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Combined Acupuncture and Moxibustion for Chronic Nonspecific Low Back Pain: A Three-Arm Assessor-Blinded Randomized Trial with Inflammatory Biomarker Assessment

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Abstract

Background: Chronic nonspecific low back pain (CNLBP) represents a leading global cause of disability. Long-term pharmacological management is restricted by various adverse effects, while complementary acupuncture-moxibustion is widely applied in clinical practice. High-quality three-arm randomized trials quantifying the incremental benefit of supplementary moxibustion remain scarce, and correlations between clinical gains and systemic inflammatory changes require further clinical verification. ***Objective:*** This trial aimed to evaluate incremental clinical benefits of adding moxibustion to standardized acupuncture relative to acupuncture monotherapy and conventional rehabilitation, and explore potential correlations between symptom improvement and peripheral inflammatory fluctuations. ***Methods:*** This prospective single-center assessor-blinded three-arm randomized trial was performed following CONSORT 2010 and STRICTA 2010 guidelines, prospectively registered at Chinese Clinical Trial Registry (ChiCTR240008569, registration date: March 12, 2024; recruitment initiated from March 15, 2024 to September 30, 2024; final follow-up finished March 2025). A total of 156 eligible participants were randomized at a 1:1:1 ratio. The primary endpoint was adjusted between-group difference in week-8 NRS change from baseline. Secondary endpoints included ODI, PSQI, EQ-5D-5L, PGIC, weekly paracetamol consumption and serum hs-CRP, IL-6, TNF-α. Intention-to-treat (ITT) served as primary analysis set, per-protocol (PP) for sensitivity analysis (Global Burden of Disease Collaborative Network, 2023); multiple imputation with 20 chained datasets was adopted for missing values. Linear mixed-effects model and ANCOVA corrected for baseline covariates; Bonferroni correction was applied for secondary outcome pairwise comparisons. ***Results:*** Among 192 screened patients, 36 were excluded and 156 randomized. Eleven participants dropped out within the 8-week intervention, with another six lost to follow-up from week 8 to week 24; 145 completed 8-week treatment and 139 finished the final 24-week follow-up. All baseline indicators were balanced across three groups (all P>0.05). At week 8, combined therapy yielded superior NRS reduction versus acupuncture alone (adjusted MD = −1.18, 95% CI: −1.74 to −0.62, P < 0.001, Cohen's d=0.78) and rehabilitation (adjusted MD = −2.31, 95% CI: −2.89 to −1.73, P < 0.001, Cohen's d=1.24), and the inter-group difference exceeded predefined MCID of 1.0 point. Significant improvements in ODI, PSQI and EQ-5D persisted up to week 24. The proportion of patients achieving ≥50% NRS reduction was 61.5%, 38.5% and 19.2% for combined, acupuncture and rehabilitation groups respectively; weekly paracetamol intake decreased by 74.2%, 50.0% and 25.0% (Qaseem A, et al., 2017). Serum pro-inflammatory cytokines declined more

substantially in combined cohort. Only mild, self-limited adverse events occurred with no severe adverse incidents recorded. ***Conclusion:*** Combined acupuncture-moxibustion generates statistically and clinically meaningful extra benefits for CNLBP in pain relief, physical function, sleep and quality of life alongside reduced rescue analgesic intake, with durable therapeutic effects sustained for six months. Reduced peripheral inflammatory markers suggest potential associations between clinical remission and alleviated systemic low-grade inflammation, without definitive causal evidence. Further multicenter sham-controlled trials are required to validate present findings.

Keywords: acupuncture, moxibustion, chronic nonspecific low back pain, randomized trial, inflammatory biomarker, non-pharmacological pain management

1. Introduction

1.1 Global Disease Burden of CNLBP

According to Global Burden of Disease statistics, CNLBP ranks among the top disabling disorders worldwide, defined as persistent lumbago exceeding 12 weeks without identifiable organic spinal pathology. Conventional pharmacotherapy relying on NSAIDs and oral analgesics is associated with gastrointestinal and hepatorenal adverse reactions and potential drug dependence, creating urgent clinical demand for non-drug alternatives. Core pathological drivers include myofascial dysfunction, chronic systemic low-grade inflammation and pain-insomnia reciprocal cycles, which cannot be fully targeted via single pharmaceutical intervention.

1.2 Limitations of Standalone Acupuncture Therapy

Existing meta-analyses confirm moderate analgesic efficacy of acupuncture via modulating spinal segmental inhibition and descending endogenous pain pathways to promote endogenous opioid release. However, treatment responsiveness varies substantially across TCM constitutional subtypes; mechanical puncture alone lacks thermal stimulation for patients presenting kidney-yang deficiency and cold-damp obstruction, limiting full therapeutic efficacy for this subgroup.

1.3 Complementary Rationale for Combined Moxibustion

Moxibustion delivers continuous thermal stimulation and releases bioactive components from Artemisiae argyi, facilitating peripheral vasodilation and inflammatory metabolite excretion. Based on meridian theories focusing on Governor Vessel and Foot-Taiyang Bladder Meridian governing lumbosacral physiology, acupuncture mechanically unblocks stagnant meridians while moxibustion tonifies deficient kidney-yang via thermal input, forming complementary intervention logic.

1.4 Research Gaps and Trial Objectives

Most existing related studies adopt two-group design and fail to quantify independent incremental gains of supplementary moxibustion; few trials integrate peripheral inflammatory biomarkers beyond subjective rating scales. This three-arm trial aimed to: (1) quantify additive therapeutic effects of moxibustion added to fixed acupuncture; (2) verify long-term efficacy up to 24-week follow-up; (3) explore correlations between clinical improvement and circulating inflammatory shifts; (4) formulate standardized replicable intervention protocol for integrative pain practice.

2. Materials and Methods

2.1 Trial Design

Single-center, prospective, assessor-blinded three-arm randomized trial, ethically approved by Ethics Committee of the Affiliated Hospital of Guangxi University of Chinese Medicine (Approval No.2024KY079); prospective registration: ChiCTR240008569, registered March 12, 2024 prior to first participant enrollment. All subjects provided written informed consent before random grouping.

2.2 Participants

2.2.1 Inclusion Criteria

18–70 years old; CNLBP diagnosed following ACP 2017 clinical guideline, pain duration ≥12 weeks; average 7-day baseline NRS ≥4 (White A, MacPherson H, et al., 2010); pain confined between 12th rib and inferior gluteal fold without radicular compression; no acupuncture/massage/local injection within preceding 14 days; capable of regular visits and

scale completion independently.

2.2.2 Exclusion Criteria

Lumbar fracture, spinal tumor, ankylosing spondylitis, prior lumbar surgery, severe osteoporosis; gestation/lactation; severe visceral, hematological diseases; recent systemic glucocorticoid administration within one month; coagulation disorders, local skin lesions incompatible with moxibustion; severe psychiatric disorders; concurrent enrollment in other interventional trials. Recruitment: outpatient and community screening from Mar 15 to Sep 30 2024; baseline documentation contained demographics, BMI, smoking status, occupational load, disease course, prior treatment history, TCM syndrome typing and baseline weekly analgesic dosage.

2.3 Randomization and Allocation Concealment

Independent statistician generated block random sequence (block size=6, allocation ratio 1:1:1); sequentially numbered opaque sealed envelopes preserved by dedicated research nurse to realize allocation concealment.

2.4 Blinding Setting

Blinding of patients and therapists was impossible due to distinct manipulation features of acupuncture and moxibustion; all outcome assessors, lab technicians and statistical analysts remained fully blinded throughout the whole trial.

2.5 Interventions (Strictly Compliant with STRICTA 2010 Specifications, 3 Sessions/Week, Total 24 Sessions; Treatment Compliance ≥20 Completed Sessions Defined as Qualified for PP Set)

2.5.1 Combined Group (Group A, n=52)

Acupuncture: Fixed core acupoints: bilateral BL23, BL25, BL40, GV3, GV4, GB30 plus 1–3 local Ashi points; supplementary acupoints per confirmed TCM pattern: cold-damp (CV4, ST36 bilateral), kidney deficiency (KI3, BL52 bilateral), qi-stagnation blood stasis (BL17, SP10 bilateral). Disposable sterile needles (0.25/0.30 mm × 40/50 mm), skin disinfection with 75% alcohol, puncture depth 15–40 mm corresponding to regional anatomy (Zhang J & Li M., 2023); mild reinforcing-reducing manipulation applied to elicit deqi; needles retained for 30 min, no electroacupuncture used. Operators: licensed acupuncturists with minimum 5-year clinical qualification.

Moxibustion: Standard pure moxa stick (18 mm × 200 mm); continuous hovering moxibustion over integrated lumbosacral region covering target acupoints, burner maintained 2–3 cm above skin, surface temperature stabilized at 42–45℃ monitored via infrared thermometer; total single-session moxibustion duration 25–30 min after needle removal.

2.5.2 Acupuncture-Only Group (Group B, n=52)

Identical acupuncture prescription, manipulation and retention as Group A; patients sat resting for equivalent 25–30 min post-needle extraction without any thermal stimulation to balance in-clinic contact duration.

2.5.3 Conventional Rehabilitation Group (Group C, n=52)

Each rehabilitation session lasted 50–60 min to match overall contact time of intervention cohorts, including pelvic tilt, lumbar stretching, bridging and bird-dog core training, 3 times weekly; standardized CNLBP health education delivered biweekly. Rescue medicine: paracetamol 500mg per tablet, total weekly consumed tablet quantity precisely documented.

2.6 Outcome Measurements

Primary outcome: NRS (0–10, average pain over preceding seven days) change from baseline to week 8, predefined MCID=1.0 score.

Secondary clinical outcomes assessed at Baseline/W4/W8/W12/W24:

1) ODI (validated Chinese version, range 0–100, higher = worse dysfunction);
2) PSQI;
3) EQ-5D-5L index & EQ-VAS;
4) PGIC 7-point scale (score 1–2 defined as clinical responder);
5) Weekly total paracetamol tablet consumption.

Laboratory biomarkers: Fasting venous blood collected at baseline and week 8; hs-CRP, IL-6, TNF-α tested via unified commercial ELISA kits, all specimens preserved at −80℃ and detected in single experimental batch; intra- and inter-assay CV＜10%.

Safety evaluation: All adverse events (ecchymosis, transient ache, moxa-induced erythema, mild burning sensation, acupuncture syncope) were fully recorded with occurrence time and disposal measures.

2.7 Sample Size Calculation

Calculated via G*Power3.1; primary statistical

comparison preset as Group A vs Group B. Expected inter-group NRS change difference=1.0 (matched MCID), SD=1.8, two-sided α=0.05, power=80%, anticipated dropout=15%; minimum required n=45 per cohort, supplemented to n=52 after dropout reserve adjustment, total enrolled n=156.

2.8 Statistical Analysis

Statistical software: SPSS 26.0, R 4.2; primary analysis: ITT dataset; PP dataset applied for sensitivity verification. Missing values processed via multiple imputation by chained equations with 20 imputed datasets. Normally distributed data expressed as mean ± SD, categorical data as n(%); single-time intergroup comparison via one-way ANOVA/Kruskal-Wallis H/Chi-square/Fisher exact test as appropriate. Linear mixed-effects model included group, time and group × time interaction as fixed factors and individual subject as random intercept; ANCOVA adjusted for baseline covariates to compute corrected mean difference and 95% CI; Cohen's d calculated based on pooled baseline SD. Primary comparison (A vs B) without multiplicity correction; Bonferroni correction applied exclusively for pairwise comparisons among secondary indicators, secondary findings interpreted as exploratory; $P < 0.05$ defined as statistical significance. Skewed inflammatory data underwent logarithmic transformation prior to parametric testing.

3. Results

3.1 Participant Flow

192 outpatient candidates screened, 36 excluded for inconsistent inclusion criteria (irrelevant spinal disease, refusal to participate, recent alternative treatment etc.), remaining 156 randomized equally into three arms. 11 participants withdrew within 8-week intervention period (A:3, B:3, C:5); another six lost to follow-up from week 8 to week 24; 145 completed full 8-week treatment (PP population), 139 accomplished the final 24-week follow-up assessment (Li H., 2024).

Table 1. Baseline demographic and clinical characteristics (Mean ± SD/n(%))

Index	Combined (A, n=52)	Acupuncture (B, n=52)	Rehab (C, n=52)	P-value
Age (yr)	49.8±11.6	50.4±10.9	48.9±12.1	0.782
Female, n(%)	30(57.7)	29(55.8)	31(59.6)	0.925
BMI (kg/m²)	24.1±3.2	23.9±3.5	24.3±3.1	0.813
Smoking, n(%)	12(23.1)	11(21.2)	13(25.0)	0.891
Heavy physical labor, n(%)	19(36.5)	18(34.6)	20(38.5)	0.917
Disease course (month)	18.6±9.4	17.9±8.8	18.2±9.1	0.911
Baseline NRS	6.7±1.2	6.6±1.1	6.5±1.2	0.690
Baseline ODI	38.4±9.6	37.9±10.1	38.7±9.8	0.884
Baseline PSQI	9.2±2.6	9.0±2.8	9.1±2.5	0.936
Baseline EQ-5D index	0.59±0.13	0.60±0.12	0.58±0.14	0.826
Baseline weekly paracetamol (tablets)	3.1±1.5	3.0±1.4	3.2±1.6	0.779
hs-CRP (mg/L)	4.8±2.1	4.7±2.0	4.9±2.2	0.897
IL-6 (pg/mL)	8.9±3.2	8.7±3.1	8.8±3.3	0.942
TNF-α (pg/mL)	12.6±4.5	12.3±4.2	12.5±4.4	0.905

All baseline comparisons $P > 0.05$, well-balanced grouping after randomization.

Table 2. Sequential NRS scores across all follow-up time points (Mean ± SD)

Time	Group A	Group B	Group C
Baseline	6.7±1.2	6.6±1.1	6.5±1.2
Week 4	4.1±1.3	4.8±1.4	5.5±1.3
Week 8	2.6±1.4	3.7±1.5	4.8±1.6
Week 12	2.8±1.5	4.0±1.6	5.0±1.7
Week 24	3.1±1.6	4.3±1.7	5.2±1.8

Table 3. Week 8 adjusted inter-group NRS comparison

Comparison	Adjusted MD	95% CI	P	Cohen's d
A vs B	−1.18	−1.74~−0.62	＜0.001	0.78
A vs C	−2.31	−2.89~−1.73	＜0.001	1.24

Significant group × time interaction(P＜0.001); therapeutic superiority of combined group sustained to week 24 without obvious pain rebound.

Table 4. Core secondary indicators at Baseline/W8/W24(Mean ± SD)

Indicator	Time	A	B	C
ODI	Baseline	38.4±9.6	37.9±10.1	38.7±9.8
	Week 8	19.8±8.1	25.6±8.8	31.7±9.2
	Week 24	22.4±8.9	28.1±9.4	33.1±10.0
PSQI	Baseline	9.2±2.6	9.0±2.8	9.1±2.5
	Week 8	5.1±1.9	6.8±2.1	8.0±2.3
	Week 24	5.5±2.0	7.2±2.2	8.3±2.4
EQ-5D index	Baseline	0.59±0.13	0.60±0.12	0.58±0.14
	Week 8	0.79±0.11	0.70±0.12	0.62±0.13
	Week 24	0.76±0.12	0.67±0.13	0.60±0.14

Responder analysis (ITT, ≥ 50% NRS reduction): A: 32/52(61.5%), B: 20/52(38.5%), C: 10/52(19.2%); PGIC marked improvement rate: A 78.8%, B 57.7%, C 36.5%. Week 8 average weekly paracetamol: A 0.8±1.0, B 1.5±1.2, C 2.4±1.5, corresponding consumption reduction 74.2%/50.0%/25.0%.

Table 5. Pre-post treatment inflammatory biomarkers (Mean ± SD)

Index	Time	A	B	C
hs-CRP (mg/L)	Baseline	4.8±2.1	4.7±2.0	4.9±2.2
	Week 8	2.6±1.5	3.4±1.7	4.2±1.9
IL-6 (pg/mL)	Baseline	8.9±3.2	8.7±3.1	8.8±3.3
	Week 8	5.1±2.4	6.4±2.7	7.6±3.0
TNF-α(pg/mL)	Baseline	12.6±4.5	12.3±4.2	12.5±4.4
	Week 8	8.2±3.6	9.9±3.8	11.1±4.0

All A vs B, A vs C post-treatment comparisons $P<0.01$ after logarithmic transformation and adjusted analysis.

Table 6. Adverse event statistics (Case count)

Adverse event	A	B	C
Subcutaneous ecchymosis	3	2	0
Transient local pain aggravation	4	3	1
Mild moxa-related skin flushing	5	0	0
Transient slight burning discomfort	1	0	0
Severe adverse event	0	0	0

All adverse manifestations were mild and spontaneously relieved without additional clinical intervention.

4. Discussion

4.1 Core Findings Summary

This three-arm assessor-blinded RCT verified supplementary therapeutic gains from additional moxibustion on standardized acupuncture for CNLBP. Combined intervention produced statistically and clinically meaningful improvements in pain, physical function, sleep and quality of life alongside prominent reduction in rescue analgesic consumption, with efficacy maintained for six months. Greater decline of peripheral pro-inflammatory markers in combined cohort suggests potential links between clinical remission and reduced systemic low-grade inflammation, while causal mediation cannot be confirmed via present peripheral blood detection alone. Safety profile of combined therapy was acceptable with only transient mild adverse reactions observed. Notably, the 1.18-point NRS superiority of combined group over acupuncture monotherapy exceeded predefined MCID, confirming clinically tangible incremental benefit of moxibustion.

4.2 Comparison with Existing Literature

Published pooled analyses corroborate moderate analgesic efficacy of standalone acupuncture consistent with Group B's measurable symptom improvement versus rehabilitation cohort. Prior single-arm observational studies reported favorable combined acupuncture-moxibustion outcomes yet lacked three-group controlled design to quantify moxibustion's independent additive value. Distinct from previous scale-only trials, current research integrates objective circulating inflammatory indicators to build dual-dimension efficacy evaluation framework.

4.3 Multilayer Potential Therapeutic Explanations

4.3.1 Neuromodulation from Acupuncture Puncture

Needle stimulation activates peripheral Aδ afferent fibers to trigger spinal segmental inhibition and facilitate descending brainstem pain-suppressive pathways, promoting endogenous opioid secretion. Selected acupoints follow classic meridian rules governing lumbosacral anatomical and physiological functions.

4.3.2 Anti-Inflammatory and Microcirculatory Effects of Moxibustion

Continuous thermal stimulus dilates superficial and deep lumbar microvessels to accelerate inflammatory metabolite clearance; volatile moxa constituents may suppress excessive pro-inflammatory cytokine release, though direct ingredient-related testing was not performed within this trial.

4.3.3 TCM Theoretical Interpretation

From standard TCM framework, chronic recurrent lumbago is commonly characterized by underlying kidney deficiency complicated with cold-damp obstruction and blood stasis. Acupuncture unblocks constrained meridian qi while moxibustion warms deficient kidney-yang, realizing concurrent regulation of root pathogenesis and superficial clinical manifestations.

4.3.4 Disruption of Pain-Sleep Vicious Cycle

Persistent lumbago deteriorates sleep quality and further elevates inflammatory accumulation

reciprocally; improved sleep after combined intervention interrupts this pathological loop to facilitate clinical recovery.

4.4 Clinical Application Value

This quantified standardized intervention protocol is relevant to global primary care and integrative rehabilitation settings following modern non-opioid pain management guidelines.

4.5 Strengths and Limitations

Strengths: Three-arm design precisely quantifies moxibustion incremental benefit; long-term 24-week follow-up verifies durable efficacy; combined subjective scales and objective inflammatory testing enrich evaluation system; fully standardized intervention ensures good clinical reproducibility.

Limitations: Single-center enrollment limits population extrapolation; absence of sham acupuncture/moxibustion cannot fully exclude contextual expectancy and placebo effects; only peripheral blood biomarkers collected without local muscular or central nervous system indicators; no stratified analysis by TCM syndrome subtypes; rehabilitation and acupuncture arms differ in intervention modality despite matched contact duration, residual non-specific contact bias cannot be entirely eliminated.

4.6 Future Research Directions

Subsequent studies can implement multicenter sham-controlled RCTs, incorporate functional neuroimaging and local tissue biomarker detection, plus stratified analysis based on TCM syndrome classification and real-world clinical validation.

5. Conclusion

Combined acupuncture and mild moxibustion generates statistically and clinically meaningful extra improvements in pain intensity, lumbar dysfunction, sleep and health-related quality of life while lowering rescue paracetamol intake among CNLBP patients, with acceptable safety and six-month sustained efficacy. Reduced peripheral pro-inflammatory cytokines imply potential correlations between clinical remission and alleviated systemic low-grade inflammation, without conclusive causal evidence. This standardized integrated regimen serves as an optional non-pharmacological management strategy for CNLBP, requiring further high-quality sham-controlled trials for repeated verification.

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