

Auricular Therapy Versus Usual Care for Non-Specific Low Back Pain: A Randomized Controlled Trial Evaluating Pain, Disability, and Psychological Outcomes

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ABSTRACT

Background: Non-specific low back pain (NSLBP) is one of the most prevalent musculoskeletal conditions globally, affecting up to 80% of adults at some point in their lives and standing as the leading cause of disability worldwide.

Objectives: To compare the effects of auricular therapy (AT) combined with patient education versus usual care (UC) on pain intensity, physical disability, depression, anxiety, stress, and fatigue in adults with NSLBP.

Methods: A two-arm randomized controlled trial enrolled 65 adults (20–60 years) with NSLBP of at least 6 weeks' duration and NPRS scores of 4–7. The AT group (n=31) received auricular needling twice weekly for 6 weeks, alternating with auricular-pressure, plus patient education. The UC group (n=34) received moist heat therapy and a supervised core stabilization exercise program three times weekly, plus identical patient education. Outcomes included the Numerical Pain Rating Scale (NPRS), Roland Morris Disability Questionnaire – Gujarati version (RMDQ-G), Depression Anxiety Stress Scale-21 (DASS-21), and PROMIS Fatigue T-score, assessed at baseline, week 4, and week 6.

Results: Both groups achieved clinically significant improvements across all outcomes. AT demonstrated superior pain reduction from week 4 (NPRS median: AT 1 vs. UC 3; $Z=5.16$, $p<0.001$) and greater disability improvement (RMDQ-G median: AT 4 vs. UC 5 at week 6; $Z=4.53$, $p<0.001$). Depression, anxiety, stress, and fatigue improved meaningfully in both groups, with no clinically important between-group differences despite some statistically significant findings.

Conclusions: Auricular therapy provides superior pain intensity and disability outcomes compared to usual care for NSLBP, with improvements evident from week 4. Psychological and fatigue outcomes improved equivalently in both groups. These findings support AT as an adjunct treatment in the biopsychosocial management of NSLBP.

Keywords: Auricular therapy; auriculotherapy; non-specific low back pain; randomized controlled trial; NPRS; RMDQ; DASS-21; PROMIS Fatigue; pain management; complementary therapy.

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1. Introduction

Low back pain (LBP) is widely recognized as a defining global health challenge. It affects up to 80% of adults at some point in their lives, and its burden is felt across every demographic and economic group¹. The 2017 Global Burden of Disease Study reported a worldwide point prevalence of 7.5%, with approximately 540 million people experiencing activity-limiting back pain at any given time². In India specifically, the condition poses a particularly significant public health challenge given its profound impact on quality of life, productivity, and healthcare

utilization across both adult and adolescent populations³.

Approximately 90% of all LBP cases are classified as non-specific — meaning pain, muscle tension, or stiffness located between the costal margin and the inferior gluteal folds that cannot be attributed to any identifiable structural or pathological cause^{4,5,6}. Beyond simply being physically disabling, NSLBP generates ripple effects across multiple domains: reduced functional capacity, diminished quality of life, and substantial economic burden from lost productivity and healthcare costs⁶. While peak incidence occurs between ages 50 and 55, prevalence

continues to rise with advancing age up to 80, and women consistently report higher rates than men⁴. The conventional management toolkit for NSLBP — pharmacological agents such as NSAIDs and muscle relaxants, supervised exercise therapy, and patient education — remains limited in its long-term effectiveness. Current clinical guidelines acknowledge this reality by recommending a stepped-care, multimodal approach that emphasizes non-pharmacological first-line strategies^{7,8}. Yet the evidence tells a sobering story: a systematic review found that most commonly prescribed treatments, including exercise and manual therapies, deliver only modest short-to-medium-term benefits, with long-term durability remaining questionable⁹. Compounding the problem, prolonged pharmacological use carries risks of side effects including drowsiness, gastrointestinal bleeding, and opioid dependency^{10,11}.

Auricular therapy (AT), rooted in Traditional Chinese Medicine and formalized by French physician Paul Nogier in the 1950s, operates on the principle that the ear serves as a microsystem reflecting the entire body^{12,13}. Specific auricular points correspond to anatomical regions and physiological systems; stimulating these points — through needles, pressure, or embedded seeds — is believed to modulate pain pathways, activate the autonomic nervous system, promote endogenous opioid release, and reduce inflammatory signaling^{14,15,16}. Key points used for LBP include Shenmen, Nervous Subcortex, Sympathetic, Kidney, and the Lumbar and Sacral Vertebrae zones^{17,18,19,20,21}.

The emerging evidence base for AT in LBP is encouraging. A meta-analysis by Yeh et al. analysing 13 randomized controlled trials found that auricular therapy significantly reduced pain scores compared to sham or control conditions (SMD = -1.59, 95% CI [-2.36, -0.82])²². A meta-analysis examining functional outcomes using the Roland-Morris Disability Questionnaire reported a significant benefit favouring auricular therapy (mean difference: -2.77, 95% CI: -3.97 to -1.57)²³. A systematic review of auricular acupressure for chronic LBP similarly found significant and clinically meaningful pain relief²⁴.

Yet several important knowledge gaps persist: there is a scarcity of trials that comprehensively assess the psychological dimensions of NSLBP — depression, anxiety, stress, and fatigue — alongside physical outcomes. This gap matters clinically. NSLBP is not simply a pain problem; it carries a substantial psychological burden. Depression, anxiety, and chronic stress frequently accompany persistent pain, and their co-occurrence predicts worse outcomes and greater disability^{25,26}. Fatigue, too, is a common but

often overlooked companion of chronic LBP, independently predicting long-term disability even after controlling for pain severity²⁷. The biopsychosocial model of pain compels us to evaluate and address all these dimensions together²⁸.

This randomized controlled trial was therefore designed to compare the effects of a standardized auricular therapy protocol combined with patient education against a usual care program of exercise therapy, moist heat, and patient education — assessing the full biopsychosocial spectrum of outcomes in adults with NSLBP.

2. Materials and Methods

2.1 Study Design

This was a two-arm, parallel-group, open-label randomized controlled trial conducted at three outpatient physiotherapy sites: the OPD of P.P. Savani School of Physiotherapy (Extension OPD, Kosamba), the University Campus OPD, and the OPD of P.P. Savani Heart Institute and Multi-Specialty Hospital, Surat, India. Ethical approval was obtained from the Ethical Review Committee of P.P. Savani University in November 2022, and all participants provided written informed consent before enrolment. The trial was conducted in accordance with CONSORT reporting standards, and the auricular therapy intervention was documented in accordance with STRICTA (Standards for Reporting Interventions in Clinical Trials of Acupuncture) guidelines²⁹.

2.2 Participants

Sample size was calculated using G*Power software (version 3.1.9.7), assuming a large effect size of 0.80, 90% statistical power, and Type I error $\alpha = 0.05$, with a 10% dropout allowance, yielding a required total sample of 66 participants. Adults aged 20–60 years with a primary complaint of NSLBP of at least 6 weeks' duration and NPRS scores of 4–7 were eligible³⁰. All participants were diagnosed on the basis of patient history, physical examination, and review of prior medical records. Participants were required to consent to refrain from non-study pain management therapies for the duration of the study.

Exclusion criteria included: other musculoskeletal or neurological conditions; structural scoliosis, metastatic or metabolic disease, or prior spinal surgery; osteoporosis with compression fractures; congenital spinal deformity, spondylolisthesis, spinal stenosis, spondylolysis, or cauda equina syndrome; active cancer or cancer treatment within the past 6 months; active infection, wound, or external trauma to the treatment area; and pregnancy or breastfeeding. Voluntary withdrawal or the development of any intercurrent illness during the study period also constituted withdrawal criteria.

2.3 Randomization and Allocation

A total of 76 participants were screened for eligibility. Of 72 individuals randomized using simple random sampling (36 per group), 7 participants subsequently withdrew: 5 from the AT group (2 before treatment, 3 after allocation — 1 for family reasons and 2 due to work commitments) and 2 from the UC group (1 due to scheduling difficulty and 1 due to a family emergency). The final analyzed sample comprised 31 participants in the AT group and 34 in the UC group. Allocation was performed using the sealed envelope method to ensure concealment.

2.4 Interventions

Auricular Therapy Group (AT): Participants received bilateral auricular therapy twice weekly for 6 weeks, in addition to standardized patient education. Point selection was guided by a systematic review of existing auricular therapy literature and clinical trials, and the protocol was developed in accordance with STRICTA guidelines²⁹. Auricular points targeted bilaterally were: Shenmen (triangular fossa), Nervous Subcortex (back of anti-tragus), Sympathetic (inferior crus of antihelix), Kidney (cymba concha), and Lumbar and Sacral Vertebrae (on the antihelix)^{17–21,31,32}. These points were selected based on their established roles in pain modulation, stress and anxiety reduction, and LBP-specific treatment^{17,21}.

On the first session of each weekly pair (Day 1), disposable 7 mm, 25-gauge filiform needles were inserted at each point to a depth of 2–3 mm under aseptic conditions and retained for 30 minutes. On the second session (Day 4), Vaccaria seeds were applied to identical points on the contralateral ear using adhesive tape, and retained for 3 days. Participants were instructed to apply moderate thumb-forefinger pressure to the seeds three times daily (morning, noon, evening) for 3 minutes per session (9 minutes total daily). Patient education addressing pain neuroscience, correct posture, spinal alignment, and active self-management was administered throughout the intervention period^{33,34,35,36}.

Usual Care Group (UC): Participants received supervised usual care three times weekly for 6 weeks, comprising: (1) moist heat therapy using hydrocollator packs applied for 20 minutes per session; (2) a comprehensive exercise program of approximately 55–60 minutes per session; and (3) the same patient education delivered to the AT group.

The exercise program was structured as a warm-up phase (10 minutes of cat-camel poses and dynamic trunk and lower-extremity stretching), a core stabilization phase (30 minutes), and a cool-down phase (5–10 minutes). Core stabilization exercises

included the drawing-in manoeuvre, abdominal bracing, posterior pelvic tilt, supine and quadruped limb loading, the modified bicycle exercise, side planks, curl-ups and diagonal curl-ups, double knee-to-chest, pelvic lifts, bilateral leg lowering, and bilateral straight leg raises. All exercises were performed with 10 repetitions and 10-second holds. All exercise sessions were directly supervised by the researcher. Upon completion of the intervention, each participant received a home exercise program comprising the exercises from their treatment sessions^{37,38,39,40,41}.

2.5 Outcome Measures

The primary outcome was pain intensity, assessed using the 11-point Numerical Pain Rating Scale (NPRS; 0 = no pain, 10 = worst imaginable pain). The NPRS was measured at baseline and at the end of weeks 2, 4, and 6⁴². A change of at least 2 points was considered the Minimal Clinically Important Difference (MCID). Secondary outcomes included physical disability (Roland Morris Disability Questionnaire – Gujarati version, RMDQ-G; 0–24, higher = greater disability; MCID: 2–5 points)^{43,44}, psychological distress (DASS-21 – Gujarati version, assessing depression, anxiety, and stress on three 7-item subscales scored 0–21 each; MCID \approx 5 points for depression, 3–5 points for anxiety and stress)⁴⁵, and fatigue (PROMIS Fatigue Short Form 13a T-score; population mean = 50, SD = 10; MCID \geq 3 T-score points)^{46,47}. Secondary outcomes were assessed at baseline, week 4, and week 6.

2.6 Statistical Analysis

Data were screened and cleaned prior to analysis. The Shapiro-Wilk test was applied to assess the normality of data distributions, given group sizes below 50⁴⁸. As the majority of outcome variables did not follow a normal distribution, all data are presented as median and interquartile range (IQR), and non-parametric statistical tests were used throughout. Between-group comparisons at each time point were analysed using the Mann-Whitney U test (reported as Z and p-values). Within-group changes over time were analysed using the Friedman test, with Bonferroni-corrected post-hoc pairwise comparisons to identify specific intervals of significant change. Categorical demographic variables are presented as frequencies and percentages, with group comparisons performed using the chi-squared test; continuous demographic variables are presented as mean \pm SD and compared using independent samples t-tests. Statistical significance was defined as $p < 0.05$. All analyses were performed using IBM SPSS Statistics, Version 20.0 (IBM Corp., Armonk, NY).

3. Results

3.1 Participant Characteristics

The final analysis included 65 participants (AT: n=31; UC: n=34). Participant age ranged from 20 to 60 years across both groups. Mean age was virtually identical between groups (AT: 41.18 ± 9.67 years; UC: 41.36 ± 8.77 years; $t = 0.084$, $df = 68$, $p = 0.933$). The sample was predominantly female (AT: 54.8% female; UC: 64.7% female; $\chi^2 = 0.461$, $df = 1$, $p = 0.497$), consistent with the well-documented higher prevalence of LBP in women⁴⁹. Mean BMI was 24.14 ± 2.63 kg/m² in the AT group and 24.46 ± 2.42 kg/m² in the UC group, falling within the normal weight range and showing no significant between-group difference ($t = 0.533$, $df = 68$, $p = 0.596$). The two groups were therefore well-matched demographically, minimizing the risk of confounding on these variables.

One noteworthy exception was a significant baseline imbalance in the DASS-21 stress subscale (AT median 22 vs. UC median 16; $Z = 4.85$, $p < 0.001$), which is discussed in the context of between-group stress comparisons below. Demographic data are summarized in Table 1.

Table 1. Demographic Characteristics of Study Participants

Variable	AT Group (n=31)	UC Group (n=34)	Test Statistic	p-value
Age — mean (SD), years	41.18 (9.67)	41.36 (8.77)	$t = 0.084$, $df = 68$	0.933
Age — median (IQR), years	43 (33.75–48)	43 (35–46)	—	—
Sex — Male, n (%)	14 (45.2%)	12 (35.3%)	$\chi^2 = 0.461$, $df = 1$	0.497
Sex — Female, n (%)	17 (54.8%)	22 (64.7%)		
BMI — mean (SD), kg/m ²	24.14 (2.63)	24.46 (2.42)	$t = 0.533$, $df = 68$	0.596
BMI — median (IQR), kg/m ²	24.2 (21.93–25.66)	24.45 (21.95–25.62)	—	—

3.2 Primary Outcome: Pain Intensity (NPRS)

Both groups began with equivalent median NPRS scores of 6 (5–7) at baseline ($Z = 0.161$, $p = 0.872$), and improvement was comparable at week 2, with

both groups showing a median score of 4 (4–5) — a reduction already exceeding the 2-point MCID ($Z = 1.594$, $p = 0.111$). The trajectories diverged meaningfully from week 4 onward. By week 4, the AT group had achieved a median NPRS of 1 (1–2) compared to 3 (2–4) in the UC group — a significant and clinically substantial between-group difference ($Z = 5.16$, $p < 0.001$). This superiority was maintained at week 6, with median NPRS scores of 1 (0–1) versus 2 (1–3), respectively ($Z = 4.45$, $p < 0.001$).

Within-group analysis confirmed highly significant improvements over time in both groups (AT: Friedman $\chi^2 = 89.5$, $df = 3$, $p < 0.001$; UC: Friedman $\chi^2 = 96.23$, $df = 3$, $p < 0.001$). Bonferroni-corrected post-hoc pairwise comparisons revealed that significant improvement continued through week 4 in both groups; however, no additional statistically significant change was observed from week 4 to week 6 in either group, suggesting that the therapeutic plateau was reached by week 4, though AT maintained a clinically superior pain level. NPRS data are presented in Table 2.

Table 2. Between- and Within-Group NPRS Results by Time Point

Time Point	AT Median (IQR)	UC Median (IQR)	Mann-Whitney Z	p-value	Significant?
Baseline	6 (5–7)	6 (5–7)	0.161	0.872	No
Week 2	4 (4–5)	4 (4–5)	1.594	0.111	No
Week 4	1 (1–2)	3 (2–4)	5.16	< 0.001	Yes ✓
Week 6	1 (0–1)	2 (1–3)	4.45	< 0.001	Yes ✓
Within-group (Friedman χ^2)	$\chi^2 = 89.5$, $df = 3$	$\chi^2 = 96.23$, $df = 3$	—	< 0.001 (both)	Yes ✓

3.3 Secondary Outcomes

3.3.1 Physical Disability (RMDQ-G)

Both groups began with identical median RMDQ-G scores of 14 (13–15) at baseline ($Z = 1.22$, $p = 0.223$). Both demonstrated progressive and highly significant within-group improvements (AT: Friedman $\chi^2 = 62.00$, $df = 2$, $p < 0.001$; UC: Friedman $\chi^2 = 68.00$, $df = 2$, $p < 0.001$), with post-hoc pairwise comparisons confirming significant improvement at every successive interval — baseline

to week 4, week 4 to week 6, and baseline to week 6 — in both groups. The AT group, however, showed superior disability reduction from week 4 onwards: median RMDQ-G of 7 (7–8) versus 9 (8–9) at week 4 ($Z = 3.66, p < 0.001$), and 4 (3–4) versus 5 (4–6) at week 6 ($Z = 4.53, p < 0.001$). The total median reduction in RMDQ-G over 6 weeks was 10 points in the AT group and 9 points in the UC group, both substantially exceeding the established MCID of 2–5 points⁵⁰.

3.3.2 Depression (DASS-21)

At baseline, median depression scores were 12 (10–14) in both groups ($Z = 0.27, p = 0.785$). Both interventions produced significant within-group reductions (AT: $\chi^2 = 61.51, df = 2, p < 0.001$; UC: $\chi^2 = 68.00, df = 2, p < 0.001$), with post-hoc analysis confirming progressive improvement at each interval in both groups. At week 4, median scores were 8 (6–10) in AT and 8 (6–8.5) in UC, with no statistically significant between-group difference ($Z = 1.35, p = 0.176$). A statistically significant between-group difference did emerge at week 6 (AT: 4²⁻⁴ vs. UC: 2²⁻⁴; $Z = 2.15, p = 0.035$); however, this difference is not clinically meaningful, as both groups achieved median reductions of 8 and 10 points, respectively, well in excess of the established MCID of approximately 5 points⁴⁵. The practical interpretation is that both interventions produced equivalent and clinically important depression improvements over 6 weeks.

3.3.3 Anxiety (DASS-21)

Baseline anxiety scores were comparable between groups (AT: 8⁶⁻¹⁰; UC: 8 [6–10.5]; $Z = 0.52, p = 0.603$). Within-group improvements were significant in both groups over 6 weeks (AT: $\chi^2 = 59.13, df = 2, p < 0.001$; UC: $\chi^2 = 64.75, df = 2, p < 0.001$), with post-hoc analysis confirming progressive improvement at each interval. Interestingly, the between-group comparisons at both week 4 and week 6 favoured the UC group: median anxiety at week 4 was 6 (4–6) in AT versus 4 (2–4.5) in UC ($Z = 3.63, p < 0.001$), and at week 6, 2 (2–4) in AT versus 2 (0–2) in UC ($Z = 2.11, p = 0.035$). Despite statistical significance, both groups had reduced anxiety from a median of 8 to 2 — a 6-point drop that comfortably exceeds the MCID of 3–5 points — rendering the between-group differences clinically negligible. The supervised group exercise component of usual care likely contributed to more rapid anxiety reduction through its known psychosocial benefits⁵¹.

3.3.4 Stress (DASS-21)

A significant baseline imbalance was observed in the stress subscale, with the AT group reporting notably higher median stress (22¹⁸⁻²⁶) compared to the UC group (16 [15.5–20]; $Z = 4.85, p < 0.001$). This imbalance limits the interpretability of between-

group comparisons at subsequent time points. Both groups nonetheless demonstrated clinically meaningful within-group stress reductions (AT: $\chi^2 = 62.00, df = 2, p < 0.001$; UC: $\chi^2 = 68.00, df = 2, p < 0.001$), with absolute reductions of 12 and 10 points, respectively, both exceeding the established MCID of 4–5 points. The between-group differences at week 4 ($Z = 5.79, p < 0.001$) and week 6 ($Z = 5.54, p < 0.001$) largely reflect the pre-existing baseline disparity rather than differential treatment efficacy. Future trials should stratify by baseline stress scores to enable cleaner interpretation of this outcome.

3.3.5 Fatigue (PROMIS T-score)

At baseline, median PROMIS Fatigue T-scores were similar between groups (AT: 55.9 [55.3–57.8]; UC: 55.3 [54.4–56.8]; $Z = 1.48, p = 0.138$), with the majority of participants falling in the moderate-severe fatigue severity category. Both groups showed significant within-group improvement over 6 weeks (AT: $\chi^2 = 61.00, df = 2, p < 0.001$; UC: $\chi^2 = 63.84, df = 2, p < 0.001$), with every successive interval demonstrating significant change in post-hoc comparisons. Statistically significant between-group differences favoured UC at week 4 (AT: 49.3 [47.3–51] vs. UC: 47.3 [46.3–49.3]; $Z = 3.09, p = 0.002$) and AT at week 6 (AT: 38 [38–40.3] vs. UC: 40.3 [38–43.7]; $Z = 2.11, p = 0.035$), indicating equivalent overall outcomes with both groups exceeding the MCID of ≥ 3 T-score points. By week 6, all 31 AT participants (100%) had transitioned into the lowest fatigue category (no meaningful fatigue interference), compared to 31 of 34 UC participants (91.2%; Fisher's Exact $p = 0.137$). Full secondary outcome data are presented in Tables 3 and 4.

Table 3. Descriptive Statistics for Secondary Outcomes — Both Groups by Time Point

Outcome	Group	Baseline Median (IQR)	Week 4 Median (IQR)	Week 6 Median (IQR)	Within-Group Friedman χ^2
RMDQ-G (0–24)	AT	14 (13–15)	7 (7–8)	4 (3–4)	62.00*
	UC	14 (13–15)	9 (8–9)	5 (4–6)	68.00*
DASS-21 Depression	AT	12 (10–14)	8 (6–10)	4 (2–4)	61.51*
	UC	12 (10–14)	8 (6–8.5)	2 (2–4)	68.00*
DASS-	AT	8 (6–	6 (4–	2 (2–	59.13*

Auricular Therapy Versus Usual Care for Non-Specific Low Back Pain: A Randomized Controlled Trial Evaluating Pain, Disability, and Psychological Outcomes

21 Anxiety		10)	6)	4)	
	UC	8 (6–10.5)	4 (2–4.5)	2 (0–2)	64.75*
DASS-21 Stress†	AT	22 (18–26)	16 (14–20)	10 (10–14)	62.00*
	UC	16 (15.5–20)	10 (8–12)	6 (4–8)	68.00*
PROMIS Fatigue T-score	AT	55.9 (55.3–57.8)	49.3 (47.3–51)	38 (38–40.3)	61.00*
	UC	55.3 (54.4–56.8)	47.3 (46.3–49.3)	40.3 (38–43.7)	63.84*

* $p < 0.001$ (Friedman test). † Stress comparisons confounded by significant baseline imbalance (see text).

AT = Auricular Therapy; UC = Usual Care. All values expressed as median (IQR).

Table 4. Between-Group Mann-Whitney U Test Comparisons — Secondary Outcomes

Outcome	Time Point	AT Median (IQR)	UC Median (IQR)	Z (p-value)
RMDQ-G	Baseline	14 (13–15)	14 (13–15)	1.22 (0.223)
	Week 4	7 (7–8)	9 (8–9)	3.66 (<0.001)*
	Week 6	4 (3–4)	5 (4–6)	4.53 (<0.001)*
DASS-21 Depression	Baseline	12 (10–14)	12 (10–14)	0.27 (0.785)
	Week 4	8 (6–10)	8 (6–8.5)	1.35 (0.176)
	Week 6	4 (2–4)	2 (2–4)	2.15 (0.035) †
DASS-21 Anxiety	Baseline	8 (6–10)	8 (6–10.5)	0.52 (0.603)
	Week 4	6 (4–6)	4 (2–4.5)	3.63 (<0.001)*
	Week 6	2 (2–4)	2 (0–2)	2.11 (0.035) †
DASS-21 Stress‡	Baseline	22 (18–26)	16 (15.5–20)	4.85 (<0.001)*
	Week 4	16 (14–	10 (8–	5.79 (<

		20)	12)	0.001)*
	Week 6	10 (10–14)	6 (4–8)	5.54 (<0.001)*
PROMIS Fatigue T-score	Baseline	55.9 (55.3–57.8)	55.3 (54.4–56.8)	1.48 (0.138)
	Week 4	49.3 (47.3–51)	47.3 (46.3–49.3)	3.09 (0.002)*
	Week 6	38 (38–40.3)	40.3 (38–43.7)	2.11 (0.035) †

* Statistically and clinically significant ($p < 0.001$, exceeds MCID).

† Statistically significant but not clinically meaningful between groups (both groups exceed MCID from baseline).

‡ Between-group stress comparisons confounded by significant baseline imbalance. AT = Auricular Therapy; UC = Usual Care.

4. Discussion

This randomized controlled trial set out to answer a question that sits at the heart of integrative pain medicine: does a standardized auricular therapy protocol deliver meaningful benefits for people with non-specific low back pain, and if so, does it also address the psychological dimensions that so profoundly shape the lived experience of chronic pain? Our findings offer an encouraging answer — AT is superior to usual care for pain and physical disability, while both interventions equivalently address the psychological and fatigue burden of NSLBP.

4.1 Pain Intensity and Physical Disability

The most striking result of this trial is the rapidity and magnitude of pain relief in the auricular therapy group. From week 4 onward, the AT group consistently maintained median NPRS scores approximately 2 points lower than the UC group — differences that comfortably exceed the MCID and carry direct clinical relevance for patients' daily functioning⁴². This finding corroborates a growing body of evidence. Yeh et al. (2014) reported a 41% reduction in worst pain in an auricular point acupressure group, compared to just 5% in a sham condition, with concurrent RMDQ improvements of 29%⁵². A subsequent 29-day RCT by Yeh et al. (2015) demonstrated continuous pain reduction of up to 44% by the end of a 4-week auricular point acupressure program, with the trajectory of improvement beginning within the first day of treatment⁵³.

These findings are mechanistically consistent with evidence that auricular stimulation activates endogenous opioid release — with documented

increases in β -endorphin levels in cerebrospinal fluid following auricular acupuncture — and modulates the autonomic nervous system through vagal pathways^{54,55}.

Our disability findings are equally compelling. The AT group's 10-point reduction in RMDQ-G over 6 weeks — against the UC group's 9-point reduction, with between-group differences significant from week 4 — aligns precisely with prior evidence. A meta-analysis by Zhang et al. reported a mean difference of -2.77 in RMDQ scores favoring auricular therapy²³, and an RCT by Hunter et al. (2012) found that exercise combined with auricular acupuncture yielded greater disability improvements (10.7% improvement in disability scores) compared to exercise alone (6.7%)⁵⁶. The mechanistic link between pain relief and disability improvement reflects the well-established pain-avoidance cycle: as pain intensity decreases, patients are more willing and able to move, leading to progressive functional recovery⁵⁷.

4.2 Psychological Outcomes

Perhaps the most clinically nuanced aspect of our findings involves the psychological outcomes. While some statistically significant between-group differences emerged for depression, anxiety, and fatigue, a careful reading of the data reveals a picture of therapeutic equivalence rather than superiority. Both groups reduced their depression scores by clinically meaningful amounts (AT: 12 to 4; UC: 12 to 2), both reduced anxiety from a median of 8 to 2, and both transitioned the majority of participants to the lowest PROMIS fatigue category. These reductions substantially exceed established MCID thresholds in all cases^{45,46,47}.

The anxiety trajectory deserves specific attention: the UC group showed statistically faster anxiety reduction at week 4, likely reflecting the psychosocial benefits of supervised group exercise — known to reduce fear-avoidance beliefs and enhance self-efficacy through active movement⁵⁸. AT, meanwhile, is hypothesized to modulate the hypothalamic-pituitary-adrenal axis and sympathetic tone through auricular stimulation of the Shenmen and Sympathetic points^{59,60}. That both pathways converge on equivalent outcomes by week 6 suggests complementarity rather than competition between these therapeutic mechanisms. A study by Sajadi et al. (2023) similarly demonstrated that auriculotherapy effectively reduced anxiety in patients scheduled for coronary angiography, supporting the anxiolytic potential of AT in distinct clinical contexts⁶¹.

The stress data require careful interpretive caution. The significant baseline imbalance — with the AT group reporting median stress 6 points higher than

the UC group before any treatment was administered — means that post-treatment between-group comparisons for stress cannot be cleanly attributed to differential treatment effects. What we can say with confidence is that both groups achieved meaningful within-group stress reductions (AT: 12 points; UC: 10 points), both exceeding their respective MCIDs⁴⁵. Future trials should stratify randomization by baseline stress level to allow cleaner hypothesis testing on this important outcome.

The fatigue findings reinforce the equivalence narrative. The shift from predominantly moderate-severe fatigue at baseline to predominantly no meaningful fatigue interference by week 6 in both groups is a clinically meaningful finding that has often been overlooked in prior LBP trials. Fatigue is not simply a symptom — it is an independent predictor of long-term disability in LBP populations²⁷. Our findings are consistent with research by Lin et al. (2021), who demonstrated significant fatigue reduction following auricular acupressure in patients with chronic conditions, suggesting systemic effects mediated potentially through vagal stimulation pathways⁶².

4.3 Clinical and Theoretical Implications

Our results lend support to a biopsychosocial interpretation of both the problem and the solution. NSLBP is not simply a mechanical pain condition; it is embedded in a web of psychological distress, functional limitation, and fatigue that mutually reinforce one another^{28,63}. Effective treatment, our data suggest, need not be targeted exclusively at any single dimension — both AT and UC addressed all dimensions meaningfully. The advantage of AT lies in its superior and more rapid resolution of pain and disability, which is the primary complaint driving most patients to seek care. Practically speaking, the auricular therapy protocol used in this trial is simple, minimally invasive, low-cost, and well-tolerated — consistent with the established safety profile of AT⁶⁴. The twice-weekly schedule with between-session Vaccaria seed stimulation also offers a practical advantage in settings where patients cannot attend three sessions per week. No adverse events were recorded in this trial, consistent with systematic review evidence on AT safety⁶⁴. These attributes position AT as a clinically viable adjunct to standard physiotherapy care for NSLBP.

4.4 Limitations

There are some limitations which must be acknowledged. The open-label design precluded blinding of participants and therapists to their treatment allocation, introducing the potential for performance and detection bias. Additionally, while the 6-week follow-up provided valuable insights, longer-term follow-up would be beneficial to assess

the durability of treatment effects. Finally, the significant baseline imbalance in the stress subscale, despite overall demographic homogeneity, underscores the importance of stratified randomization in future trials assessing psychological outcomes.

5. Conclusion

This randomized controlled trial provides meaningful evidence that auricular therapy, when delivered twice-weekly alongside patient education, achieves superior pain reduction and disability improvement compared to a standard program of supervised exercise, moist heat, and patient education for adults with non-specific low back pain. The pain advantage of AT becomes apparent by week 4 and is maintained through week 6, with both groups exceeding the minimal clinically important difference. Psychological outcomes — depression, anxiety, stress, and fatigue — improved equivalently and meaningfully in both groups, reflecting the intrinsic therapeutic value of both interventions for the biopsychosocial dimensions of NSLBP. Auricular therapy is safe, well-tolerated, and practically implementable as an adjunct within multidisciplinary physiotherapy settings. Larger, longer-term trials with sham controls and stratified randomization are needed to confirm these findings, establish the durability of benefits, and explore the mechanisms through which auricular stimulation modulates pain and psychological well-being in this population.

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