained benefit through Week 8. The Comparator demonstrated comparable efficacy to the CurcIR and CurcXR groups and showed a significant improvement versus placebo at Week 8 ($p = 0.01$) (Table 3).

Table 3: Patient's Global Assessment

Study visits	CurcIR (T1)	CurcXR (T2)	Comparator (C)	Placebo (P)	p-value among groups
Baseline	6.08 ± 1.5	5.76 ± 1.05	6.4 ± 1.29	6.2 ± 1.16	0.38
Week 4	*5 ± 1.44	*5.08 ± 1.22	5.56 ± 1.69	6.12 ± 1.13	0.01
Post study	*4 ± 1.96	*3.96 ± 1.51	*4.68 ± 2.16	5.8 ± 1.16	<0.0001
p-value (Baseline and Post study) within group	<0.0001	<0.0001	<0.0001	0.1	-

*These groups showed a statistically significant reduction in pain scale compared to placebo group

Score 0 indicates no pain, 1–3 represents mild pain with no functional limitation, 4–6 indicates moderate pain with some activity restriction, 7–9 reflects severe pain with marked impairment, and 10 denotes the worst possible pain with inability to perform daily activities.

WOMAC analysis demonstrated clinically significant improvement across multiple functional domains, predominantly in the CurcIR and CurcXR groups. Significant reductions in pain were observed at Week 8, with CurcIR and CurcXR consistently outperforming placebo and showing outcomes comparable to the active comparator. Stiffness parameters, including morning stiffness and stiffness after sitting or walking, also improved significantly in the CurcIR and CurcXR groups. Physical function measures such as stair climbing, bending, dressing, and rising from a chair showed improvement as shown in Figure 1.

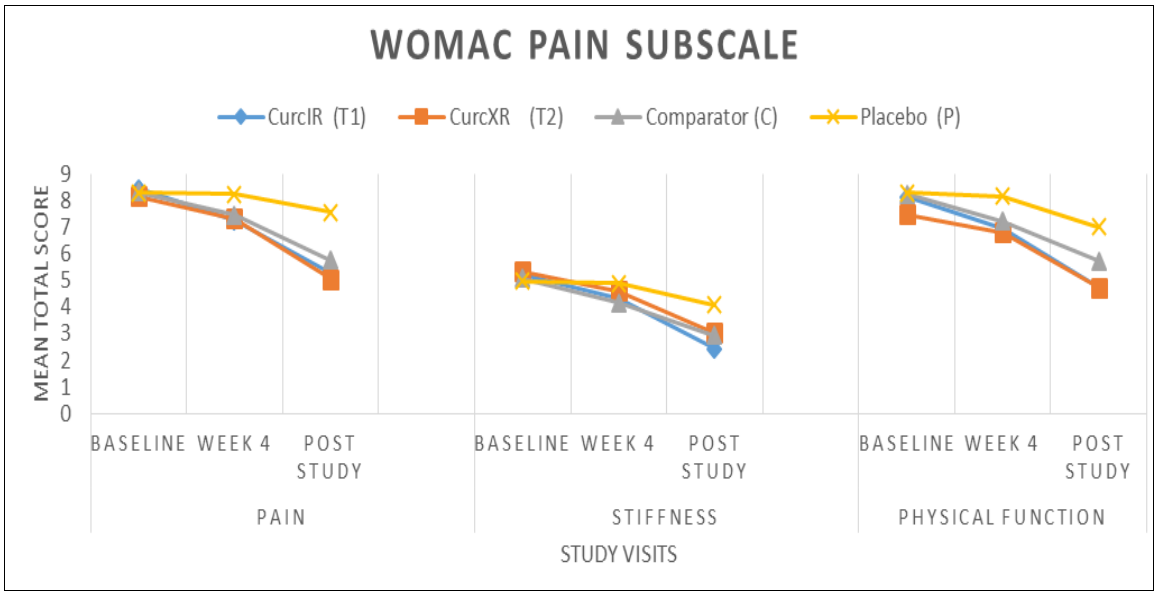

Fig 2: WOMAC Pain Scale

OMERACT–OARSI outcomes demonstrated consistent and clinically significant improvements in pain intensity, pain frequency, emotional impact, and quality of life, predominantly in the CurcIR and CurcXR groups, while quality-of-life improvement was observed in the Comparator group. Significant reductions in constant and intermittent hip/knee pain, including severe pain episodes, were observed, with earlier onset from Week 4 in the CurcIR and Comparator groups, while similar improvements were observed by Week 8 in the CurcXR group. Across parameters assessing frustration, worry, sleep disturbance, and daily functioning, CurcIR and CurcXR demonstrated significantly greater benefits than placebo, indicating effectiveness in enhanced well-being.

SF12 (QoL) Assessment at Week 8, demonstrated a significant improvement within-group in general health perception, emotional well-being, vitality, and social functioning in the CurcIR, CurcXR and Comparator groups. Pain intensity significantly reduced in the CurcIR, CurcXR and Comparator groups, supported by among-group differences favoring active treatments over placebo. Although most physical activities (moderate activities and stair climbing) did not show significant change across groups CurcIR and CurcXR demonstrated improvement in emotional functioning (work accuracy and performance). Overall, CurcIR and CurcXR consistently showed superior outcomes compared with placebo and comparable to active comparator, indicating enhancement in health perception, emotional well-being, energy, and social participation, along with significant pain reduction by end of study. The haematological and biochemical parameter evaluations suggest that the interventions (CurcIR and CurcXR) were well-tolerated, with no evidence of treatment-related safety concerns when compared to other groups.

Adverse Events

Adverse events were reported across all study groups. The CurcXR group reported constipation and self-resolved gastritis. In contrast, the CurcIR group reported more events, including nausea, constipation, and gastritis. The Comparator group also reported multiple adverse events, including gastritis, constipation, and episodes of dark yellow (concentrated) urine lasting for a few days. Similarly, in the Placebo group, participants experienced dark yellow (concentrated) urine, gastritis, and abdominal pain.

Concomitant or Rescue medication use was highest in the placebo group and Comparator group, while the CurcIR group required the least, indicating better pain control. The CurcXR group showed usage of Paracetamol 650 mg in comparison to other groups.

Discussion

The statistical analyses confirmed that there were no significant demographic differences including gender, age, BMI, among the study groups, ensuring comparability at baseline. The test groups in this study received a daily dose of 200 mg CurcXR formulation and 200mg of CurcIR formulation while the comparator group received a higher dose of 1000 mg/day. Despite the lower dosage, test groups demonstrated significant intra-group improvements across multiple efficacy endpoints.

Curcumin, the active compound in turmeric, has garnered attention for its potential therapeutic effects in osteoarthritis (OA), a prevalent degenerative joint disease [8]. This clinical trial evaluated its efficacy in comparison to placebo and standard treatments.

Pain Reduction

Both immediate-release (CurcIR) and sustained-release (CurcXR) formulations demonstrated significant reductions in Visual Analog Scale (VAS) scores from week 4 onwards, sustained throughout the study period. The CurcXR formulation exhibited reduction in pain at week 8, while the CurcIR formulation showed earlier performance effect in 4 weeks. These findings align with previous studies indicating curcumin's efficacy in reducing OA pain, with some suggesting its effectiveness comparable to nonsteroidal anti-inflammatory drugs (NSAIDs) like diclofenac [9].

Inflammatory Biomarkers

Both curcumin formulations (CurcXR and CurcIR) showed significant reductions in erythrocyte sedimentation rate (ESR) levels, indicating decreased systemic inflammation. C-reactive protein (CRP) levels showed mild reductions in both the groups, with no statistical significance. Previous studies have reported significant reductions in CRP and ESR levels with curcumin supplementation, suggesting its potential to modulate inflammatory responses in OA patients [10, 11].

WOMAC & OMERACT- OARSI

Both OMERACT-OARSI and WOMAC assessments indicated that curcumin treatment, in both immediate-release (CurcIR) and sustained-release (CurcXR) formulations, significantly improved pain, stiffness, and physical function compared to placebo. The CurcIR formulation demonstrated an earlier onset of effect from Week 4, whereas the CurcXR formulation showed more pronounced improvements at Week 8. Both formulations consistently reduced pain during activities such as walking, standing, and squatting, and enhanced overall quality of life and emotional well-being. Overall, these findings support the efficacy of curcumin in alleviating osteoarthritis symptoms and improving patient-reported outcomes across multiple domains. These findings are consistent with previous studies demonstrating the anti-inflammatory and analgesic effects of curcumin in patients with osteoarthritis, supporting its role as an effective adjunct therapy for symptomatic relief [12, 13].

Conclusion

Curcumin CurcXR and CurcIR formulations, demonstrate statistically significant efficacy in reducing pain and improving functional outcomes in OA patients. While both formulations are effective, the CurcXR formulation may offer more pronounced benefits at later time points. Curcumin's anti-inflammatory properties, as evidenced by reductions in ESR and CRP levels, further support its therapeutic potential. Given its favourable safety profile, curcumin presents a promising adjunctive treatment option for OA management. However, further large-scale studies are warranted to confirm these findings and establish standardized dosing regimens.

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