Efficacy and Safety of a Turmeric Lemonade Energy Drink in the Management of Moderate Knee Osteoarthritis: A Randomized, Double-blind, Placebo-controlled Clinical Trial

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Abstract

Introduction: The purpose of this study was to compare the efficacy and safety of turmeric lemonade energy drink manufactured by Golden Tiger Life Corp, USA, in the treatment of patients with moderate knee osteoarthritis (OA).

Methods: In this single-center, randomized, double-blind, placebo-controlled pilot study, 27 patients with knee OA were randomly assigned to receive either a turmeric lemonade energy drink (Golden Tiger Life Corp, USA) or a placebo, twice daily, meaning one 12 FL oz bottle for 28 days. Patients underwent assessment at baseline and days 14, and 28. The main outcome measure was the mean change from baseline to end of treatment in Knee Injury and Osteoarthritis Outcome Score (KOOS) and the change in endurance from baseline to end of treatment was assessed by the distance covered in 6 min' walk test at days 14 and 28. Changes in joint pain (Visual Analog Scale [VAS] score), metabolic panel, lipid profile, analgesic (paracetamol) requirement, and global tolerability on a 3-point scale were included as secondary outcome measures. Safety after treatment was evaluated by recording adverse events (AEs) and laboratory investigations.

Results: At days 14 and 28, patients receiving turmeric lemonade energy drink showed consistently greater numerical improvement across all subscales of KOOS, and a significant increase in walking distance compared to those receiving a placebo. Both treatment groups showed a significant reduction in VAS scores from baseline by day 28 (P < 0.01). No major AEs were reported associated with study treatments. Patients' and physician's global assessment of therapy was similar in the two treatment groups.

Conclusion: The study confirms curcumin's potential in moderate knee OA management, with Golden Tiger Turmeric Lemonade Energy Drink in improving pain, mobility, and metabolic stability over placebo. Overall, the product offers a safe, effective alternative to conventional knee OA treatments, paving the way for nutraceutical advancements.

Keywords: Turmeric-lemonade, Osteoarthritis, Curcumin, Bioactive.

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Introduction

Knee osteoarthritis (OA) is the most prevalent degenerative joint disease, resulting from wear and tear and progressive cartilage loss. According to the International Classification of Diseases, it is classified as unilateral or bilateral primary, post-traumatic, or secondary knee OA [1]. Clinically, it manifests with pain, inflammation, stiffness, and reduced mobility, often progressing to disability and impaired quality of life (QoL) if untreated [2, 3].

The Global Burden of Disease Study (2020) estimated OA prevalence at 7.6% globally, with knee OA affecting 4307 individuals per 100,000. Its prevalence is projected to rise by

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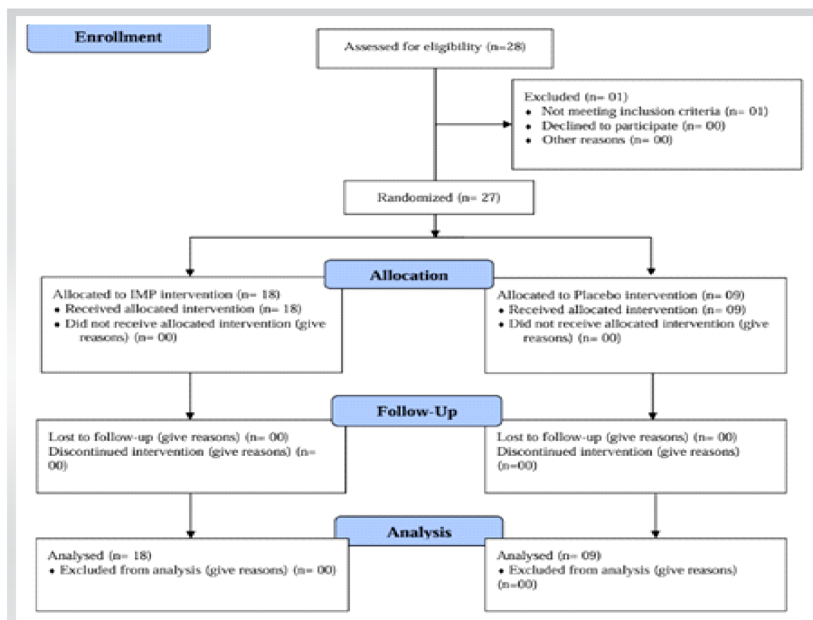

Figure 1: Study flow chart.

74.9% by 2050, posing a major healthcare challenge [3]. In India, a community-based study reported a 28.7% prevalence [4].

Pain being the central cause of disability in OA, treatment primarily aims to relieve pain and improve function [5, 6, 7]. Current management strategies include pharmacological, non-pharmacological, and surgical options. Among these, pharmacological therapies such as nonsteroidal antiinflammatory drugs (NSAIDs), acetaminophen, cyclooxygenase 2 (COX-2) inhibitors, glucosamine, and steroids are most commonly used [2, 8, 9]. However, these provide only symptomatic relief, and long-term use raises safety concerns [2]. Consequently, interest has grown in natural and traditional therapies, especially turmeric (Curcuma longa L.), long valued in Asian medicine for its health benefits.

In particular, due to the safety concerns associated with the long-term use of these pharmacological treatments, there is growing interest in exploring safer natural therapies. This growing interest in natural therapies has sparked attention towards traditional remedies, with turmeric standing out because of its health benefits since ancient times. Curcuminoids (4–6%) are the major phytochemicals found in the rhizome of the turmeric plant (C. longa L.), of which curcumin (77%) is the major phytoactive and the other two are demethoxycurcumin (17%) and bisdemethoxycurcumin (3%). Curcuminoids possess anti-inflammatory, antioxidant, antitumor, lipid-regulating, and anticoagulant properties [10, 11, 12]. Curcumin is one of the most potent and safe nutraceuticals for reducing OA pain and improving function, supported by robust evidence [13, 14, 15, 16, 17, 18]. However, its poor absorption and low bioavailability, which necessitate the administration of multiple daily doses, might affect treatment adherence, especially during long-term use. High doses of turmeric extract and curcumin (>4000 mg/day) are associated with gastrointestinal and liver enzyme abnormalities, and urticaria [19, 20, 21].

Currently, most bioavailable turmeric extracts in the market are with synthetic excipients and contain up to 20% active ingredients, requiring higher doses to achieve clinical efficacy [22]. The researchers suggest that the usefulness of curcumin could be minimized because of its poor oral bioavailability [23]. Dhillon et al. in their study showed that only 22–41 ng/mL were detectable in plasma even when 8 g curcumin/day was given orally [24]. Thus, there exists a gap in developing a turmeric formulation that can deliver therapeutic benefits at lower doses. To address these limitations Kurien and Scofield in their research showed that the solubility of curcumin can be increased 12-fold by heating a solution of curcumin in water to boiling for 10 min [25].

The Golden Tiger Turmeric Lemonade Energy Drink used as the treatment arm in the study contained 100 mg of bioactive Curcumin. In order to be effectively absorbed by the gut, Curcumin must be made bioavailable. Top research scientists across the world have tried different methods, such as nanoparticle, liposomal encapsulation, heating, or synthetic

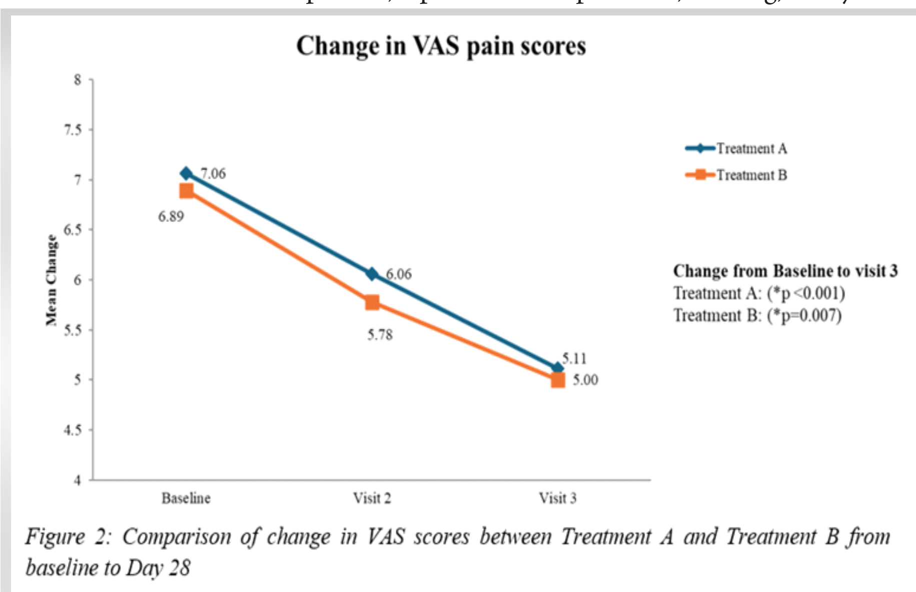

Figure 2: Comparison of change in visual analogue scale scores between treatment A and treatment B from baseline to day 28.

curcumin. Golden tiger, through extensive research, found that Curcumin reaches its highest healing potential only when it is heated during the preparation process. Accordingly, a proprietary chemistry process was employed to heat Curcumin to a specific temperature (to avoid thermal degradation), creating a bioactive formula designed for maximum absorption [26]. This inclusion of 100 mg of bioactive Curcumin aligns with methodological standards discovered previously by Kurien et al. in 2007, giving the study's compliance with validated formulations. Bioactive curcumin here refers to the form of curcumin that is absorbed, remains active, reaches the target site, and produces a biological effect [27]. Golden Tiger Turmeric Lemonades energy drink not only contains 100 mg of bioactive curcumin but is the only beverage on the market that can claim bioactive curcumin on its packaging. The lemonades are packed with powerful organic superfoods such as ginger, green tea, lemon, and lime that build immunity, promote recovery, and provide plant-based energy [28, 29, 30, 31, 32]. Hence, the hypothesis proposed for this study was that heat-solubilized curcumin in combination with active components of ginger (phenolic and terpene compounds), tea (phenolic compounds), and lemon plus lime (ascorbic acid) may ameliorate moderate OA. In view of this, the present study aimed to evaluate the efficacy, safety, and tolerability of turmeric lemonade energy drink manufactured by Golden Tiger Life Corp, USA, in the treatment of patients with moderate knee OA.

Methods

Ethics and participants' confidentiality

This study was conducted in accordance with the Good Clinical Practice (GCP) guidelines, including archiving of essential documents, AYUSH Guidelines, Indian-GCP, New Drugs and Clinical Trial Rules, 2019, and other applicable regulations. Ethics committee approval was obtained from the Institutional Ethics Committee, Sangvi Multispeciality Hospital, Pune, India, before initiating the study (registration number: ECR/1865/Inst/MH/2023). Before any study-related screening procedures, voluntary written, valid informed consent was obtained by the principal investigator from each participant before enrollment in the study in the language best understood by them. The study was registered under Clinical Trial Registry of India (CTRI) before enrolment of the first study participant (CTRI/2024/11/076875). Each participant was identified only by the unique study participant number throughout the study, and all documents in the study were identified by using the initials and study number. The participant identification information was handled only by delegated site staff and stored in a controlled access, accessible only to authorized study staff.

Trial design and participant selection

This single-centre, randomized, double-blind, placebo-controlled pilot study aimed to assess the efficacy, safety, and tolerability of a turmeric lemonade energy drink containing bioactive curcumin, green tea, ginger, lemon, and lime, manufactured by Golden Tiger Life Corp, for treating moderate knee OA. Twenty-eight prospective participants were screened, and out of these, 27 were enrolled based on predefined inclusion and exclusion criteria. Eligible participants were randomly assigned to receive either the Golden Tiger Turmeric Lemonade Energy Drink or a placebo, per the randomization allocation schedule generated using IBM Statistical Package for the Social Sciences (SPSS) Statistics for Windows, Version 26.0, Armonk, NY: IBM Corp (IBM Corp., 2019). An independent pharmacist who was not involved in any other study assessment activities supervised the dispensing and proper administration of the study treatments.

The study was conducted at Sangvi Multispeciality Hospital Pvt. Ltd., Pune, Maharashtra, India, involving male and non-pregnant, non-lactating females aged 38–65 with moderate unilateral or bilateral OA for at least >3 months and with Radiographic Evidence of OA, as determined by Kellgren –Lawrence grade III. Eligible participants met the American College of Rheumatology criteria, reported index knee pain ≤44 on a 100-point pain-knee injury and osteoarthritis outcome score (KOOS) scale, and could walk for at least 6 min at a moderate-to-brisk pace. Exclusion criteria covered inflammatory arthropathies, severe OA, rheumatoid arthritis, gout, systemic lupus erythematosus, prior knee joint replacement surgery, and mild (Grade I/II) or severe (Grade IV) OA per the Kellgren-Lawrence Scale. Participants who had taken corticosteroids, indomethacin, glucosamine-chondroitin within three months, or received intra-articular injections of corticosteroids, hyaluronic

Table 1: Demographic and baseline characteristics in patients with knee osteoarthritis

Patient characteristics	Treatment A (*n*=18)	Treatment B (*n*=09)
Age (Years)	52.89±06.29	52.56±05.27
Gender (%)		
Male	12 (66.7)	07 (77.8)
Female	06 (33.3)	02 (22.2)
Weight (kg)	56.50±03.76	59.36±07.11
body mass index (kg/m^2)	21.66±02.58	22.72±04.26
Baseline pain intensity as per KOOS score	34.94±06.47	35.13±05.67
Baseline pain intensity as per VAS score	07.06±00.64	06.89±00.60

Values are expressed in mean±standard deviation except for the gender variable (presented as number of patients and percentage of patients in each category). Visual Analog Scale is from 0 to 10, where 0 indicates "No pain" and 10 indicates "Worst possible pain". KOOS: Knee injury and osteoarthritis outcome score

Table 2: Assessment of knee injury and osteoarthritis outcome score subscale in patients			
Visits	Treatment A (n=18)	Treatment B (n=09)	P-value
Pain			
Baseline	34.11±10.94	36.11±11.79	0.737
Visit 2	42.44±10.77	43.52±10.67	0.979
Visit 3	52.62±09.36	51.23±05.22	0.714
Change at visit 2	08.33±12.05	07.41±13.89	
(*P*-value)	(* 0.011)	-0.159	
Change at visit 3	18.52±15.12	11.74±14.64	
(*P*-value)	(*<0.001)	(*0.018)	
Symptoms			
Baseline	34.72±11.08	34.92±08.89	0.979
Visit 2	44.84±09.27	43.25±08.46	0.775
Visit 3	50.20±07.40	48.41±07.17	0.272
Change at visit 2	10.12±11.57	08.33±13.13	
(*P*-value)	(*0.003)	-0.122	
Change at visit 3	15.48±13.49	10.95±08.71	
(*P*-value)	(*<0.001)	(*0.018)	
ADL function			
Baseline	35.46±09.71	35.46±07.19	0.999
Visit 2	40.52±10.51	42.81±04.85	0.553
Visit 3	51.39±06.02	48.37±03.71	0.224
Change at visit 2	05.07±09.44	07.35±10.27	
(*P*-value)	(*0.043)	(*0.044)	
Change at visit 3	15.39±12.91	08.10±07.38	
(*P*-value)	(*<0.001)	(*0.009)	
Sport and recreation function			
Baseline	33.89±16.85	35.56±10.74	0.756
Visit 2	37.50±15.65	40.56±11.84	0.586
Visit 3	49.72±12.06	50.00±10.31	0.876
Change at visit 2	03.61±20.99	05.00±07.91	
(*P*-value)	-0.433	-0.124	
Change at visit 3	15.83±14.44	18.64±05.27	
(*P*-value)	(*0.005)	(*0.009)	
Quality of life			
Baseline	35.76±14.35	31.25±17.12	0.344
Visit 2	35.07±13.75	36.11±11.17	0.979
Visit 3	52.78±14.57	54.86±08.14	0.895
Change at visit 2	00.69±20.21	04.86±19.96	
(*P*-value)	-0.815	-0.551	
Change at visit 3	17.01±23.61	21.63±16.47	
(*P*-value)	(*0.007)	(*0.013)	

Higher score indicated better improvement. Values are expressed in mean±standard deviation. Change in mean score at days 14 and 28 is calculated from baseline KOOS for each subscale. KOOS: Knee injury and osteoarthritis outcome score, ADL: Activities of daily living

acid, or omega-3 supplements within 6 months were excluded. Participants with a history of allergy or sensitivity to curcumin and related compounds were excluded. Acetaminophen/paracetamol was the only permitted rescue medication during the 4-week treatment period.

Intervention and dosage

The treatment arm A was a turmeric lemonade energy drink manufactured by Golden Tiger Life Corp. The formulation included active ingredients of bioactive compounds such as organic curcumin (100 mg), turmeric extract (95% curcumin), organic brewed green tea, organic agave, organic lime, and organic lemon juice concentrate, organic ginger extract, organic lemon extract, ascorbic acid, and organic stevia leaf extract. The beverage prepared with sparkling or filtered water was heat-treated, cooled and bottled at a commercial bottling facility under GMP conditions. The matching placebo (Treatment arm B) was also manufactured by Golden Tiger Life Corp. The Investigational Medicinal Product (IMP) was administered to the study participants as per randomization, twice daily, meaning one 12 FL oz bottle in the morning and one in the evening, approximately at the same time every day for a period of 28 days. Each participant was given instructions to separate the intake of the IMP from other medications by 4 h and to maintain approximately the same daily dosing interval between IMP doses. Treatment compliance was determined using the empty containers counts before dispensing and at return.

Assessments

Screening assessments included informed consent, demographics, medical and prior treatment history, physical examination, vital signs, KOOS, and Visual Analog Scale (VAS) scores, a 6-min walk test, Complete Metabolic Panel (CMP), lipid profile, and urine pregnancy test (for females of childbearing potential). Participants were evaluated at baseline (day 1), week 2 (day 14), and week 4 (day 28). Primary outcomes included the mean Change from Baseline to End of Treatment in KOOS and Change in Endurance from Baseline to End of Treatment assessed by distance covered in 6 min' walk test. Secondary outcomes assessed changes in joint pain (VAS score), metabolic panel and lipid profile, analgesic (paracetamol) requirement, and global tolerability on a 3-point scale (ranging from mild/no side effects to severe). The weight-lowering effect and sleep quality were assessed by comparing the mean weight reduction and improvement in sleep quality determined by recording sleep disturbances on day 28 with baseline values. The proportion of patients reporting adverse events (AEs) or serious AEs (SAEs) was also considered as a secondary outcome. Study visits ensured medication compliance, and all observed or reported AEs were documented in the case report form.

Statistical analysis

All statistical summaries and analyses were performed using IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp (IBM Corp. Released 2019). Pair-wise changes were assessed using a least significant difference test across all possible comparisons. The significance of treatment effects was evaluated through a t-test or Wilcoxon signed-rank test, with results deemed statistically significant at a $P < 0.05$. Change of

VAS score from baseline at Day 14 and Day 28 was analyzed using a paired t-test (two-sided test, $\alpha = 0.05$) with the null hypothesis equal to zero. The Shapiro–Wilk test was used to test the normality of the change in VAS score from baseline at Day 14 and Day 28. If the change did not satisfy the normal distribution, the Wilcoxon signed-rank test was performed. The Biostatistics and Statistical Programming team conducted the data analysis.

Results

Demographic details

Of the 28 participants screened, 27 eligible participants were randomized to either the IMP (n = 18) or placebo (09) group in a 2:1 ratio. All enrolled participants (n = 27) completed the study, and the data obtained were subjected to statistical analysis (Fig. 1).

The mean age of participants was 52.89 years for treatment A and 52.56 for treatment B, and body mass index was 21.66 kg/m2 and 22.72 for treatment A and B, respectively. The demographic characteristics of the study population, along with baseline pain intensity as per KOOS and VAS, are summarized in Table 1.

Efficacy results

Assessment of KOOS subscales

The changes in KOOS subscale scores from baseline to the end of treatment (day 28) are summarized in Table 2. Both Treatment A and B groups demonstrated progressive improvement in all five KOOS subscales. Notably, at Visit 3 (Day 28), the mean KOOS scores in the Treatment A group showed consistently greater numerical improvement across all subscales compared to Treatment B.

KOOS – pain

Compared to Treatment B, the Treatment A group exhibited a significant improvement in KOOS-pain scores as early as Visit 2 (Day 14) (*P = 0.011), and this improvement was sustained through Visit 3 (Day 28) (*P < 0.001). The mean change from baseline to Visit 3 was 18.52 ± 15.12 in the Treatment A group and 11.74 ± 14.64 in the Treatment B group (*P = 0.018), indicating a more pronounced reduction in pain severity in patients receiving Treatment A.

KOOS – symptoms

The mean KOOS-symptom score significantly improved in the Treatment A group from baseline to Visit 2 (*P = 0.003) and continued to improve through Visit 3 (*P < 0.001). In comparison, Treatment B also showed a statistically significant change at Visit 3 (*P = 0.018), although the magnitude of improvement was less than that seen with Treatment A (15.48 ± 13.49 vs 10.95 ± 8.71).

KOOS – activities of daily living (ADL)

Significant improvements in the KOOS-ADL scores were observed in both groups at Visit 2 (*P = 0.043 for Treatment A; *P = 0.044 for Treatment B). However, at Visit 3, the Treatment A group continued to show a higher mean change from baseline (15.39 ± 12.91) compared to Treatment B (8.10 ± 7.38), with both changes being statistically significant (*P < 0.001 and *P = 0.009, respectively).

KOOS – function in sports and recreation

While improvements in KOOS-function in sports and recreation were observed in both groups at Visit 2, the changes were not statistically significant. However, by Visit 3, both groups demonstrated significant improvement compared to baseline (Treatment A: 15.83 ± 14.44, *P = 0.005; Treatment B: 18.64 ± 5.27, *P = 0.009), with comparable levels of enhancement in sports and recreational function.

KOOS – knee-related QoL

KOOS-QoL scores remained largely unchanged at Visit 2 in both groups. However, by Visit 3, both groups exhibited statistically significant improvements from baseline (Treatment A: 17.01 ± 23.61, *P = 0.007; Treatment B: 21.63 ± 16.47, *P = 0.013), with a slightly greater numerical change observed in the Treatment B group.

Table 3: Summary of mean change in distance (meters) covered in 6 min walk test

Visits	Treatment A (n=18)	Treatment B (n=09)	P-values
Baseline/Visit 1	340.56±60.82	326.11±86.23	0.617
Visit 2	405.56±61.57	422.22±83.33	0.561
Visit 3	422.22±71.17	405.56±52.70	0.541
Change from baseline at visit 2 (P-values)	65.00±84.52 (*0.003)	96.11±100.93 (*0.029)	
Change from baseline at visit 3 (P-values)	81.67±79.87 (*<0.001)	79.44±100.20 (*0.031)	

Treatment A: Turmeric Lemonade Energy Drink. Treatment B: Placebo. Source Listing: 6 min walk test

Six (6) min' walk test

When compared to baseline, Treatment A showed a significant increase in walking distance from baseline to the end of treatment (P < 0.001). Further, Treatment B showed a significant increase in walking distance from baseline to the end of treatment (P = 0.031). Both groups improved their walking distances over 6 minutes at the end of treatment, a sign of enhanced physical capacity, with no statistically significant difference (P = 0.541) (Table 3).

Table 4: Changes in biochemical and lipid profiles following treatment

Parameters	Mean changes in lab values (X̄±SD)						Between group (Treatment A vs. Treatment B) P-values
	Treatment B (n=18)			Treatment B (n=09)			
	Baseline visit	EOT (Day 28)	Within group P-values	Baseline Visit	EOT (Day 28)	Within group P-values	
Glucose (mg/dL)	97.56±22.20	108.94±63.03	0.475	102.56±36.44	96.33±20.95	0.663	0.494
Calcium (mg/dL)	09.09±00.40	08.99±00.63	0.586	09.11±00.50	09.08±00.38	0.9	0.71
Alanine transaminase (IU/L)	21.51±14.16	22.02±12.62	0.91	18.93±11.49	24.59±14.98	0.382	0.186
Aspartate transaminase (IU/L)	30.38±07.68	28.49±14.16	0.623	32.78±12.77	29.51±11.44	0.576	0.78
Total protein (g/dL)	07.31±00.38	07.26±00.50	0.739	07.62±00.49	07.69±00.39	0.755	0.597
Albumin (g/dL)	04.25±00.45	04.16±00.47	0.546	04.32±00.45	04.28±00.36	0.82	0.756
Total bilirubin (mg/dL)	00.54±00.27	00.51±00.28	0.672	00.56±00.11	00.59±00.28	0.77	0.661
Creatinine (mg/dL)	00.76±00.21	00.77±00.18	0.867	00.82±00.18	00.82±00.17	0.926	0.963
Blood urea nitrogen (mg/dL)	09.42±02.24	08.65±02.85	0.377	09.08±01.83	09.13±02.33	0.956	0.463
Potassium (mEq/L)	04.81±00.49	04.79±00.37	0.94	04.81±00.41	04.52±00.50	0.2	0.354
Sodium (mEq/L)	138.22±02.71	137.56±03.63	0.537	139.00±02.55	138.22±02.68	0.537	0.949
Chloride (mmol/L)	102.66±02.46	103.22±02.62	0.512	103.37±02.35	102.58±03.35	0.571	0.247
Total cholesterol (mg/dL)	179.11±39.85	173.11±36.48	0.64	172.56±39.19	157.00±29.48	0.355	0.482
Triglycerides (mg/dL)	122.83±70.39	136.28±84.15	0.606	137.33±79.52	105.44±45.57	0.312	0.169
High-density lipoprotein (mg/dL)	49.18±16.54	52.31±22.38	0.637	49.76±00.40	51.39±16.57	0.832	0.872
Low-density lipoprotein (mg/dL)	105.36±34.79	93.55±33.84	0.309	95.33±37.60	84.52±25.78	0.487	0.915
Very-low-density lipoprotein (mg/dL)	24.57±14.08	27.26±16.83	0.606	27.47±15.90	21.09±09.11	0.312	0.169

Data is expressed as mean±standard deviation

Assessment of pain intensity using VAS

Both treatment groups showed a significant reduction in VAS scores from baseline by Visit 3 (Day 28) (*P < 0.01). At Visit 2 (Day 14), mean VAS scores had already decreased significantly in both the Treatment A group (from 7.06 ± 0.64 to 6.06 ± 0.42, *P < 0.001) and the Treatment B group (from 6.89 ± 0.60 to 5.78 ± 0.44, *P = 0.010). By Visit 3, further reductions were observed, with mean VAS scores reaching 5.11 ± 0.32 in the Treatment A group and 5.00 ± 0.00 in the Treatment B group (*P < 0.001 and *P = 0.007, respectively) (Fig. 2). However, the difference in pain reduction between the two groups was not statistically significant at any time point (Visit 2: P = 0.128; Visit 3: P = 0.335), suggesting comparable efficacy in reducing pain intensity.

Rescue medication usage

At Baseline and Visit 2 (Day 14), no participants in either treatment arm consumed any rescue medication. However, by Visit 3 (Day 28), both Treatment A and B groups had an identical mean consumption of 0.67 tablets per subject, with slightly higher variability observed in the Placebo group (standard deviation [SD] = 1.12) compared to the Treatment A group (SD = 0.91).

Sleep disturbances and weight-lowering effects

Sleep quality significantly improved in Treatment A (P = 0.004), while weight remained stable, unlike the Treatment B group, which showed an increase in weight at the end of the study.

Safety variable

No clinically significant abnormalities in CMP parameters were observed in either group, supporting a stable safety profile. Most values remained within normal limits at Week 4 (Day 28). Blood Urea Nitrogen had the highest frequency of non-clinically significant abnormalities, affecting 55.6% in Treatment A and 44.4% in Treatment B. No treatment-related trends were identified, confirming the IMP's overall tolerability. Between-group comparisons showed no significant differences in any parameter, confirming that the IMP had no adverse impact on metabolic measures compared to placebo. Glucose values varied at Day 28, especially in Treatment A, but without statistical significance. These findings affirm the metabolic safety of Turmeric Lemonade Energy Drink throughout the 28-day treatment period.

No statistically significant lipid changes were observed within or between groups. Treatment A showed improvements in total cholesterol and low-density lipoprotein (LDL), while Treatment B favored high-density lipoprotein (HDL) and triglycerides. Very-low-density lipoprotein remained largely unchanged. Findings confirm the metabolic safety of both interventions, with Treatment A showing no clinically meaningful impact on lipid metabolism over 28 days (Table 4).

Data regarding the consumption of concomitant medication depicted that paracetamol 500 mg was used concomitantly by 8

Table 5: Global assessment by physicians and patients after study drug treatment

Global assessment rating	Physician's global assessment		Patient's global assessment	
	Treatment A (*n*=18)	Treatment B (*n*=09)	Treatment A (*n*=18)	Treatment B (*n*=09)
	n (%)	*n* (%)	*n* (%)	*n* (%)
Good	16 (88.9)	06 (66.7)	16 (88.9)	06 (66.7)
Moderate	02 (11.1)	03 (33.3)	02 (11.1)	03 (33.3)
Poor	00 (00.0)	00 (00.0)	00 (00.0)	00 (00.0)
P-value	0.374		0.374	

study participants (44.4%) in Treatment A and 3 study participants (33.3%) in Treatment B.

The Treatment A demonstrated strong tolerability, with 88.9% of study participants and the investigator rating it as "Good" after 28 days of treatment. No participants reported poor tolerability, and the investigator and study participant assessments were consistently aligned. These findings highlight the drink's favorable acceptance and potential for further clinical exploration (Table 5).

The safety analysis confirmed that Turmeric Lemonade Energy Drink was well tolerated and comparable to a placebo, with fewer AEs and good compliance. No deaths or SAEs were reported, and vital signs remained within normal limits throughout the study. Physical examinations showed no clinically significant abnormalities. Clinical chemistry parameters, including glucose and liver enzymes, remained stable, supporting its biochemical safety.

Discussion

The findings of this study indicate that Golden Tiger Turmeric Lemonade Energy Drink significantly improved pain, symptoms, and mobility in patients with moderate knee OA. The KOOS score improvements suggest enhanced knee function, particularly at weeks 2 and 4, aligning with previous research demonstrating curcumin's efficacy in knee OA management [15]. Curcumin's bioactivated form has demonstrated significant anti-inflammatory and analgesic effects. Research indicates that turmeric supplementation effectively reduces pain and enhances physical function in OA patients, showing results comparable to NSAIDs [15]. Curcuminoids have been found to provide notable pain relief, with studies confirming substantial reductions in pain severity [33]. As for the available data sources, the therapeutic potential of curcumin may be limited due to its low oral bioavailability [24]. One of the authors, a Director of Nutrition and Board-Certified Sports Dietitian, highlights the game-changing benefits of this product for athletes, noting its particular effectiveness in reducing inflammation, improving gut health, and speeding up recovery after demanding workouts or games. The product's unique blend of ingredients could also play a role in easing soreness and aiding post-game recovery for athletes.

The Golden Tiger Turmeric Lemonade Energy Drink used as the treatment arm in the study contained 100 mg of bioactive curcumin. This inclusion of 100 mg of bioactive curcumin aligns with methodological standards discovered previously by Kurien et al. (2007), giving the study's compliance with validated formulations. This consistency may enhance reproducibility in future investigations evaluating curcumin's bioactivity [27]. The observed decrease in VAS scores in this study further supports curcumin's efficacy as a pain-relieving agent. The 6-min walk test results showed endurance improvements in both groups, with Golden Tiger Turmeric Lemonade Energy Drink consistently demonstrating greater mobility gains. Research has indicated that curcumin enhances physical function in OA patients by reducing inflammation and improving muscle performance, contributing to better mobility outcomes [11]. The sustained progress observed here aligns with previous findings, reinforcing curcumin's potential in supporting functional improvements in OA management [34].

The study confirmed no clinically significant abnormalities in CMP parameters, reinforcing the metabolic safety of Golden Tiger Turmeric Lemonade energy drink. Regarding metabolic safety, curcumin has been shown to improve glucose homeostasis, lipid profiles, and inflammatory markers, making it a promising candidate for managing chronic inflammatory metabolic diseases [35]. A systematic review confirmed curcumin's ability to reduce fasting blood glucose, total cholesterol, LDL, and triglycerides, while improving HDL levels [36]. Still, lipid changes in this study were not statistically significant. In addition, curcumin has been shown to reduce systemic inflammation and oxidative stress, further contributing to its safety profile [11]. The absence of SAEs and stable biochemical markers in this study supports Golden Tiger Turmeric Lemonade Energy Drink's tolerability, with minimal AEs and good compliance, compared to placebo in safety.

Interestingly, sleep quality improvements were observed in the Golden Tiger Turmeric Lemonade Energy Drink group, likely due to curcumin's neuroprotective and mood-enhancing effects. Research suggests that curcumin modulates neurotransmitters such as serotonin and dopamine, which play crucial roles in sleep regulation and stress response [37]. In addition, curcumin has been found to reduce neuronal loss and structural changes associated with chronic sleep deprivation, further supporting its role in improving sleep patterns [38]. These findings reinforce curcumin's potential in enhancing sleep quality and overall well-being.

Limitation of the study

Despite demonstrating promising clinical benefits, this study has several limitations. First, the sample size was small (n = 27), consistent with the pilot design, limiting statistical power. The study findings are preliminary evidence and require mechanistic long-term studies, including measures like gait analysis and muscle strength testing for confirmation in the future. As a single-centre trial from Pune, generalizability to broader OA populations is restricted. The 28-day follow-up captured short-term symptomatic changes only and cannot reflect long-term efficacy, safety, or structural effects. The 2:1 randomization, chosen to maximize safety exposure, may have widened confidence intervals. Primary outcomes relied on subjective instruments (KOOS, VAS), and the absence of biomarkers (e.g., C-reactive protein, interleukin-6, cartilage oligomeric matrix protein, C-terminal telopeptide of collagen type II) restricts mechanistic insight. Participants were aged 38–65 years, and exclusion of severe (KL-IV) OA limits application to elderly or advanced disease groups. Diet, activity, and sleep were not controlled, which could influence symptoms. The use of paracetamol as rescue medication, though low and separated from dosing, may still confound pain assessments; however, the same is true for the placebo group. The placebo beverage, while visually matched, lacked complete sensory characterization. Finally, because the investigational drink was commercially manufactured in the United States of America (and not available in the Indian market), perceived sponsorship bias cannot be fully excluded, despite strict blinding.

Conclusion

The study confirms curcumin's potential in OA management, with Golden Tiger Turmeric Lemonade Energy Drink significantly improving pain, mobility, and metabolic stability over placebo. Curcumin's anti-inflammatory action through nuclear factor-kappa B and COX-2 inhibition contributes to its analgesic effects, reducing reliance on rescue medication. Enhanced KOOS scores and 6-min walk test results highlight curcumin's role in preserving cartilage integrity, muscle endurance, and joint function, reinforcing its therapeutic benefits. The small sample size and short study duration warrant larger, long-term trials to confirm curcumin's effectiveness in managing knee OA. Overall, the Golden Tiger Turmeric Lemonade Energy Drink offers a safe, effective alternative to conventional OA treatments, paving the way for nutraceutical advancements.

Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given his consent for his images and other clinical information to be reported in the Journal. The patient understands that his name and initials will not be published, and due efforts will be made to conceal his identity, but anonymity cannot be guaranteed.

Conflict of Interest: NIL; **Source of Support:** NIL

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