

# Effects of Iyengar Yoga and Yoga Nidra on inflammation, sleep, and disability in older men with chronic low back pain

Efectos del Yoga Iyengar y Yoga Nidra sobre la inflamación, el sueño y la discapacidad en hombres mayores con dolor lumbar crónico

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#### **Abstract**

Background: Chronic low back pain (CLBP) is a widespread and debilitating condition in older adults, often involving both physical and psychological difficulties. Despite growing interest in mind-body therapies, there is limited evidence regarding the effects of structured yoga interventions specifically targeting older men with CLBP.

Objectives: This study aimed to examine the effects of a combined Iyengar yoga and Yoga Nidra program on inflammatory markers, sleep quality, and functional impairment in older male patients with CLBP.

Methodology: Fifty-five men aged 55–65 years with chronic low back pain were randomly assigned to either a 3-month combined Iyengar yoga and Yoga Nidra program (n=28) or standard care (n=27). Primary outcomes included inflammatory biomarkers (hs-CRP, IL-6, TNF- $\alpha$ ), while secondary measures assessed sleep quality, functional disability, depression, and pain catastrophizing, with assessments conducted at baseline and after 3 months by blinded evaluators.

Results: Compared to controls, the intervention group demonstrated significantly greater reductions in all three inflammatory markers (p < 0.001), along with notable improvements in sleep quality (p < 0.001), functional disability (p < 0.001), depressive symptoms (p < 0.001), and pain catastrophizing (p < 0.001). No serious adverse effects were reported.

Discussion: The integrated yoga protocol effectively improved both physiological and psychological outcomes in older men with CLBP. These results suggest strong potential for using combined Iyengar yoga and Yoga Nidra as a holistic, safe, non-pharmacological approach to chronic pain management in aging populations.

Conclusions: This intervention holds promise for improving multidimensional health outcomes in older men with CLBP.

## Keywords

Back pain; disability; inflammatory marker; relaxation; sleep quality.

#### Resumen

Introducción: El dolor lumbar crónico (DLC) es una afección común y debilitante en adultos mayores, que a menudo implica dificultades tanto físicas como psicológicas. A pesar del creciente interés en las terapias mente-cuerpo, existe evidencia limitada sobre los efectos de las intervenciones estructuradas de yoga dirigidas específicamente a hombres mayores con DLC.

Objetivos: Este estudio tuvo como objetivo examinar los efectos de un programa combinado de yoga Iyengar y Yoga Nidra sobre los marcadores inflamatorios, la calidad del sueño y la discapacidad funcional en hombres mayores con diagnóstico de DLC.

Metodología: Cincuenta y cinco hombres de entre 55 y 65 años con dolor lumbar crónico fueron asignados aleatoriamente a un programa combinado de yoga Iyengar y Yoga Nidra de 3 meses (n=28) o a un grupo de atención estándar (n=27). Los resultados primarios incluyeron biomarcadores inflamatorios (hs-CRP, IL-6, TNF- $\alpha$ ), mientras que las medidas secundarias evaluaron la calidad del sueño, la discapacidad funcional, la depresión y la catastrofización del dolor. Las evaluaciones se realizaron al inicio y después de 3 meses por evaluadores enmascarados.

Resultados: En comparación con el grupo control, el grupo de intervención mostró reducciones significativamente mayores en los tres marcadores inflamatorios (p < 0.001), junto con mejoras notables en la calidad del sueño (p < 0.001), la discapacidad funcional (p < 0.001), los síntomas depresivos (p < 0.001) y la catastrofización del dolor (p < 0.001). No se reportaron efectos adversos graves.

Discusión: El protocolo de yoga integrado mejoró eficazmente los resultados fisiológicos y psicológicos en hombres mayores con DLC. Estos resultados sugieren un gran potencial para el uso del yoga Iyengar combinado con Yoga Nidra como enfoque holístico, seguro y no farmacológico para el manejo del dolor crónico en poblaciones envejecidas.

Conclusiones: Esta intervención muestra un gran potencial para mejorar los resultados de salud multidimensionales en hombres mayores con DLC.

# Palabras clave

Calidad del sueño; discapacidad; dolor de espalda; marcadores inflamatorios; relajación.





#### Introduction

Chronic low back pain (CLBP) constitutes a substantial global health burden (Vignesh et al., 2024), with recent estimates indicating a worldwide prevalence of approximately 7.5% and significantly higher rates among older adults (Wu et al., 2020). Particularly concerning is the observed increase in CLBP prevalence among men in their sixth and seventh decades of life (Vignesh et al., 2024), with epidemiological studies suggesting that up to 40% of men aged 55-65 years' experience persistent low back symptoms (Angst et al., 2017; Mattiuzzi et al., 2020). This demographic faces unique challenges in pain management due to physiological changes associated with aging, comorbidities, and psychosocial factors that may complicate treatment (Safiri et al., 2023).

Conventional therapeutic approaches for CLBP, including pharmacological interventions, physical therapy, and surgical procedures, often provide suboptimal outcomes, with many patients reporting persistent pain and functional limitations despite treatment (Ketenci & Zure, 2021; Zhao et al., 2019). These traditional approaches frequently fail to address the multidimensional nature of chronic pain, which encompasses not only nociceptive components but also neuroinflammatory processes, sleep disturbances, psychological factors, and functional limitations that collectively contribute to pain chronicity and decreased quality of life (Urits et al., 2019).

Growing evidence suggests that chronic pain conditions, including CLBP, are associated with systemic inflammation, as indicated by elevated levels of pro-inflammatory cytokines such as interleukin-6 (IL-6), tumor necrosis factor-alpha (TNF- $\alpha$ ), and acute-phase reactants like C-reactive protein (CRP) (Van den Berg et al., 2018). These inflammatory mediators not only contribute to peripheral and central sensitization but also potentially exacerbate comorbid conditions common in older adults, such as cardiovascular disease and mood disorders, creating a complex interplay between pain, inflammation, and overall health (da Cruz Fernandes et al., 2018).

Sleep disturbances represent another critical dimension of CLBP, with approximately 50-80% of chronic pain patients reporting impaired sleep quality (Chang et al., 2022). The relationship between pain and sleep appears bidirectional, with poor sleep quality enhancing pain sensitivity and pain disrupting sleep architecture, potentially creating a self-perpetuating cycle that exacerbates both conditions (Van Looveren et al., 2021). These sleep disruptions may further contribute to systemic inflammation, potentially creating additional pathways through which sleep, pain, and inflammation interact in CLBP patients (Chang et al., 2022).

Mind-body interventions have emerged as promising complementary approaches for managing chronic pain conditions, with systematic reviews supporting moderate evidence for yoga in reducing pain intensity and improving function in CLBP patients (Lee et al., 2014; Wankhar et al., 2024). Iyengar yoga, characterized by precise anatomical alignment, detailed instructions, and the use of props, may be particularly beneficial for individuals with physical limitations or chronic conditions (Williams et al., 2005). Similarly, Yoga Nidra, a systematic meditation technique inducing deep relaxation while maintaining awareness, has demonstrated benefits for stress reduction, anxiety management, and improved sleep quality (Ragavee et al., 2024; Ravi et al., 2024; Vanitha et al., 2018).

Despite the potential of these approaches, evidence for their effects on inflammatory biomarkers, sleep quality, and functional outcomes in older men with CLBP remains limited. Existing studies have predominantly included female participants or mixed populations, creating uncertainty about effectiveness specifically for older men, who may present with different physiological, psychological, and behavioral responses to both pain and mind-body interventions.

The present study addresses these knowledge gaps by evaluating the effects of a combined Iyengar yoga and Yoga Nidra program on inflammatory markers (hs-CRP, IL-6, TNF- $\alpha$ ), sleep quality, functional disability, depression, and pain catastrophizing in men aged 55-65 years with CLBP. By examining these multidimensional outcomes, we aim to provide comprehensive evidence regarding the potential physiological and psychological mechanisms through which this integrated mind-body approach may address the complex nature of chronic pain in this specific demographic.





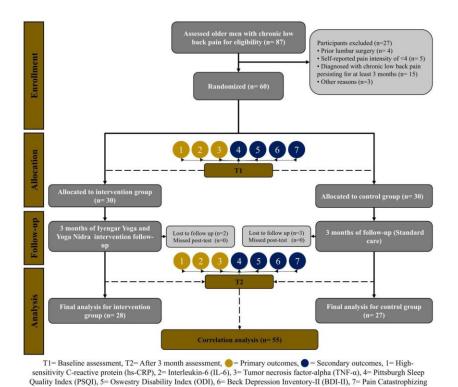
### Method

## **Participants**

We conducted a prospective, randomised, parallel-group, controlled trial with a 1:1 allocation ratio. The study adhered to the Consolidated Standards of Reporting Trials (CONSORT) guidelines. Participants were recruited from outpatient clinics and community health centers in Dhenkanal, Odisha, India. The trial was conducted at Saundarya (NGO) in Dhenkanal from January 3 to April 3, 2025.

Between January and March 2024, 87 men with chronic low back pain were assessed for eligibility, of whom 60 met inclusion criteria and were randomized to either the intervention group (n=30) or the control group (n=30). Five participants (two from the intervention group, three from the control group) withdrew from the study, resulting in 55 participants (28 intervention, 27 control) completing the 3-month protocol Figure 1.

Figure 1. Consort flow diagram



T1 demographic and clinical characteristics were similar between groups (Table 1). The mean age of participants was 59.3 years (SD 4.7) in the intervention group and 60.1 years (SD 4.3) in the control group. The mean duration of low back pain was 42.5 months (SD 28.3) in the intervention group and 45.2 months (SD 30.1) in the control group. Comorbidities were common in both groups, with hypertension being the most prevalent (53.3% in the intervention group, 56.7% in the control group).

Scale (PCS),

Table 1. Baseline characteristics of study participants

Characteristic	Intervention group (n=30)	Control group (n=30)	
Demographics			
Age (years)	59.3 (4.7)	60.1 (4.3)	
BMI (kg/m²)	27.2 (3.8)	26.8 (4.1)	
Education (years)	13.6 (3.5)	13.2 (3.7)	
Pain characteristics			
Duration of low back pain (months)	42.5 (28.3)	45.2 (30.1)	
Pain intensity (VAS 0-10)	6.8 (1.3)	6.7 (1.4)	
Inflammatory biomarkers			





3.89 (1.78)	3.92 (1.82)
4.62 (1.73)	4.58 (1.68)
7.26 (1.45)	7.31 (1.49)
11.4 (3.2)	11.2 (3.4)
44.2 (10.5)	43.8 (10.3)
19.4 (7.8)	18.9 (7.5)
26.7 (9.3)	27.1 (9.6)
24 (80.0)	25 (83·3)
18 (60.0)	19 (63.3)
16 (53.3)	17 (56.7)
8 (26.7)	7 (23.3)
5 (16.7)	6 (20.0)
	4·62 (1·73) 7·26 (1·45) 11·4 (3·2) 44·2 (10·5) 19·4 (7·8) 26·7 (9·3) 24 (80·0) 18 (60·0) 16 (53·3) 8 (26·7)

Eligible participants were men aged 55-65 years with chronic low back pain persisting for at least 3 months, self-reported pain intensity of ≥4 on a 10-point Visual Analog Scale (VAS) at baseline, and ability to attend regular intervention sessions over a 3-month period. Exclusion criteria included history of psychosis, depression, mania, or brain damage; suicidal ideation or significant aggression/violence; active clinically significant disorders requiring surgical intervention; prior lumbar surgery; presence of neurological deficit, vertebral fracture, or dislocation; presence of any tumor or varicose veins; blood clotting disorders; and current use of prolonged anticoagulant medication. Additionally, we excluded participants with acute inflammatory conditions, autoimmune disorders, current use of corticosteroids or immunosuppressants, recent (<3 months) major surgery, and diagnosed sleep disorders requiring specific medical treatment. All participants provided written informed consent before enrolment. The study protocol was approved by the Ethics Committee of Meenakshi Medical College Hospital & Research Institute (approval number: MAHER/IEC/PhD/36/Nov24).

## Randomisation and Masking

Participants were randomly assigned to either the intervention group (combined Iyengar yoga and Yoga Nidra) or the control group (standard care) using computer-generated random numbers created by an independent statistician. Allocation concealment was maintained using sequentially numbered, opaque, sealed envelopes opened only after participant enrolment. Due to the nature of the intervention, participants and yoga instructors could not be blinded; however, outcome assessors, laboratory personnel analyzing biomarkers, and data analysts were blinded to group assignment throughout the study.

# Procedure

Intervention Group Participants in the intervention group received a 3-month combined Iyengar yoga and Yoga Nidra program:

**Iyengar Yoga Component:** 

- Frequency: Three 60-minute sessions per week
- Setting: Group sessions (10-15 participants) led by certified Iyengar yoga instructors with minimum 5 years of experience teaching older adults and those with chronic pain
- Content: Structured sequences focusing on nine specific poses (Adhomukha Svanasana, Uttanasana, Viparita Dandasana, Marichyasana, Parsva Virasana, Supta Padangusthasana, Setubandha Sarvangasana, Viparita Karani, Savasana) with appropriate props (blocks, straps, bolsters)
- Progression: Poses were introduced progressively based on individual capacity, with modifications tailored to participants' limitations
- Special emphasis was placed on alignment principles to improve postural stability, enhance spinal mobility, and develop core strength without exacerbating pain

Yoga Nidra Component:

Frequency: 20-30 minutes per session, integrated with yoga practice





- Content: Standardized guided meditation protocol focusing on body awareness, breath regulation, and visualization techniques
- Specific attention was directed toward cultivating interoceptive awareness, releasing muscle tension, and developing non-reactive attention to bodily sensations
- Delivery: Audio-recorded instructions were used to ensure standardization across sessions Home Practice:
- Participants were encouraged to practice specific poses and meditation techniques at home for 15-20 minutes daily
- Illustrated handouts and audio recordings of the Yoga Nidra protocol were provided
- Adherence was tracked via home practice logs reviewed weekly by instructors Control Group Participants in the control group received standard care:
- Continuation of prescribed pharmacological pain management as directed by their healthcare providers
- Physical therapy as recommended by their healthcare providers (typically consisting of heat therapy, gentle stretching, and strengthening exercises)
- Educational materials about CLBP self-management
- No additional interventions involving yoga or meditation during the study period
- Monthly check-in calls to maintain engagement and address any questions

All participants in both groups were advised to maintain their usual activities and any ongoing treatments but to refrain from beginning new pain management therapies during the study period unless medically necessary.

#### Outcomes

All assessments were conducted at T1, and T2 (3 months) by trained assessors blinded to group assignment. Blood samples were collected in the morning (8:00-10:00 AM) after an overnight fast. Participants were instructed to avoid strenuous exercise, alcohol consumption, and anti-inflammatory medications for 24 hours before blood collection.

# **Primary Outcomes**

- 1. *Inflammatory Biomarkers*:
- High-sensitivity C-reactive protein (hs-CRP): Measured using immunoturbidimetric assay (Roche Diagnostics, normal range <3.0 mg/L)
- Interleukin-6 (IL-6): Quantified using enzyme-linked immunosorbent assay (ELISA) (R&D Systems, normal range <5.0 pg/mL)
- Tumor necrosis factor-alpha (TNF- $\alpha$ ): Measured using ELISA (R&D Systems, normal range <8.1 pg/mL)

# Secondary Outcomes

- 1. Sleep Quality: Assessed using the Pittsburgh Sleep Quality Index (PSQI), a 19-item self-report questionnaire evaluating sleep quality and disturbances over a one-month period. The PSQI yields a global score ranging from 0-21, with scores >5 indicating poor sleep quality. The instrument has demonstrated good internal consistency (Cronbach's  $\alpha$  = 0.83) and test-retest reliability (r = 0.85) in chronic pain populations (Smyth, 1999).
- 2. Functional Disability: Measured using the Oswestry Disability Index (ODI), a condition-specific, self-administered questionnaire comprising 10 sections related to various activities of daily living. Each section is scored from 0-5, with higher scores indicating greater disability. The total score is expressed as a percentage (0-100%), with 0-20% representing minimal disability, 21-40% moderate disability, 41-60% severe disability, 61-80% crippled, and 81-100% bed-bound or exaggerating symptoms. The





ODI has been extensively validated in CLBP populations with excellent psychometric properties (Cronbach's  $\alpha = 0.87$ , test-retest reliability r = 0.91) (Fairbank & Pynsent, 2000).

- 3. Depression: Evaluated using the Beck Depression Inventory-II (BDI-II), a 21-item self-report questionnaire assessing the severity of depression symptoms. Each item is scored on a scale of 0-3, with total scores ranging from 0-63. Scores of 0-13 indicate minimal depression, 14-19 mild depression, 20-28 moderate depression, and 29-63 severe depression. The BDI-II has demonstrated high internal consistency (Cronbach's  $\alpha$  = 0.92) and good test-retest reliability (r = 0.93) in older adult populations (Inventory-Ii, 2010).
- 4. Pain Catastrophizing: Assessed using the Pain Catastrophizing Scale (PCS), a 13-item self-report measure evaluating the degree to which individuals experience catastrophic thoughts and feelings when in pain. Items are rated on a 5-point scale from 0 (not at all) to 4 (all the time), with total scores ranging from 0-52. Higher scores indicate greater pain catastrophizing, with scores  $\geq$ 30 considered clinically significant. The PCS has shown good internal consistency (Cronbach's  $\alpha$  = 0.87) and test-retest reliability (r = 0.75) in chronic pain populations (Sullivan et al., 1995).

# Exploratory Outcomes:

Pain Medication Use: Self-reported frequency and dosage of analgesic medication use was recorded weekly using standardized logs.

1. Treatment Satisfaction: Assessed at study completion using a Visual Analog Scale (0-10) and a brief semi-structured interview.

#### Adverse Events

Adverse events were systematically monitored throughout the study period. Participants were instructed to report any unusual symptoms or experiences related to the intervention. Adverse events were classified as minor (resolving within 72 hours without requiring medical attention) or serious (requiring medical attention, hospitalization, or resulting in persistent disability).

# Data analysis

Sample size calculation was based on detecting a clinically significant difference in hs-CRP levels between groups. Assuming a medium effect size (Cohen's d = 0.5), 80% power, a two-sided alpha of 0.05, and an anticipated attrition rate of 15%, we calculated a required sample size of 60 participants (30 per group) using G\*Power software version 3.1. Data were analyzed using intention-to-treat principles. Missing data were handled using multiple imputation techniques. Continuous variables were presented as mean ± standard deviation (SD). Baseline comparisons between groups were performed using independent t-tests for continuous variables and chi-square tests for categorical variables. For primary and secondary outcomes, between-group differences at T1 and T2 were analyzed using analysis of covariance (ANCOVA), adjusting for baseline values. Within-group changes were assessed using paired t-tests. For inflammatory markers, log transformation was applied before analysis to address potential skewness in the distribution. The relationship between changes in inflammatory markers and changes in clinical outcomes was examined using Pearson correlation coefficients. Exploratory subgroup analyses were conducted to identify potential moderators of treatment response. P-values <0.05 were considered statistically significant. All statistical analyses were performed using SPSS software version 27.0 (IBM Corp.).

## Results

#### **Primary Outcomes**

At T2, participants in the intervention group showed significantly greater reductions in all inflammatory biomarkers compared with the control group (Table 2). High-sensitivity C-reactive protein decreased from 3.89 mg/L (SD 1.78) at T1 to 1.97 mg/L (SD 0.92) at T2 in the intervention group, compared with a change from 3.92 mg/L (SD 1.82) to 3.43 mg/L (SD 1.46) in the control group (adjusted mean difference -1.43 mg/L, 95% CI -1.98 to -0.88; p<0.001) (Figure 2).



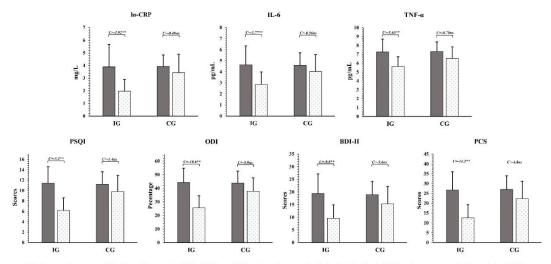


Table 2. Changes in inflammatory biomarkers and clinical outcomes from T1 to T2

Outcome measure	Intervention	Control group (n=27)	Adjusted mean difference (95% CI)	p-value
	group (n=28)			
	Inf	lammatory biomarkers		
hs-CRP (mg/L)				
T1	3.89 (1.78)	3.92 (1.82)	-1.43 (-1.98 to -0.88)	< 0.001
T2	1.97 (0.92)	3.43 (1.46)	_	
Change	-1.92 (0.98)	-0.49 (0.54)	_	
Clinically meaningful reduction*, n (%)	20 (71.4)	6 (22.2)	-	< 0.001
		IL-6 (pg/mL)		
T1	4.62 (1.73)	4.58 (1.68)	-1.21 (-1.65 to -0.77)	< 0.001
T2	2.85 (1.14)	4.02 (1.52)		
Change	-1.77 (0.87)	-0.56 (0.42)		
Clinically meaningful reduction*, n (%)	18 (64.3)	5 (18.5)	-	< 0.001
TNF-α (pg/mL)				
T1	7.26 (1.45)	7.31 (1.49)	-0.84 (-1.16 to -0.52)	< 0.001
T2	5.63 (1.08)	6.52 (1.32)		
Change	-1.63 (0.75)	-0.79 (0.48)		
Clinically meaningful reduction*, n (%)	16 (57.1)	4 (14.8)	-	< 0.001
Secondary outcomes				
	Pittsburg	gh Sleep Quality Index (0-2	1) _	
T1	11.4 (3.2)	11.2 (3.4)	-3.8 (-4.9 to -2.7)	< 0.001
T2	6.2 (2.4)	9.8 (3.1)	_	
Change	-5.2 (2.1)	-1.4 (1.2)		
Good sleep quality†, n (%)	19 (67.9)	9 (33.3)	-	0.009
	Oswe	estry Disability Index (%)		
T1	44.2 (10.5)	43.8 (10.3)	-12.7 (-16.4 to -9.0)	< 0.001
T2	25.6 (8.9)	37.9 (9.8)		
Change	-18.6 (7.2)	-5.9 (4.1)		
Clinically meaningful improvement‡, n (%)	22 (78.6)	8 (29.6)	-	< 0.001
	Beck De	pression Inventory-II (0-63		
T1	19.4 (7.8)	18.9 (7.5)	-6.2 (-8.5 to -3.9)	< 0.001
T2	9.6 (5.3)	15.3 (6.8)		
Change	-9.8 (4.5)	-3.6 (2.8)		
	Pain Ca	atastrophizing Scale (0-52)		
T1	26.7 (9.3)	27.1 (9.6)	-9.4 (-12.7 to -6.1)	< 0.001
T2	12.5 (6.8)	22.3 (8.9)		
Change	-14.2 (6.5)	-4.8 (3.2)		
	E	xploratory outcomes		
Reduced pain medication use§, n (%)	16 (57.1)	5 (18.5)	-	0.003
Treatment satisfaction (0-10)	8.2 (1.4)	5.3 (2.1)	-	< 0.001

Note: - Data are mean (SD) unless otherwise specified, \*Defined as  $\geq$ 25% decrease from baseline (T1), †Defined as PSQI score  $\leq$ 5, ‡ Defined as  $\geq$ 10 percentage point reduction, § Defined as  $\geq$ 25% decrease in weekly dosage.

Figure 2. Mean changes and significance levels of outcome measures



IG= Intervention group, CG= Control group, hs-CRP= High-sensitivity C-reactive protein, IL-6= Interleukin-6, TNF-α = Tumor necrosis factor-alpha, PSQI= Pittsburgh Sleep Quality Index, ODI= Oswestry Disability Index, BDI-II= Beck Depression Inventory-II, PCS= Pain Catastrophizing Scale, \*\*=p<0.01, C= Changes of mean differences, ■ = Baseline (T1), □ = 3 month (T2).



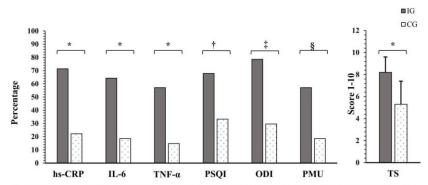


Interleukin-6 decreased from 4.62 pg/mL (SD 1.73) at T1 to 2.85 pg/mL (SD 1.14) at T2 in the intervention group, compared with a change from 4.58 pg/mL (SD 1.68) to 4.02 pg/mL (SD 1.52) in the control group (adjusted mean difference -1.21 pg/mL, 95% CI -1.65 to -0.77; p<0.001) (Figure 2).

Tumor necrosis factor-alpha decreased from 7.26 pg/mL (SD 1.45) at T1 to 5.63 pg/mL (SD 1.08) at T2 in the intervention group, compared with a change from 7.31 pg/mL (SD 1.49) to 6.52 pg/mL (SD 1.32) in the control group (adjusted mean difference -0.84 pg/mL, 95% CI -1.16 to -0.52; p<0.001) (Figure 2).

The proportion of participants achieving clinically meaningful reductions in inflammatory markers (defined as  $\geq$ 25% decrease from baseline) at T2 was significantly higher in the intervention group than in the control group for hs-CRP (20 [71·4%] vs. 6 [22·2%]; p<0·001), IL-6 (18 [64·3%] vs. 5 [18·5%]; p<0·001), and TNF- $\alpha$  (16 [57·1%] vs. 4 [14·8%]; p<0·001) (Figure 3).

Figure 3. Clinically Meaningful Improvements Reported by Participants in Both Groups Across Various Percentages and Scores from T1.



IG= Intervention group, CG= Control group, hs-CRP= High-sensitivity C-reactive protein, IL-6= Interleukin-6, TNF-α = Tumor necrosis factor-alpha, PSQI= Pittsburgh Sleep Quality Index, ODI= Oswestry Disability Index, PMU= Pain Medication Use , TS= Treatment Satisfaction, \*= $\geq$ 25% decrease from baseline (T1), \*\*=p<0.01, †= PSQI score  $\leq$ 5, ‡ =  $\geq$ 10 percentage point reduction, \$= $\geq$ 25% decrease in weekly dosage

# **Secondary Outcomes**

Sleep quality, as measured by the Pittsburgh Sleep Quality Index, improved significantly more in the intervention group than in the control group at T2 (adjusted mean difference -3·8 points, 95% CI -4·9 to -2·7; p<0·001) (Figure 2). The proportion of participants with good sleep quality (PSQI  $\leq$ 5) increased from 7 (23·3%) at T1 to 19 (67·9%) at T2 in the intervention group, compared with an increase from 6 (20·0%) to 9 (33·3%) in the control group (p=0·009) (Figure 3).

Functional disability, assessed using the Oswestry Disability Index, decreased significantly more in the intervention group than in the control group at T2 (adjusted mean difference -12·7 percentage points, 95% CI -16·4 to -9·0; p<0·001) (Figure 2). The proportion of participants achieving a clinically meaningful improvement in disability ( $\geq$ 10 percentage points) was significantly higher in the intervention group (22 [78·6%]) than in the control group (8 [29·6%]; p<0·001) (Figure 3).

Depression scores, measured by the Beck Depression Inventory-II, showed significantly greater improvement in the intervention group compared with the control group at T2 (adjusted mean difference -6·2 points, 95% CI -8·5 to -3·9; p<0·001). Similarly, pain catastrophizing, assessed using the Pain Catastrophizing Scale, decreased significantly more in the intervention group than in the control group (adjusted mean difference -9·4 points, 95% CI -12·7 to -6·1; p<0·001) (Figure 2).

# **Exploratory Outcomes**

Pain medication use decreased significantly more in the intervention group compared with the control group. By T2, 16 (57·1%) of 28 participants in the intervention group reported a reduction in analgesic use (defined as  $\geq$ 25% decrease in weekly dosage), compared with 5 (18·5%) of 27 participants in the control group (p=0·003).

Treatment satisfaction at study completion was significantly higher in the intervention group (mean 8.2, SD 1.4) than in the control group (mean 5.3, SD 2.1; p<0.001). Qualitative feedback from the semi-





structured interviews revealed themes of improved body awareness, enhanced coping strategies, and greater perceived control over pain in the intervention group (Figure 3).

# **Correlation Analysis**

Changes in inflammatory biomarkers were significantly correlated with changes in clinical outcomes (Table 3). Reductions in hs-CRP were moderately correlated with improvements in sleep quality (r = 0.41, p=0.002), functional disability (r = 0.38, p=0.004), depression (r = 0.36, p=0.007), and pain catastrophizing (r = 0.42, p=0.001). Similar correlations were observed for IL-6 and TNF- $\alpha$ .

Table 3. Correlations between changes in inflammatory biomarkers and clinical outcomes

Clinical outcome	Change in hs-CRP	Change in IL-6	Change in TNF-α
Sleep quality (PSQI)			
Correlation coefficient (r)	0.41	0.38	0.35
p-value	0.002	0.004	0.009
Functional disability (ODI)			
Correlation coefficient (r)	0.38	0.37	0.34
p-value	0.004	0.005	0.011
Depression (BDI-II)			
Correlation coefficient (r)	0.36	0.33	0.31
p-value	0.007	0.013	0.021
Pain catastrophizing (PCS)			
Correlation coefficient (r)	0.42	0.39	0.37
p-value	0.001	0.003	0.006

Note: Correlation coefficients represent Pearson's r values for the association between changes in inflammatory biomarkers and changes in clinical outcomes across the entire study sample (n=55). Positive correlation coefficients indicate that greater reductions in inflammatory markers are associated with greater improvements in clinical outcomes. PSQI = Pittsburgh Sleep Quality Index; ODI = Oswestry Disability Index; BDI-II = Beck Depression Inventory-II; PCS = Pain Catastrophizing Scale.

#### Adherence and Adverse Events

Adherence to the yoga intervention was high, with participants attending a mean of 31.4 (SD 4.8) of 36 sessions (87.2%). Home practice adherence, defined as completing at least 15 minutes of the prescribed exercises, was reported on a mean of 68.3 (SD 14.7) of 90 days (75.9%). Six minor adverse events were reported in the intervention group: muscle soreness (n=3), temporary increase in back pain (n=2), and mild dizziness during meditation (n=1), all of which resolved within 72 hours without requiring medical attention. No serious adverse events were recorded in either group.

## Discussion

In this randomized controlled trial, a 3-month program combining Iyengar yoga and Yoga Nidra significantly reduced inflammatory biomarkers, improved sleep quality, and decreased functional disability, depression, and pain catastrophizing in men aged 55-65 years with chronic low back pain compared with standard care. The magnitude of these improvements was both statistically significant and clinically meaningful.

The significant reductions in inflammatory biomarkers observed in this study provide novel evidence for potential anti-inflammatory mechanisms underlying the effects of mind-body interventions on chronic pain. The mean reduction in hs-CRP of 1.92 mg/L in the intervention group represents a 49.4% decrease from T1, exceeding the threshold for clinically meaningful change ( $\geq$ 25%) and approaching levels associated with lower cardiovascular risk (Yousuf et al., 2013). Similar substantial reductions were observed for IL-6 (38.3% decrease) and TNF- $\alpha$  (22.5% decrease), suggesting broad effects across multiple inflammatory pathways.

These findings align with emerging research on the anti-inflammatory effects of mind-body practices, although the magnitude of changes observed in our study appears larger than those reported in previous yoga interventions, which typically demonstrate reductions of 10-25% in inflammatory markers (Djalilova et al., 2019). The enhanced effect may be attributed to several factors, including the integration of Iyengar yoga's precise biomechanical approach with Yoga Nidra's stress-reduction techniques, the relatively high intervention "dose" (three 80-90 minute sessions weekly), and the





targeted focus on an older male population with established chronic pain, who may exhibit more pronounced baseline inflammatory dysregulation.

The improvements in sleep quality are particularly noteworthy given the bidirectional relationship between sleep disturbances and chronic pain. The mean reduction of 5.2 points on the PSQI in the intervention group exceeds the minimal clinically important difference of 3 points established for chronic pain populations (Longo et al., 2021) and represents a substantial improvement from T1 (PSQI 11.4) to post-intervention (PSQI 6.2), bringing many participants below the threshold for clinically significant sleep disturbance (PSQI >5).

These sleep improvements may result from multiple mechanisms, including the direct relaxation effects of Yoga Nidra, reduced pain-related sleep disruption, decreased pre-sleep rumination, and improved sleep architecture related to reduced inflammatory burden (Moszeik et al., 2022). The significant correlation between reductions in inflammatory markers and improvements in sleep quality observed in our correlation analysis supports the growing body of evidence linking inflammation and sleep disturbances, particularly in older adults with chronic pain conditions (Dzierzewski et al., 2020).

The reduction in functional disability, as measured by the Oswestry Disability Index, reflects meaningful improvements in participants' ability to perform activities of daily living. The mean reduction of 18·6 percentage points in the intervention group exceeds the established minimal clinically important difference of 10 percentage points for this instrument (de Vet et al., 2015) and represents a shift from moderate disability at T1 (ODI 44·2%) to minimal disability post-intervention (ODI 25·6%). These functional improvements likely reflect a combination of enhanced physical capacity, reduced pain-related movement limitations, and increased confidence in performing physical activities.

The significant reductions in depression and pain catastrophizing suggest that this integrated mindbody approach effectively addresses psychological dimensions of chronic pain that contribute to its maintenance and exacerbation (Padmavathi et al., 2023). The mean reduction of 9.8 points on the BDI-II in the intervention group exceeds the established minimal clinically important difference of 5 points (Hengartner & Plöderl, 2022) and represents a shift from mild depression at T1 (BDI-II 19.4) to minimal depressive symptoms post-intervention (BDI-II 9.6). Similarly, the mean reduction of 14.2 points on the Pain Catastrophizing Scale reflects a substantial decrease in maladaptive cognitive responses to pain, which may contribute to improved pain coping and reduced pain-related disability (Wheeler et al., 2019). The significant correlations observed between changes in inflammatory biomarkers and improvements in clinical outcomes suggest potential interconnected mechanisms through which this intervention may exert its effects. While correlation does not establish causation, these relationships align with growing evidence for bidirectional interactions between inflammatory processes, sleep regulation, mood, and pain perception in chronic pain conditions (Herrero Babiloni et al., 2020).

Several potential mechanisms may underlie the observed benefits of the combined Iyengar yoga and Yoga Nidra intervention. From a physiological perspective, the precise alignment focus of Iyengar yoga may optimize biomechanical function, reducing physical stress on pain-sensitive structures and enhancing proprioceptive awareness (Maheshkumar et al., 2022). The parasympathetic activation associated with Yoga Nidra may attenuate stress-induced inflammatory responses through neuroendocrine pathways, including hypothalamic-pituitary-adrenal axis regulation and sympathetic nervous system modulation (Musto & Hazard Vallerand, 2023).

From a psychological perspective, both components of the intervention may enhance pain self-efficacy, body awareness, and acceptance-based coping, which have been identified as important mediators of pain outcomes in mind-body interventions (de Jong et al., 2016). The integration of physical practice with meditative techniques may address both sensory and cognitive-affective dimensions of pain experience, providing a more comprehensive approach than interventions focusing exclusively on either physical or psychological aspects (LaRowe et al., 2023).

The high adherence rates observed in this study  $(87\cdot2\% \text{ for supervised sessions and } 75\cdot9\% \text{ for home practice})$  are noteworthy, particularly given that men typically demonstrate lower participation rates in mind-body interventions. This suggests that when appropriately structured and culturally contextualized, yoga-based interventions can achieve good engagement even in populations traditionally less represented in mind-body research.





### **Conclusions**

This study provides evidence that a combined Iyengar yoga and Yoga Nidra program effectively reduces inflammatory biomarkers, improves sleep quality, and decreases functional disability, depression, and pain catastrophizing in older men with chronic low back pain. The substantial effects observed across multiple physiological and psychological domains suggest this approach may address the complex, multidimensional nature of chronic pain more comprehensively than conventional single-modality treatments.

Future research should examine the long-term sustainability of these benefits, explore dose-response relationships, identify mediators and moderators of treatment response, compare this integrated approach with its individual components, and investigate effectiveness in more diverse populations. Additionally, implementation studies addressing barriers to adoption in clinical and community settings would facilitate broader dissemination of this promising intervention.

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