A Prospective Randomized Controlled Study of Acupuncture to Manage Pain, Self-Rated Disability, Depression, Anxiety, Stress, and Fatigue in Patients with Non-Specific Low Back Pain: A Study Protocol

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Abstract

Background: Non-Specific Low Back Pain (NSLBP) is a widespread health concern that significantly affects quality of life and imposes considerable economic costs globally. Although numerous pharmacological and therapeutic interventions exist, treatment outcomes remain variable, and high disability rates persist. Conventional treatments often offer limited or transient relief, leading to increased interest in evidence-based complementary therapies. Acupuncture—the insertion of fine sterile needles at anatomically defined acupoints along established meridian pathways—has a growing evidence base across diverse pain conditions and has been recommended for low back pain in several international clinical guidelines. This study protocol describes a prospective randomized controlled trial designed to assess the efficacy and clinical applications of acupuncture in managing NSLBP, along with its associated Self-Rated Disability, Depression, Anxiety, Stress, and Fatigue.

Methods/design: For this prospective randomized controlled study, participants will be randomly assigned to two groups: (1) Intervention group—Acupuncture at eight standardized body acupoints (BL23, BL25, GV4, GB30, GB34, BL40, ST36, LR3) plus Patient Education; and (2) Control group—Usual Care comprising a supervised Therapeutic Exercise regimen, Moist Hot Packs, and Patient Education. Treatment effects will be measured via the Numerical Pain Rating Scale (NPRS), the Roland Morris Disability Questionnaire (RMDQ) in patients' native language, the 21-question version of the Depression Anxiety Stress Scale (DASS-21) in patients' native language, and PROMIS Fatigue Short Form 13a in patients' native language.

Discussion: This study is expected to provide robust and clinically relevant evidence on the effect of body acupuncture on the multidimensional symptom burden of Non-Specific Low Back Pain, including pain intensity, physical disability, and psychosocial outcomes. The protocol is designed to address methodological gaps in the current literature and to align with international standards for acupuncture clinical trial reporting.

Keywords: Acupuncture; body acupuncture; Non-Specific Low Back Pain; NSLBP; pain; disability; depression; anxiety; stress; fatigue; De-qi; STRICTA; randomized controlled trial; study protocol

1. Introduction

Non-specific low back pain (NSLBP) is one of the most prevalent musculoskeletal conditions worldwide, affecting 60–70% of adults in industrialized countries at some point during their lives, and up to 60–70% of the adult population in India [1,2]. It is a leading cause of disability, work absenteeism, and healthcare utilization, generating a substantial global economic burden. According to the Global Burden of Disease Study 2021, NSLBP accounts for more years lived with disability than any other musculoskeletal condition, with projections indicating continued increase to 2050 [3]. While various treatments exist, including pharmacological interventions, physical therapy, and cognitive behavioural therapy, their effectiveness is often limited, particularly in the long term, and they may carry risks of side effects or dependency [4].

Beyond pain intensity, NSLBP commonly co-occurs with significant psychological comorbidities—depression, anxiety, and perceived stress—and pronounced fatigue, all of which substantially impair daily function and quality of life [5]. These biopsychosocial dimensions are recognized as key drivers of pain chronicity and disability, yet most existing treatment protocols address them inadequately. This underscores the need for interventions that target the full multidimensional burden of NSLBP.

Acupuncture—a foundational component of Traditional Chinese Medicine (TCM) involving the insertion of fine sterile needles at specific anatomical locations called acupoints—has emerged as a clinically significant, evidence-supported non-pharmacological therapy for musculoskeletal pain [6]. Unlike auricular (ear) acupuncture, which stimulates points on the external ear as a microsystem, body acupuncture targets acupoints distributed along meridian pathways across the body, providing local, segmental, and systemic therapeutic effects [7]. The theoretical framework of acupuncture holds that stimulation of acupoints regulates the flow of qi (vital energy), activates ascending sensory afferents, modulates the autonomic nervous system, and initiates endogenous analgesic and anti-inflammatory cascades [8].

A landmark individual patient data meta-analysis by Vickers et al. (2018), pooling data from 39 high-quality RCTs involving 20,827 patients, confirmed that acupuncture is statistically and clinically superior to sham acupuncture and usual care for chronic pain conditions including low back pain, with treatment effects that persist over time and are not fully attributable to non-specific effects [9]. More recently, a comprehensive network meta-analysis by Weng et al. (2025) encompassing 63 RCTs (n = 9,454) specifically for chronic NSLBP demonstrated that individualized acupuncture and electroacupuncture combined with lumbar–pelvic training significantly reduced pain intensity compared to placebo, supporting acupuncture's role in evidence-based NSLBP management [10].

Recent systematic reviews have further demonstrated that acupuncture, both as an alternative and as an adjunct to conventional therapy, reduces pain (SMD = −0.70, 95% CI −0.94 to −0.46) and disability (SMD = −0.95, 95% CI −1.36 to −0.54) in NSLBP compared to non-pharmacological care alone [11], and produces superior outcomes to oral medications for pain reduction and functional improvement in acute and subacute NSLBP [12]. Beyond analgesia, acupuncture has demonstrated significant effects on depression, anxiety, and stress through modulation of the hypothalamic–pituitary–adrenal (HPA) axis, normalization of monoaminergic neurotransmitter systems (serotonin, noradrenaline, dopamine), and reduction of pro-inflammatory cytokines including IL-6 and TNF-α [13,14].

2. Objectives

Primary Objective:

- To evaluate the effectiveness of acupuncture in reducing pain intensity in patients with NSLBP over a 6-week intervention period, compared to a usual care programme of supervised therapeutic exercises, moist heat, and patient education.

Secondary Objectives:

- To assess the impact of acupuncture on self-rated physical disability in NSLBP patients.
- To evaluate the effect of acupuncture on depression, anxiety, and stress in NSLBP patients.
- To assess the impact of acupuncture on fatigue in NSLBP patients.
- To explore potential predictors of treatment response, including age, sex, duration of symptoms, baseline pain intensity, and baseline psychological distress.
- To evaluate the safety profile of acupuncture in this population by systematic monitoring and reporting of adverse events.

3. Study Design

This will be a prospective, randomized, single-blind clinical trial, designed in accordance with CONSORT guidelines for non-pharmacological treatments [15] and reported following the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist [16]. The acupuncture intervention is reported in accordance with the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) extension to CONSORT [17].

3.1 Study Setting

The study will be conducted at three Outpatient Physiotherapy Clinics. These sites collectively serve a socioeconomically and occupationally diverse adult population in the Surat district.

3.2 Recruitment

Potential participants will be recruited through referrals from primary care physicians and orthopaedic/neurology departments at participating hospitals, physiotherapy outpatient waitlists, and information flyers posted at clinic sites. A dedicated research coordinator at each site will conduct initial screening of potential participants for eligibility using a standardized telephone pre-screening checklist. Eligible individuals will be invited for an in-person screening visit. Multi-pronged, clinic-based recruitment has been shown to be effective in clinical trials for pain management conditions [18].

3.3 Patient Selection

3.3.1 Inclusion Criteria

Participants will be eligible to participate if they meet all of the following criteria:

- Primary complaint of Non-Specific Low Back Pain of at least 6 weeks' duration
- Both male and female, aged 20 to 60 years
- Pain score of 4–7 points on an 11-point Numeric Pain Rating Scale (NPRS) at screening
- Willingness to refrain from non-study therapies for the management of low back pain throughout study participation

- Physical diagnosis of NSLBP based on review of patient history, physical examination, and prior medical records
- Willingness and ability to provide written informed consent
- No contraindications to acupuncture needling (e.g., no bleeding disorder, no anticoagulant therapy, no needle phobia)

3.3.2 Exclusion Criteria

Participants will be excluded if they meet any of the following criteria:

- Other significant musculoskeletal or neurological conditions likely to confound outcome assessment
- Specific spinal pathology: structural scoliosis, metastatic or metabolic spinal disease, spondylolisthesis, spinal stenosis, spondylolysis, cauda equina syndrome
- Prior spinal surgery
- Osteoporosis with compression fractures
- Congenital deformity of the spine
- Active malignancy or cancer treatment within the preceding 6 months
- Active infection, open wound, dermatological condition, or external trauma at intended needling sites
- Pregnancy or breastfeeding
- Bleeding disorders or current anticoagulant/antiplatelet therapy
- Needle phobia or previously documented severe adverse reaction to acupuncture
- Concurrent participation in another clinical trial

3.4 Screening and Baseline Assessment

Initial screening will be conducted via a standardized telephone questionnaire covering eligibility criteria, medical history, and current pain characteristics. Eligible individuals will be invited for an in-person baseline assessment visit, during which they will:

a) Provide written informed consent after thorough explanation of the study purpose, procedures, risks, and benefits, and their right to withdraw at any time without consequence
b) Undergo a physical examination and clinical history review to confirm the diagnosis of NSLBP and rule out specific pathology
c) Complete all baseline assessments using validated outcome instruments (detailed in the Outcome Measures section)
d) Be assessed for acupuncture contraindications by the study acupuncturist

3.5 Randomization

Eligible participants will be randomly assigned (1:1 ratio) to either the intervention group (acupuncture plus patient education) or the control group (usual care) using a computer-generated randomization sequence. Allocation will be concealed using sequentially numbered, opaque, sealed envelopes prepared by an independent statistician not involved in participant care, recruitment, or data collection—a method shown to be effective in maintaining allocation concealment [19]. Group assignment will be revealed only at the point of first treatment.

3.6 Blinding

Due to the inherent nature of the acupuncture intervention, full blinding of participants and treating acupuncturists is not feasible; this is a recognized and accepted limitation of acupuncture RCT methodology [17]. Blinding will be achieved as follows:

- Outcome assessors will be blinded to group allocation throughout the study
- Data analysts will be blinded to group allocation during primary analysis
- Participants will be informed that two different active treatments are being evaluated and will be asked not to discuss their allocated treatment with the outcome assessor

4. Interventions

An overview of the pre-assessment, intervention, and post-assessment schedule is provided in Table 1.

Table 1. Study Assessment and Intervention Schedule

	Group A (Intervention)	Group B (Control)
Pre-Assessment	Pain, Self-Rated Disability, Depression, Anxiety, Stress, and Fatigue	Pain, Self-Rated Disability, Depression, Anxiety, Stress, and Fatigue

Intervention	Acupuncture (8 body acupoints: BL23, BL25, GV4, GB30, GB34, BL40, ST36, LR3) + Patient Education	Usual Care: Therapeutic Exercise, Moist Hot Packs (Hydrocollator), + Patient Education
Frequency & Duration	Twice weekly for 6 weeks (12 sessions total)	Three times weekly for 6 weeks (18 sessions total)
Session Length	30–40 minutes per session	55–60 minutes per session
Post-Assessment: NPRS	End of Week 2, 4, and 6	End of Week 2, 4, and 6
Post-Assessment: Disability, Depression, Anxiety, Stress, Fatigue	End of Week 4 and Week 6	End of Week 4 and Week 6

NPRS: Numeric Pain Rating Scale. All instruments are administered in participants' native (Gujarati) language.

4.1 Group A – Intervention Group: Acupuncture plus Patient Education

Participants assigned to the intervention group will receive body acupuncture twice weekly for 6 weeks (12 sessions total). Each session will last approximately 30–40 minutes. The acupuncture protocol has been developed based on a systematic review and network meta-analysis of acupoints for low back pain by Kim et al. (2023, American Journal of Chinese Medicine) [20], a network analysis of acupoint combinations for LBP by Lee et al. (2013) [21], and the Hong Kong Taskforce Clinical Practice Guideline for Acupuncture in Low Back Pain [22]. The protocol follows STRICTA reporting requirements [17].

4.1.1 Acupoint Selection Rationale

Eight principal acupoints have been selected for this protocol, chosen on the basis of the highest reported frequency of use and highest average effect sizes for low back pain in systematic reviews and network analyses [20,21]. The selected points encompass both local lumbar points and distal points along related meridian pathways, targeting both segmental spinal innervation and systemic neurobiological mechanisms:

Table 2. Acupuncture Points Selected for the Intervention Protocol

Point	Name (TCM)	Anatomical Location	TCM Function / Clinical Rationale	Type
BL23	Shenshu	1.5 cun lateral to the lower border of the L2 spinous process	Primary back-shu point of the Kidney; tonifies Kidney Qi; key point for lumbar pain and fatigue; highest frequency of use across LBP RCTs	Local
BL25	Dachangshu	1.5 cun lateral to the lower border of the L4 spinous process	Large Intestine back-shu point; relieves lumbar stiffness; among highest effect-size acupoints for LBP in network analysis	Local
GV4	Mingmen	Posterior midline, in the depression below the L2 spinous process	Gate of Life; warms Kidney Yang; relieves lumbar cold and stiffness; paired with BL23 for maximum local lumbar effect	Local

GB30	Huantiao	Junction of lateral 1/3 and medial 2/3 of line from greater trochanter to sacral hiatus	Major point for hip, gluteal, and lumbar pain; activates Qi and Blood in lumbar region; highest effect size in network analysis	Local
GB34	Yanglingquan	Anterior and inferior to the head of the fibula	Influential point for sinews and tendons; relaxes lumbar and lower limb muscles; distal point on Gallbladder meridian	Distal
BL40	Weizhong	Midpoint of the popliteal transverse crease	Command point for the back; relieves acute and chronic lumbar pain; frequently combined with BL23 in clinical practice	Distal
ST36	Zusanli	3 cun below ST35, 1 finger breadth lateral to anterior tibial crest	Tonifies overall Qi and Blood; supports immune and anti-inflammatory function; supports fatigue and psychological outcomes	Distal
LR3	Taichong	Dorsum of foot, depression proximal to 1st metatarsophalangeal joint	Soothes Liver Qi stagnation; addresses emotional tension, anxiety, stress, and irritability related to chronic pain	Distal

TCM: Traditional Chinese Medicine. LBP: Low Back Pain. BL: Bladder meridian; GV: Governing Vessel; GB: Gallbladder meridian; ST: Stomach meridian; LR: Liver meridian. Bilateral needling will be applied for all paired points (BL23, BL25, GB30, GB34, BL40, ST36, LR3); GV4 is a single midline point.

4.1.2 Needling Procedure

All acupuncture sessions will be administered by a trained physiotherapist-acupuncturist. The following standardized needling procedure will be followed in each session:

- Patient positioning: Prone for BL23, BL25, GV4, GB30; lateral or supine for GB34, BL40, ST36, LR3 as clinically appropriate
- Skin preparation: Affected areas cleaned with 70% isopropyl alcohol swabs under standard aseptic conditions
- Needle type: Single-use sterile disposable stainless steel filiform needles, 0.25 × 40 mm (standard) or 0.30 × 40 mm (adipose regions);
- Insertion depth and angle:
  - BL23, BL25: Perpendicular or obliquely toward spine, 20–30 mm depth
  - GV4: Oblique upward insertion, 15–20 mm depth
  - GB30: Perpendicular, 30–40 mm depth
  - GB34, BL40, ST36, LR3: Perpendicular, 20–25 mm depth
- De-qi elicitation: Needles will be gently rotated using lifting-thrusting and rotating manipulation techniques to achieve De-qi—the characteristic therapeutic sensation of heaviness, distension, soreness, or numbness—in all participants at each needling session [8]. De-qi has been identified as a clinically important component of acupuncture treatment effect in systematic reviews [11]
- Needle retention: 30 minutes per session
- Post-session: All needles removed under aseptic conditions; skin inspected for bleeding or haematoma; sites swabbed as needed

- One to two additional points may be selected at the treating practitioner's discretion based on presenting associated symptoms (e.g., EX-B7 Yaoyan for acute lumbar spasm; HT7 Shenmen for marked anxiety), following the flexible individualization approach recommended in clinical practice guidelines [22]

4.1.3 Patient Education

All participants in the intervention group will also receive structured patient education encompassing: pain neuroscience education (central sensitisation and the biopsychosocial model of pain); anatomy of the lumbar spine and core musculature; principles of correct spinal posture and ergonomic body mechanics; active self-management strategies including pacing and activity modification; and a written home exercise programme provided at the conclusion of the supervised treatment period.

4.2 Group B – Control Group: Usual Care

Participants assigned to the control group will receive a supervised usual care programme three times weekly for 6 weeks (18 sessions total). Each session will last 55–60 minutes and will comprise the following evidence-based structured components [23]:

4.2.1 Warm-up (10 minutes)

- Cat-camel stretches (quadruped spinal flexion-extension)
- Dynamic trunk and lower extremity stretching exercises

4.2.2 Lumbar Stabilisation Exercises (30 minutes)

The stabilisation exercise programme will progress through the following exercises; each performed for 10 repetitions with 10-second holds:

Drawing-in manoeuvre (transversus abdominis activation)	Side plank
Abdominal bracing	Curl-ups and Diagonal curl-ups
Posterior pelvic tilt	Double knee-to-chest
Limb loading in supine positions	Pelvic lifts (bridging)
Quadruped limb loading (bird-dog exercise)	Prone bridging
Modified bicycle (Extremity loading)	Bilateral straight leg raise and lowering

4.2.3 Moist Heat Therapy

Moist heat packs (hydrocollator packs) will be applied to the lumbar region for 15–20 minutes per session as part of usual care.

4.2.4 Cool-Down and Patient Education (10 minutes)

Cool-down will include arm swings, walking, and gentle stretching. The same patient education programme as delivered to the intervention group will also be administered to control group participants.

5. Outcome Measures

5.1 Primary Outcome Measure

Pain intensity will be assessed using the Numeric Pain Rating Scale (NPRS)—an 11-point scale (0 = no pain; 10 = worst imaginable pain). The NPRS has well-established reliability, validity, and responsiveness in chronic low back pain populations, with a minimal clinically important difference (MCID) of 2 points [24]. NPRS will be evaluated at baseline and at the end of week 2, week 4, and week 6.

5.2 Secondary Outcome Measures

All secondary outcomes will be evaluated at baseline, end of week 4, and end of week 6 using validated instruments in participants' native Gujarati language. Above tools will be used after taking due permissions.

(i) Self-Rated Disability: The Roland Morris Disability Questionnaire (RMDQ) will be used to measure physical disability.

(ii) Depression, Anxiety, and Stress: The DASS-21 is extensively validated for use in chronic pain populations and captures the biopsychosocial burden that is central to NSLBP chronicity [5].

(iii) Fatigue: The PROMIS Fatigue Short Form 13a in its validated Gujarati version will be used to measure fatigue level. PROMIS Fatigue is reported as a T-score calibrated to the general population mean of 50 (SD 10); higher scores indicate greater fatigue; MCID is 3 T-score points. Severity categories are: CI (none/mild: $T < 55$), CJ (moderate: $55 \leq T < 70$), and CK (severe: $T \geq 70$).

6. Follow-up

NPRS scores will be evaluated at baseline and at the end of week 2, week 4, and week 6. Self-Rated Disability (RMDQ), Depression, Anxiety, Stress (DASS-21), and Fatigue (PROMIS) will be evaluated at baseline and at the end of week 4 and

week 6. All assessments will be conducted by an outcome assessor blinded to group allocation. Participants will be asked to maintain a daily pain and medication log diary throughout the study period to improve the accuracy of pain and concomitant medication reporting [25].

7. Adherence and Retention

The following strategies will be employed to maximize adherence and minimize attrition:

- Reminder calls or text messages will be sent to each participant 24 hours before every scheduled session and outcome assessment visit, a strategy shown to improve adherence in clinical trials [26]
- Participants who miss a scheduled session will be contacted within 24 hours to reschedule
- An attendance log will be maintained for all sessions; participants attending fewer than 80% of sessions will be analysed separately in a per-protocol sensitivity analysis
- All reasons for dropout or session non-attendance will be recorded prospectively and reported in accordance with CONSORT guidelines
- Participants who withdraw will be asked (but not required) to complete the outcome assessments at the scheduled time points to facilitate intention-to-treat analysis

8. Concomitant Treatments

Participants will be permitted to continue their current medications and therapies for NSLBP but will be asked to refrain from commencing any new non-study treatments (pharmacological or non-pharmacological) during the study period. Any concomitant treatments taken during the trial will be recorded at each assessment visit using a standardized concomitant medication log and will be accounted for in statistical analyses as covariates.

9. Adverse Events

Acupuncture has an established safety record for musculoskeletal conditions. A comprehensive review of acupuncture adverse events (Huang et al., 2024) found that serious adverse events occur at a rate of approximately 0.04–0.08 per 10,000 treatments, with commonly reported minor adverse events including local bruising, haematoma, minor bleeding at needling sites, and vasovagal reactions such as dizziness or temporary light-headedness [27]. A systematic review by Chan et al. (2017) confirmed that serious complications are rare when acupuncture is administered by trained practitioners under aseptic conditions [28].

The following procedures will govern adverse event monitoring in this trial:

- Participants will be monitored for adverse events at every acupuncture session and at each outcome assessment visit, and will be actively encouraged to report any unusual symptoms between scheduled visits
- A standardized adverse event report form will record the nature, severity, onset, duration, and clinical management of any adverse event, following guidance for harms reporting in RCTs [29]
- Serious adverse events (SAEs)—defined as any event resulting in hospitalization, persistent significant disability, or that is life-threatening—will be reported to the Institutional Ethics Committee within 24 hours of the researcher's awareness
- The principal investigator and site acupuncturist will be trained in management of common acupuncture adverse events including vasovagal reactions, haematoma, and stuck needles
- Specific contraindications to needling at each session (e.g., active local infection, skin lesion, pregnancy) will be checked prospectively at every session

10. Data Collection and Management

Data will be collected using standardized, pre-piloted case report forms (CRFs) at each scheduled assessment visit and entered into a secure, password-protected electronic database by trained research coordinators within 48 hours of each visit. Range and consistency checks will be applied at data entry. A 10% sample of electronic data entries will be independently verified against source CRFs by the study coordinator to ensure accuracy. Regular data quality checks will be performed throughout the trial. Data management will follow Good Clinical Data Management Practices (GCDMP) guidelines [30]. Participant data will be coded to protect confidentiality; only the principal investigator will hold the key linking codes to participant identities. Data will be stored securely for a minimum of five years after study completion.

11. Statistical Analysis

Data will be cleaned for completeness and paucity prior to analysis. Categorical variables will be presented as frequencies and percentages; continuous variables as mean and standard deviation (for normally distributed data) or median and interquartile range (for non-normal distributions). Normality will be assessed using the Shapiro–Wilk test, appropriate for group sizes less than 50. Both parametric and non-parametric tests will be applied as appropriate.

- Within-group changes over time will be analyzed using the Friedman test (for non-parametric data) or repeated measures ANOVA (for parametric data), with post-hoc pairwise comparisons applying Bonferroni correction

- Between-group differences at each assessment point will be assessed using the Mann–Whitney U test (non-parametric) or independent samples t-test (parametric), as appropriate
- Primary analysis will follow an intention-to-treat (ITT) principle; a per-protocol sensitivity analysis will be performed for participants with ≥80% session attendance
- Missing data will be handled using multiple imputation under a missing-at-random (MAR) assumption
- Categorical outcome data (e.g., PROMIS fatigue severity category distributions) will be compared using Fisher's Exact Test
- Exploratory regression analyses will be performed to identify baseline predictors of treatment response (e.g., age, sex, symptom duration, baseline pain, baseline psychological distress)
- Statistical significance will be set at $p < 0.05$ (two-tailed). All analyses will be conducted using IBM SPSS Statistics version 26.0 (Armonk, NY, USA)

11.1 Sample Size

Sample size will be calculated using G*Power 3.1.9.7 based on the primary outcome (NPRS). Assuming a large effect size (Cohen's $d = 0.80$) based on prior acupuncture RCTs for low back pain [9,20], 90% statistical power, a two-sided alpha of 0.05, and a 10% dropout allowance, the estimated required sample size is 66 participants (33 per group). This target is consistent with published RCT protocols for acupuncture in NSLBP [6].

12. Timeline

Table 3. Projected Study Timeline

Phase	Activity
Months 1–2	Final protocol preparation, acupuncturist training and certification, IRB submission, regulatory approvals, database setup, staff training
Months 3–4	Participant recruitment, telephone screening, in-person baseline assessment and randomization
Months 4–9	Intervention period: Acupuncture sessions (Group A) and usual care sessions (Group B)
Months 5–8	End-of-treatment outcome assessments (Week 4 and Week 6 evaluations)
Months 8–10	Follow-up assessments (3-month and 6-month post-intervention); adverse event monitoring
Months 10-12	Data cleaning, statistical analysis, interpretation, dissemination, manuscript preparation and submission

Discussion

The protocol is distinguished by its broad outcome assessment—encompassing pain, physical disability, depression, anxiety, stress, and fatigue—in a single, rigorously designed RCT, addressing a meaningful gap in the existing acupuncture literature where most trials have evaluated pain as the sole primary outcome.

The landmark IPD meta-analysis by Vickers et al. (2018) confirmed clinically meaningful treatment effects for body acupuncture in chronic musculoskeletal pain [9], while a 2025 network meta-analysis (n = 9,454) identified individualized body acupuncture as producing the most significant pain reduction among all acupuncture modalities for chronic NSLBP [10]. Body acupuncture acts on multiple levels of the nervous system simultaneously: peripheral A-delta and C afferents initiate opioidergic analgesia; ascending sensory pathways and the periaqueductal grey coordinate descending serotonergic and noradrenergic inhibition; and supraspinal limbic, hypothalamic, and prefrontal cortex circuits are modulated to address the affective-motivational dimension of pain [8]. These multilevel neurobiological effects explain why body acupuncture may be particularly well-suited to the multidimensional symptom burden of NSLBP.

The acupoint protocol developed for this trial is evidence-based and clinically grounded. The eight selected points—BL23, BL25, GV4, GB30, GB34, BL40, ST36, and LR3—represent the highest-frequency and highest-effect-size acupoints across published LBP RCTs and network analyses [20,21], combining local lumbar points targeting the segmental innervation of the lumbar spine with distal points on Bladder, Gallbladder, Stomach, and Liver meridians that provide

systemic neurobiological effects. The inclusion of ST36 and LR3 is specifically motivated by their demonstrated relevance to psychological and fatigue outcomes: ST36 has immunomodulatory and anti-inflammatory properties relevant to fatigue in chronic conditions [13], while LR3 is a principal point for Liver Qi stagnation—the TCM correlate of emotional dysregulation, anxiety, and stress [27]. The flexible provision for one to two additional symptom-guided points preserves clinical authenticity without compromising protocol standardization.

The requirement for De-qi elicitation at each session reflects current evidence that De-qi is associated with greater therapeutic effect in manual acupuncture for pain conditions [11]. The twice-weekly frequency is designed to maintain therapeutic momentum while remaining feasible for working-age participants—consistent with schedules used in RCTs reporting significant outcomes [10,12]. The STRICTA-compliant reporting of all needling parameters ensures transparency and reproducibility [17].

The selection of validated outcome instruments—NPRS, RMDQ-G, DASS-21, and PROMIS Fatigue 13a—in participants' native language addresses the measurement requirements of a biopsychosocial outcome framework. PROMIS instruments, developed using item response theory and calibrated to population norms, provide superior measurement precision compared to older condition-specific fatigue scales and have been recommended for clinical trial use by the US National Institutes of Health. The DASS-21 captures the three key psychological comorbidities of chronic pain within a single instrument with well-established factorial validity. The use of Gujarati-language validated versions of all instruments ensures cultural and linguistic appropriateness for our study population.

A key strength of this protocol is its comprehensive adverse event monitoring framework, which follows international harms-reporting guidelines [29]. As documented in a comprehensive review by Huang et al. (2024), serious adverse events attributable to acupuncture are rare (approximately 0.04–0.08 per 10,000 treatments) when conducted by trained practitioners under aseptic conditions, and the most commonly reported events are minor (bruising, localized soreness, vasovagal reactions) [27].

Acknowledged limitations of this protocol include the absence of a sham acupuncture control arm, which would be necessary to distinguish specific needling effects from non-specific therapeutic effects including expectation and therapeutic alliance. This is a deliberate decision given the resource constraints of the current trial; however, future definitive trials should incorporate a credible sham control (e.g., Streitberger placebo needle or superficial needling at non-acupoints) to address this question. Additionally, the 6-week intervention period does not permit evaluation of long-term durability of effects, and future work should include follow-up assessments at 3 and 6 months post-treatment. The open-label design introduces potential performance bias, which is inherent to all acupuncture clinical trials and mitigated in this protocol by blinding of outcome assessors and data analysts.

This study will provide clinically relevant evidence for acupuncture as a safe, multidimensional, non-pharmacological intervention for NSLBP in an Indian outpatient physiotherapy setting. If the anticipated treatment effects are confirmed, findings will support integration of acupuncture into clinical pathways for NSLBP management in India and similar healthcare contexts, contribute to the global evidence base, and inform future large-scale confirmatory trials with longer follow-up and sham controls.

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