

The Clinical Efficacy and Safety of Electroacupuncture (EA) in Perioperative Rehabilitation of Rotator Cuff Repair Surgery: A Protocol for a Single-Centre, Randomized Controlled Trial

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Purpose: Pain is one of the main complications after rotator cuff repair. If acute postoperative pain is not effectively controlled, it may lead to chronic persistent pain after surgery. Electroacupuncture (EA) is an effective tool for pain control. However, EA specifically for alleviating postoperative pain after rotator cuff repair has not been studied in randomized controlled trials (RCTs). This pilot study aims to design a RCT to assess the efficacy and safety of EA as an adjunctive therapy during the perioperative period of rotator cuff repair.

Patients and Methods: This single-center, subject-and-assessor-blinded, randomized, sham-controlled trial will enroll 112 participants diagnosed with rotator cuff tears and who are scheduled to undergo unilateral arthroscopic rotator cuff repair (ARCR). Participants will be allocated at a 1:1 ratio to receive either EA or sham electroacupuncture (SEA) (using blunt-tip needles and no electrical current). Treatments will be administered 2 hours before surgery, 2 hours after surgery and once daily for the following surgery for 2 days (4 treatment sessions in total), and then be followed up for another 1 week. The primary outcome is the changes in visual analogue scale (VAS) scores for resting pain in the affected shoulder. The secondary outcome measures include VAS scores for pain during movement of the affected shoulder, limb swelling scores, dosage of postoperative analgesic drugs, frequency of postoperative nausea and vomiting, heart rate and blood pressure after the operation, sleep quality during the hospital stay.

Conclusion: This pilot study will discuss whether EA is a valuable adjunct in postoperative care at relieving pain and improving patients' quality of life. This RCT will inform the design of a further full-scale trial.

Trial Registration: Chinese Clinical Trials Registry, ChiCTR2500103323. Registered on 28 May 2025.

Keywords: electroacupuncture, postoperative pain, rotator cuff repair surgery, randomized controlled trial

Introduction

Rotator cuff injuries are common rotator cuff tendon disorders and a leading cause of shoulder pain and dysfunction with prevalence increasing with age.^{1,2} These injuries, often caused by trauma, sports-related injuries or degeneration, can progress to rotator cuff tears.³ In China, the incidence has risen with population aging and national fitness initiatives, reaching up to 20%.² Untreated injuries may lead to cartilage damage, glenohumeral osteoarthritis, and a heavy healthcare burden.⁴

Arthroscopic rotator cuff repair (ARCR) is now the gold standard for symptomatic rotator cuff tears, offering faster recovery and lower infection risk, with utilization rising more than 600% in recent years.⁵⁻⁷ However, postoperative complications remain frequent, including pain, stiffness, and muscle atrophy, which may progress to adhesive capsulitis

and impair the tendon-to-bone healing.^{5,8} Pain is particularly prominent.⁹ Poorly control of acute postoperative pain not only disrupts sleep but also contributes to psychological distress, which in turn exacerbates pain and dysfunction, further increasing the risk of adhesive capsulitis.^{10,11} Effective pain management is therefore essential for recovery and long-term outcomes.^{12,13}

Multimodal analgesic is widely advocated for ARCR, mainly involving pharmacological agents such as paracetamol, cyclooxygenase-2 inhibitors, gabapentin, and intravenous dexamethasone, etc.^{9,14} Yet many patients continue to experience moderate-to-severe pain, with stiffness rates up to 32.7%.¹⁵ Drug therapies may also cause adverse effects and increase psychological stress. Integrating non-pharmacological therapies into multimodal strategies is therefore important. Evidence supports that exercise, manual therapy, and electrotherapy benefit patients with rotator cuff disorders.¹⁶

Acupuncture, a traditional non-pharmacological therapy rooted in Traditional Chinese Medicine (TCM), recognized for safety and minimal side effects, is strongly recommended in the “Guidelines for Integrated Traditional Chinese and Western Medicine Diagnosis and Treatment of Rotator Cuff Injuries (2023 Edition)”.¹⁷ Acupuncture has been shown to inhibit pain transmission at peripheral, spinal, and central levels.^{18,19} Electroacupuncture (EA), combining traditional acupuncture with electrical stimulation, has demonstrated superior efficacy compared to manual acupuncture in relieving shoulder pain and restoring joint function.²⁰ Randomized controlled trial (RCT) evidence supports the role of EA in musculoskeletal rehabilitation, showing reduced pain, lower opioid use, and improved joint function.^{21–23} In perioperative care, EA has also reduced pain and anesthesia requirements in spinal and neurological surgeries.²⁴ However, during the perioperative period of ARCR, multimodal analgesia remains predominantly drug-based and do not integrate TCM-based non-pharmacological modalities. Consequently, there is a pressing need for clinical studies to evaluate the efficacy and safety of EA for managing acute postoperative pain following rotator cuff repair.

This placebo-controlled trial aims to evaluate the superiority of EA over sham EA (SEA) in managing acute pain and other postoperative symptoms after rotator cuff repair. The study seeks to provide high-quality evidence supporting EA in perioperative pain management and promote broader integration of TCM into multimodal analgesia. As a protocol paper, it also enhances methodological transparency and helps prevent unnecessary duplication.

Methods and Design

Study Design

This study is a single-center, randomized, patient- and assessor-blinded, placebo-controlled trial. Patients diagnosed with rotator cuff tears who are scheduled to undergo ARCR at the Sports Medicine Department of Shanghai Sixth People’s Hospital will be recruited. A total of 112 eligible participants will be randomly assigned in a 1:1 allocation ratio to either the treatment group (receiving EA combined with postoperative basic therapy) or the control group (receiving sham EA combined with postoperative basic therapy). Participants will receive a total of 4 sessions of EA or SEA, administered at the following time points: 2 hours before surgery, 2 hours after surgery, 24 hours after surgery, and 48 hours after surgery. A follow-up period of one week will be conducted postoperatively to assess outcomes. This trial will adhere to the Consolidated Standards of Reporting Trials (CONSORT) guidelines²⁵ and fulfil the requirements outlined in the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist (see [Supplementary Table S1](#)).²⁶ A detailed flowchart of the trial process is shown in [Figure 1](#).

Recruitment and Ethic

This trial protocol was approved by the Ethics Committee of Shanghai Sixth People’s Hospital on 18 May 2025 (Approval No. 2025–060) and has been registered in the Chinese Clinical Trial Registry (Registration No. ChiCTR2500103323). All participants will receive a detailed explanation of the study procedures and objectives, and written informed consent will be obtained prior to enrollment. The trial will be conducted in strict accordance with the Helsinki Declaration. The study schedule is illustrated in [Table 1](#).

Participants

Eligible patients must meet the diagnostic criteria for rotator cuff injuries as outlined in the “American Academy of Orthopaedic Surgeons (AAOS): Management of Rotator Cuff Injuries Clinical Practice Guideline”²⁷ and have confirmed

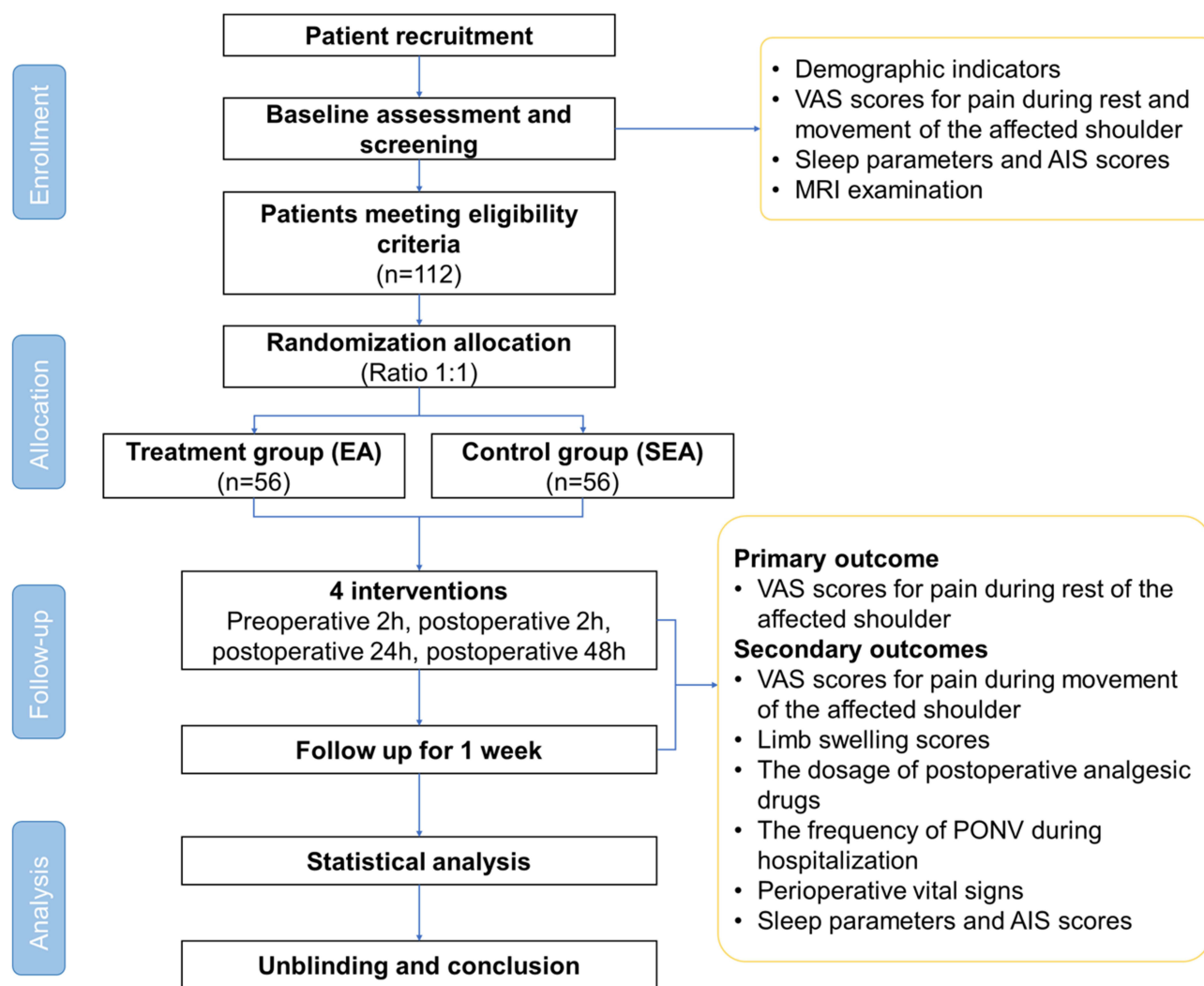


Figure 1 Flowchart for this study.

Abbreviations: AIS, Athens Insomnia Scale; EA, electroacupuncture; SEA, sham electroacupuncture; MRI, magnetic resonance imaging; PONV, postoperative nausea and vomiting; VAS, Visual Analogue Scale.

rotator cuff tears identified via magnetic resonance imaging (MRI) prior to surgery. The rotator cuff tear should be classified as a full-thickness tear less than 5-cm in size, according to the Ellman classification.²⁸ In addition, patients should be between 40 and 70 years of aged, with no restriction on gender, and must be scheduled to undergo unilateral ARCR at Shanghai Sixth People's Hospital. Since ARCR is usually performed in conjunction with other procedures such as subacromial decompression or distal clavicle resection, these surgeries are permitted to enhance generalizability of the study. Participants must voluntarily agree to join the study, be willing to undergo all required examinations and treatments, and be able to cooperate with follow-up. Recruitment is scheduled to begin in June 2025 and is expected to conclude in December 2026.

Exclusion criteria include: shoulder pain or movement limitation due to cervical disc herniation, shoulder tumors, dislocation, fractures, stroke-induced hemiplegia, etc; concurrent surgeries in other anatomical regions; severe comorbidities involving the heart, liver, kidney, hematopoietic system, endocrine system, immune system, nervous system, malignancies and psychiatric disorders; history of alcohol or anesthetic drug abuse, or preoperative opioid use for pain management; known allergy to nonsteroidal anti-inflammatory drugs (NSAIDs); acupuncture treatment received within the past 6 months; allergies to acupuncture needles, with localized skin ulcer infections, needle-phobia, or with blood disorders (such as coagulation disorders, bleeding disorders, etc).

Table 1 Schedule of Enrollment, Intervention and Assessments

	Study Period										
	Enrollment/ Allocation	Preoperation	Operation	Postoperation						Discharge Day	Follow-Up
		Treatment Phase									
Timepoints	Day -1	Day 0 (Within 2h)	Operation	Within 2h	6h	12h	24h	36h	48h	Discharge Day	1-week postoperation
Enrollment:											
Eligibility screening	x										
Signed inform consent	x										
Allocation	x										
Intervention:											
Electroacupuncture ^a		x		x			x		x		
Sham electroacupuncture		x		x			x		x		
Assessments:											
VAS scores for pain during rest of the affected shoulder	x			x	x	x	x	x	x		x
VAS scores for pain during movement of the affected shoulder	x						x		x		x
Muscle swelling scores							x		x		
The frequency of PONV during hospitalization										x	
The dosage of postoperative analgesic drugs										x	x
Perioperative vital signs		x	x	x							
Sleep quality (sleep monitoring ring and AIS scores)	x						x		x		
Blinding assessment										x	
Safety assessment		x	x	x	x	x	x	x	x	x	x

Note: ^aExample illustrates delivery of intervention or assessments at discrete timepoints.

Abbreviations: AIS, Athens Insomnia Scale; PONV, postoperative nausea and vomiting; VAS, Visual Analogue Scale.

Participants will be withdrawn from the trial if they are found to have a full-thickness rotator cuff tear that does not meet the Ellman classification criteria of less than 5-cm. Participants will also be discontinued from the trial if they receive treatment other than the approved protocol or experience serious postoperative adverse events, such as severe incision infections, fractures, or dislocations, etc.

Randomization and Allocation Concealment

Block randomization will be employed for group assignment, and an independent statistician will generate the randomization sequence to allocate participants into the treatment and control groups in a 1:1 ratio. The block size will be 4, with 2 subgroups. A random number table will be generated using the Statistical Package for Social Science (SPSS, version 26.0, IBM, USA) software. Randomization will be implemented using sealed and opaque envelopes, prepared in duplicate for both the research initiator and the research center to ensure allocation concealment. According to the group assignment indicated in the envelopes, eligible participants will be randomly assigned to either the treatment group or control group. The study does not stratify randomization by specific tendon repaired, as the primary outcome is acute postoperative pain, which is more closely related to the overall surgical intervention than to isolated tendon pathology. However, surgical reports will document repaired tendons to enable exploratory subgroup analyses.

This trial employed a single-blind design. Patients will be blinded to group allocation; however, blinding of acupuncturists is not feasible due to the nature of the intervention. Prior to treatment, participants will be informed that they have an equal chance of being assigned to either group. To maintain blinding during the intervention, participants will wear an eye mask. The principal investigator, data analysts, outcome assessors, and the statistician will remain blinded throughout the trial. All study staff will be trained on trial procedures and are required to strictly adhere to the principle of role separation.

Qualification of Practitioners

All acupuncturists will receive standardization training from the principal investigator (YM) prior to the start of the trial to ensure protocol compliance and treatment consistency. EA procedure will be performed following the guidance for the clinical practice of acupuncture.²⁹ All acupuncturists must be licensed, hold at least a master's degree and have a minimum of 3 years of clinical experience in acupuncture practice.

Interventions

Operative Treatment

All patients will undergo ARCR and all arthroscopic procedures will be performed by the same surgical team led by surgeon (JZ). Standard ARCR will be conducted under general anesthesia (via laryngeal mask) combined with regional nerve block. The torn tendon will be reattached to the greater tuberosity using suture anchors, with either a simple single-row or a double-row suture bridge techniques, selected at the discretion of the surgeon based on the size, shape, and the surgeon's clinical experience. Surgeons may routinely perform biceps tenotomy or tenodesis when pathology of the long head of the biceps tendon is observed. Additional, distal clavicle resection, subacromial decompression, or acromioplasty may be performed if deemed necessary. Participants will be transferred to the ward within 2 hours after surgery.

Postoperative Basic Treatment

All patients in the trial will receive standard postoperative analgesia and rehabilitation.

Postoperative analgesia: (1) Intravenous patient-controlled analgesia (PCA) pump: At the end of surgery, a PCA pump containing tramadol hydrochloride injection will be set up and activated in continuous infusion mode for 48 hours postoperatively. (2) Additional analgesics: Intravenous infusion of Flurbiprofen Axetil Injection (50-mg/day) for 2 days; intramuscular injection of Parecoxib Sodium (40-mg) on the night of surgery. Etoricoxib tablets (60-mg/day) as needed for intolerable pain.

Postoperative rehabilitation during hospitalization: Patients will wear a shoulder abduction brace postoperatively. The brace may be loosened and relaxed appropriately for 5–10 minutes each day when patient is awake, but must be worn at other times, including while sleeping. Active shoulder abduction is prohibited, and passive abduction within 30° is

allowed. Starting on postoperative day 1, patients will perform 20 shoulder shrugs, 2 sets each day; perform 20 passive forward flexions each day, 2 sets each day; perform 20 forward-backward arm swings in a standing position (30° flexion followed by 30° extension), 2 sets each day; and perform 20 passive external rotations (prohibited in cases involving subscapularis muscle repair), 2 sets each day. Upon completing all exercises, patients may apply ice packs to the shoulder for 30 minutes, wrapped in a thin towel to keep the surgical site dry.

Rehabilitation instructions will be given by a physiotherapist on the first postoperative day. Thereafter, patients will perform the exercises independently using the printed rehabilitation manuals and instructional videos. Adherence will be monitored during the daily morning and evening ward rounds.

EA or SEA Intervention

EA or SEA will be administered 2 hours before surgery, 2 hours after surgery and once daily for the following surgery for 2 days (4 treatment sessions in total). Any participant who drops out before completing all sessions will have the reason documented.

The acupuncture methods are described in Table 2. During each session, patients will lie in a supine position in a private treatment area while wearing an eye mask to maintain blinding. The researcher will sterilize the patient's skin with 75% alcohol wipes before treatment. After skin disinfection, sterile adhesive pads will be placed on the acupoints, and the needles will be slowly and vertically inserted through the adhesive pads. Each treatment session will last for 30 minutes. When the needles are removed, the researcher will use a clean piece of cotton wool to apply pressure to the points to prevent bleeding. In each treatment session, 6 acupoints will be used during the postoperative treatments. The selected acupoints and their rationale are summarized in Figure 2 and Table 3.

Treatment Group

Participants in the treatment group will receive EA treatment in addition to standard postoperative analgesia and rehabilitation. Sterile, disposable acupuncture needles made of standard stainless steel (0.30 × 40 mm; Wuxi Jiajian Medical Co Ltd, Wuxi, China) will be used. Treatment will involve 6 standardized acupoints: bilateral Hegu (LI4), bilateral Neiguan (PC6), Shousanli (LI10) on the affected side, and Quchi (LI11) on the affected side. Acupoint locations will be determined according to the "National Standard of the People's Republic of China" (GB/T 12346–2006). First, the researcher will manually manipulate the needle until the patient reports needling sensations (de-qi sensation), including soreness, distension, heaviness, or numbness. An electric stimulator (SUKO, XS-998B06, Nanjing, China) will then be connected to two pairs of needles (LI4-PC6 bilaterally) to deliver a sparse-and-dense wave-type current (2-Hz/100-Hz) at 2-mA.

Control Group

Participants in the control group will receive SEA intervention in addition to the standard postoperative analgesia and rehabilitation. Placebo blunt-tip needles (0.30mm×40mm) without needle tips will be used to avoid skin penetration. The acupoints used in the control group will be the same as those in the treatment group, and the treatment procedures—including the placement of EA electrodes will also be identical. However, the EA device will be deactivated (zero output) and no electrical current will be delivered.

Table 2 Treatment Methods of Electroacupuncture and Acupoints

	Treatment Group	Control Group
Acupoints	LI4, PC6, LI10, LI11	LI4, PC6, LI10, LI11
Depth of insertion	10mm: LI4 30mm: PC6, LI10, LI11	No insertion
Needle type	Steel needles (Wuxi Jiajian Medical Co Ltd, Wuxi, China)	Blunt-tip needles
Needle sensation	With de-qi sensation	Without de-qi sensation
Electric stimulation	Two pairs of needles: LI4-PC6 (bilaterally) Connected to an electric stimulator (SUKO, XS-998B06, Nanjing, China) Deliver a sparse-and-dense wave-type current (2-Hz/100-Hz) at 2-mA.	Two pairs of needles: LI4-PC6 (bilaterally) Connected to an electric stimulator (SUKO, XS-998B06, Nanjing, China) No electrical current delivered

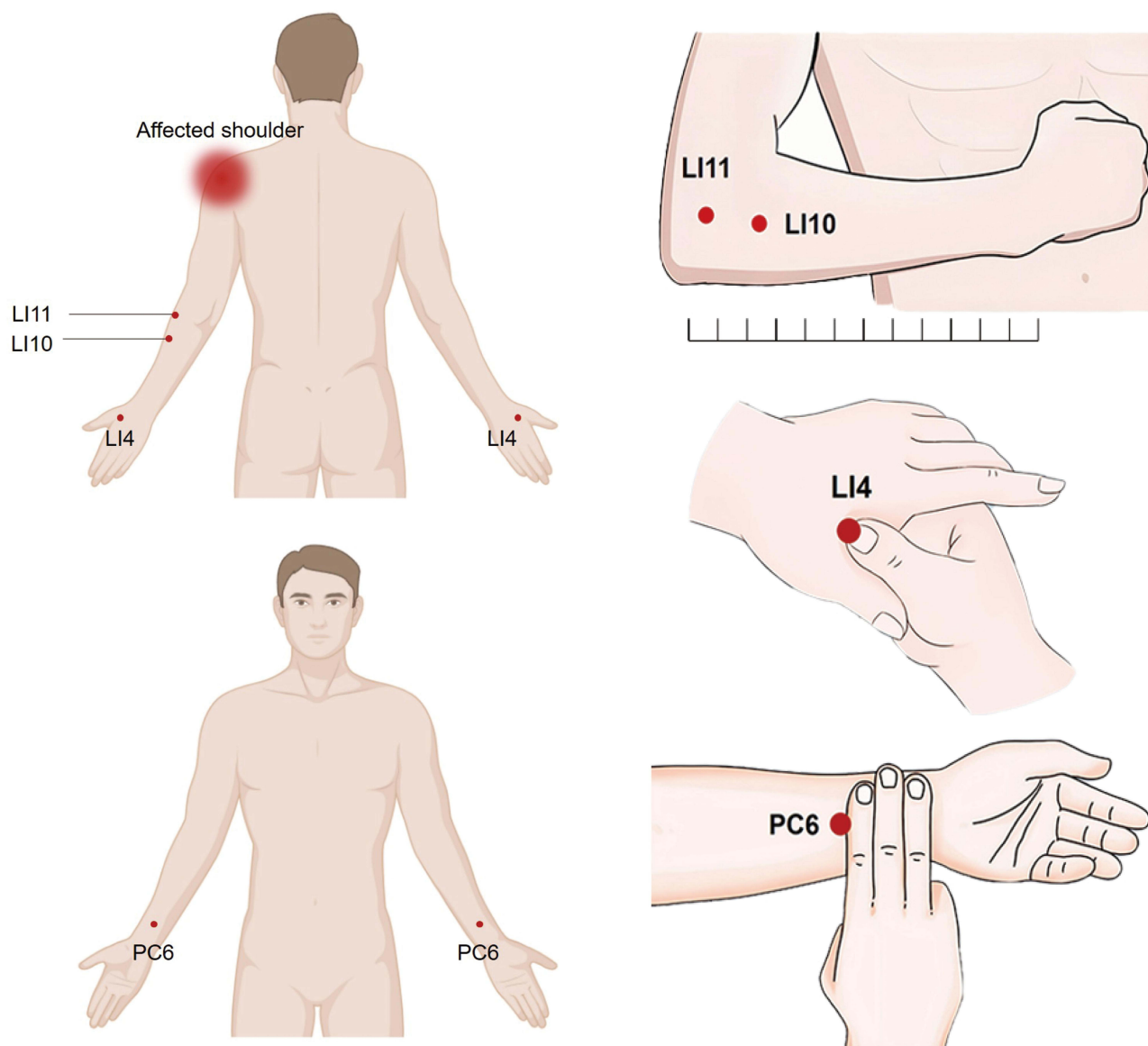


Figure 2 Acupoint locations.

Throughout the trial, all participants will be prohibited from receiving any analgesic treatment not specified in the protocol. However, treatment for other comorbidities will not be restricted. For instance, patients with hypertension may continue their antihypertensive medication. All concomitant medication use will be recorded in detailed but will not interfere with the ongoing treatment or follow-up process of the trial.

Outcomes

Primary Outcome

Visual Analogue Scale (VAS) scores³⁰ for resting pain in the affected shoulder at 12 hours postoperatively: Pain intensity is indicated on a 100 mm line, with one end representing “no pain” and the other end representing “severe pain”. The assessor asks the patient to mark their perceived pain intensity on the line by drawing an “×”. The distance from the “no pain” end to the “×” mark is then measured in millimeters and used as the pain score. Assessment will be conducted at baseline, at 2 and 6 hours postoperatively, and every 12 hours thereafter until discharge. An additional assessment will be

Table 3 Acupoint Selection and Rationale Based on Traditional Chinese Medicine

Acupoint	Location	Traditional Chinese Medicine Indication	Suggested Technique
LI4 (Hegu)	Dorsum of hand, at the level of the midpoint of the second metacarpal bone, between the first and second metacarpal bones	Alleviates pain in the upper limbs.	Needle perpendicular, 0.5–1.0 cun
PC6 (Neiguan)	On the palmar side of the forearm, 2 cun above the transverse wrist crease, between the tendon of the palmaris longus and the tendon of the flexor carpi radialis.	Helps in relieving nausea and vomiting, treating insomnia and alleviating pain in the upper limbs.	Needle perpendicular, 0.5–1.0 cun
LI10 (Shousanli)	On the dorsal side of the forearm, on the radial side, 2 cun below the transverse crease of the elbow, on the line connecting Yangxi (LI5) and Quchi (LI4).	Helps in relieving the meridians and collaterals, and alleviating swelling and pain in the upper limbs.	Needle perpendicular, 0.8–1.2 cun
LI11 (Quchi)	Bend the elbow at a right angle, at the midpoint of the line connecting the lateral end of the transverse elbow crease and the lateral epicondyle of the humerus.	Helps in relieving the meridians and collaterals, and alleviating swelling and pain in the upper limbs.	Needle perpendicular, 1.0–1.5 cun

conducted at the 1-week postoperative follow-up. The Chinese-language version of the VAS had good reliability and validity when used with Chinese adults, demonstrating high cultural appropriateness.³¹

Secondary Outcomes

1. VAS scores for resting pain in the affected shoulder at other time points.
2. VAS scores for pain during movement of the affected shoulder. This will be assessed at baseline and every 24h during hospitalization until discharge. An additional assessment will be conducted at the 1-week postoperative follow-up.
3. Limb swelling scores: 0 point: No swelling, normal skin elasticity; 1 point: slightly swollen compared to normal skin, dermatoglyphics still visible; 2 points: increased skin tension, dermatoglyphics disappear, no tension blister; 3 points: obvious swelling, higher skin temperature, and presence of tension blisters.³² The swelling score will be assessed every 24h postoperatively during hospitalization.
4. Dosage of postoperative analgesic drugs: The total consumption of etoricoxib tablet will be recorded at discharge, as well as the cumulative consumption at the 1-week postoperative follow-up.
5. Frequency of postoperative nausea and vomiting (PONV) during hospitalization: The number of patient's PONV will be recorded throughout the postoperative hospitalization and summarized at discharge.
6. Perioperative vital signs: Heart rate (HR), mean arterial pressure (MAP), and peripheral blood oxygen saturation (SpO₂) will be recorded at three time points: 1 hour before surgery, 30 minutes after tracheal intubation, and 1 hour after surgery.³³
7. Perioperative sleep status:

Sleep parameter: A sleep monitoring ring (Mega Health, ZG-P11H, Hangzhou, China) will be worn on the finger of the non-affected hand every night (from 9:00 PM to 7:00 AM), and total sleep time (TST), rapid eye movement sleep (REM) and sleep efficiency (SE) will be recorded. Sleep parameters will be monitored for one night before surgery and two nights after surgery.

Athens Insomnia Scale (AIS) scores: This scale includes 8 items, with the first 5 items assessing sleep difficulties and the last 3 items assessing daytime dysfunction. Total score ranges from 0 to 24, with higher scores indicating poorer sleep quality.³⁴ The AIS will be completed on the morning following each sleep monitoring session. The Chinese-language version of the AIS demonstrates solid reliability and validity and holds potential for application across various demographic groups in China.³⁵

Safety Outcomes

Safety outcomes include the incidence of all adverse events (AEs), treatment-related AEs, and serious adverse events (SAEs). AEs include any events reported by patients or determined by clinicians that are not attributable to the natural progression of rotator cuff tears. "Treatment-related AEs" refers to events deemed by clinicians to be directly associated with the EA or SEA intervention. Anticipated treatment-related AEs include needle site pain, bleeding or subcutaneous hematoma, needle fainting, needle breakage, and localized infection. SAEs are defined as those resulting in prolonged hospitalization, disability, life-threatening conditions, or death during the trial. AEs will be monitored at each visit, and any AEs associated with intervention or not will be evaluated. Once any AE occurs, the ethics committee will evaluate the severity and determine whether to suspend the trial. Following investigation, participants will receive necessary medical treatment and appropriate financial compensation at no cost.

Blinding Evaluation

Before enrollment, participants will be informed that they will have an equal opportunity of receiving EA or SEA intervention. After the treatment is completed, the success of blinding will be evaluated by asking the participants the following question: "Which type of treatment do you think you received?" Three choices will be provided for participants: EA group, SEA group, and uncertain. If a participant selects either EA or SEA (rather than "uncertain"), they will be asked to explain the reason for their choice.³⁶

Data Collection and Management

Before initiating the trial, a multidisciplinary research team consisting of acupuncture specialists, orthopedic specialists, ethicists, and statisticians will be established to ensure data quality and safety monitoring. All researchers, including acupuncturists, outcome assessors and data analysts, will undergo training in standardized procedures. Baseline and follow-up assessment for each participant will be evaluated by the same researcher to ensure data consistency. Paper case report forms (CRFs) will be securely stored in locked filing cabinets and managed by an independent researcher. The clinical trial data will be managed using the ResMan platform. All the participant data will undergo double entry and be independently verified by two personnel. Visit management, and query management by two different personnel. After the double-entry is completed, the data management department will audit, review, correct, and export the dataset. The final database will be locked after verification, and submitted for statistical analysis.

Monitoring and Quality Control

The Clinical Evaluation and Analysis Centre of Shanghai Sixth People's Hospital which is not taking part in and with no conflict of interests in the trial will be responsible for monitoring the data, controlling the bias and suspending or terminating the study. With the management of the Clinical Evaluation and Analysis Centre, quality control will be conducted throughout the trial. Before participating in the trial, all researchers should receive professional trial method training and regular monitoring technique to ensure the consistency of methods. Any corrections or modifications to the study protocol should be submitted to the ethics committee and informed Clinical Evaluation and Analysis Centre.

Sample Size Calculation

The sample size is calculated based on the primary outcome (VAS score), using GPower program (v3.1.9.7; Heinrich-Heine-Universität, Düsseldorf, Germany). According to our small pilot study, the mean and standard deviation of VAS in treatment group ($n=11$) after intervention was 53.95 and 12.58. While in control group ($n=11$), the mean and standard deviation of VAS after intervention was 61.27 and 11.70. Therefore, assuming an effect size of 0.60, an alpha error of 0.05, and a power of 80%, a total of 90 participants are needed to detect significant differences between groups. Considering a 20% dropout rate, the final sample size required is 112 participants (56 per group).

Statistical Analysis

All statistical analyses will be performed using SPSS 26.0 software by an independent statistician blinded to the group assignments. Analyses will follow the intention-to-treat (ITT) principle, including data from all participants, even those who withdraw. Missing data will be addressed using the last observation carried forward (LOCF) method.

Continuous variables with normal distribution will be presented as means \pm standard deviations (SD), and those with non-normal distribution as median and interquartile range. Categorical variables will be reported as counts and percentages. Normality will be assessed using the Kolmogorov–Smirnov test with Lilliefors correction. Appropriate parametric or non-parametric tests will be applied based on the results of homogeneity and normality analysis. A generalized linear mixed model will be used to analyze the effects of treatment, time, and their interaction. Within-group comparisons will be performed using two-sided paired *t* tests. Categorical variables and adverse effects will be analyzed using the chi-square test of Fisher's exact test.

Exploratory post-hoc subgroup analyses will investigate potential interactions between tendon type (categorized as supraspinatus-dominant, multi-tendon, etc, based on surgical findings) and treatment effects, if the subgroup sizes are sufficient ($n \geq 20$ per group). All *p*-values will be two-sided, $P < 0.05$ considered statistically significant. Confidence intervals will be established at the 95%.

Discussion

This single-center, subject-and-assessor-blinded, randomized, sham-controlled trial aims to evaluate the efficacy and safety of EA in perioperative rehabilitation after rotator cuff repair, focusing on pain management and recovery. Acute pain is common after ARCR, and if not well controlled, may progress to chronic pain, impair tendon-to-bone healing and

delay recovery.^{9,10} Current multimodal analgesia mainly relies on drugs, which may cause adverse reactions and psychological burden, underscoring the need for safe, non-pharmacological adjuncts. Evidence shows microcurrent stimulation and extracorporeal shock wave therapy can effectively reduce postoperative pain.^{6,37} These findings highlight the potential of non-pharmacological interventions, particularly electrotherapy, in optimizing multimodal analgesic strategies to accelerate pain relief and enhance tendon-to-bone healing.³⁸

Electroacupuncture, an advanced form of traditional acupuncture, delivers a controlled electrical current through acupuncture needles. By applying specific stimulation parameters, EA can provide more consistent and objective therapeutic input. It has demonstrated superior effects in analgesia and sedation, promoting blood circulation, and modulating muscle tension.³⁹ Studies have shown that EA reduces inflammation responses, restores bioelectrical homeostasis in tissues, and promotes the release of specific neuropeptides in the central nervous system, resulting in the analgesic effect.^{40–42} Systematic reviews support its role in shoulder pain management and frozen shoulder,²⁰ and studies report its safety and effectiveness in long-term rehabilitation after rotator cuff repair.^{43,44} However, most have small samples or lack placebo controls, limiting generalizability.

In postoperative pain management, a meta-analysis of 13 RCTs found acupuncture significantly reduced day-1 pain and opioid use.⁴⁵ Other studies report EA benefits in abdominal, nasal, and gynecological surgeries, improving pain control, reducing anesthetic needs, lowering PONV incidence, and accelerating recovery.^{33,46,47} In arthroscopic rehabilitation, EA also improved short-term pain and mobility after triangular fibrocartilage complex repair.⁴⁵ Collectively, these findings support EA as a safe adjunct in multimodal analgesia.

Musculoskeletal rehabilitation studies further suggest EA reduces pain and improves function by modulating pain sensitization pathways. A meta-meta-analysis indicates manual therapies, including acupuncture, may desensitize central and peripheral pain.⁴⁸ Emerging evidence highlights molecular mechanisms, such as modulation of tryptophan-derived metabolites and gut microbiota in osteoarthritis-related pain.^{49–51} These results suggest EA exerts not only localized but also systemic modulatory effects. Nonetheless, evidence on EA after rotator cuff repair remains scarce. If effective and safe, EA could become a standard perioperative intervention in both TCM and Western contexts.

This study proposed an integrated perioperative intervention model combining Chinese and Western medicine, using EA as an adjunctive therapy to alleviate postoperative pain and discomfort. To our knowledge, no prior RCTs have directly compared EA with sham EA after rotator cuff repair. Beyond pain, this trial also evaluates sleep quality, hemodynamics, and anesthesia-related adverse effects. Its rigorous design and comprehensive outcomes will provide robust evidence for EA's role in enhancing postoperative recovery.

The further strength of this trial is the reasonable control design and the implementation of participant blinding. Previous study showed verbal suggestion can influence post-treatment pain perception, emphasizing the need to control placebo effects.⁵² Placebo responses in acupuncture vary by stimulation level, from acupoint insertion to non-penetrating sham.⁵³ To minimize the placebo effect and enhance the integrity of blinding, we selected participants who have not received acupuncture treatments in the past 6 months, reducing their familiarity with EA treatment. Blinding efficacy will be assessed by evaluating both overall and within-group perceptions after treatment. Considering some evidence that EA's effects may be short-lived,^{54,55} this study also includes a 1-week follow-up to assess persistence after treatment cessation.

Nonetheless this study faces several limitations. Firstly, to reduce heterogeneity within the study population, patients with different types of rotator cuff disease will be screened, and only those classified as having full-thickness tears of less than 5-cm according to the Ellman classification will be included. Secondly, although the sustained effects of EA at the end of treatment are significant clinical relevance for recovery after rotator cuff repair, due to funding constraints, the extended follow-up period is limited to only 1 week, which may be insufficient to capture medium- and long-term outcomes, thereby warranting further investigation. Finally, as this is a single-center study conducted in China, the generalizability of the findings may be limited. Further validation through multicenter studies will likely be necessary after obtaining results.

Conclusion

This randomized controlled trial will provide robust evidence on the efficacy and safety of EA in perioperative rehabilitation after rotator cuff repair. If proven effective, EA may serve as a valuable adjunct to postoperative care, enhancing analgesia, reducing side effects, and accelerating recovery. The findings could lay the groundwork for large-

scale, multicenter trials and inform the development of multimodal pain management strategies that integrate traditional Chinese medicine. Ultimately, this study may contribute to refining clinical practice guidelines and optimizing post-operative care for rotator cuff repair.

Trial Status

Protocol: version 1.0, 10 April 2025.

The study was launched on 1 June 2025 and participant recruitment is currently ongoing. Recruitment is expected to be completed by the end of December 2026.

Abbreviations

AEs, Adverse events; AIS, Athens Insomnia Scale; ARCR, arthroscopic rotator cuff repair; CONSORT, Consolidated Standards of Reporting Trials; CRFs, case report forms; EA, Electroacupuncture; HR, Heart rate; ITT, intention-to-treat; LOCF, last observation carried forward; MAP, mean arterial pressure; MRI, magnetic resonance imaging; PONV, postoperative nausea and vomiting; RCT, randomized controlled trial; REM, rapid eye movement; SD, standard deviations; SE, sleep efficiency; SEA, Sham electroacupuncture; SPIRIT, Standard Protocol Items, Recommendations for Interventional Trials; TCM, Traditional Chinese Medicine; TST, total sleep time; VAS, visual analogue scale.

Data Sharing Statement

The datasets collected during the current study are available from either of the corresponding author upon reasonable request.

Ethics Approval and Informed Consent

The trial protocol was approved by the Ethics Committee of Shanghai Sixth People's Hospital on 15 May 2025 (Approval No.2025-060). All eligible participants will be required to sign a written informed consent form after receiving a full explanation of the study. All procedures will be conducted in accordance with the ethical standards outlined in the declaration of Helsinki.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare no conflicts of interest related to this work.

References

1. Teunis T, Lubberts B, Reilly BT, et al. A systematic review and pooled analysis of the prevalence of rotator cuff disease with increasing age. *J Shoulder Elbow Surg.* 2014;23(12):1913–1921. doi:10.1016/j.jse.2014.08.001
2. Yamamoto A, Takagishi K, Osawa T, et al. Prevalence and risk factors of a rotator cuff tear in the general population. *J Shoulder Elbow Surg.* 2010;19(1):116–120. doi:10.1016/j.jse.2009.04.006

3. Rezaie M, Negahban H, Mostafae N, et al. Comparison of the physiotherapy with and without focus on the scapulothoracic joint on pain, range of motion, functional disability, quality of life, and treatment effectiveness of patients after arthroscopic shoulder rotator cuff tendon repair: a randomized controlled trial with short-term follow-up. *J Hand Ther.* 2024;37(3):319–330. doi:10.1016/j.jht.2023.09.009
4. Takagishi K, Shitara H, Kobayashi T, et al. Risk factors for shoulder osteoarthritis with rotator cuff tear in the elderly general population. *J Shoulder Elbow Surg.* 2022;31(12):2562–2569. doi:10.1016/j.jse.2022.05.005
5. Dipompeo CM, Inabathula A, Kaym K, Miltom AJ, El Bitar Y. Complications and retears following arthroscopic repair of full thickness rotator cuff tears. *SN Compr Clin Med.* 2023;5(1):62. doi:10.1007/s42399-023-01400-8
6. Shao H, Zhang S, Chen J, et al. Radial extracorporeal shockwave therapy reduces pain and promotes proximal tendon healing after rotator cuff repair: randomized clinical trial. *Ann Phys Rehabil Med.* 2023;66(4):101730. doi:10.1016/j.rehab.2023.101730
7. Colvin AC, Egorova N, Harrison AK, et al. National trends in rotator cuff repair. *J Bone Joint Surg Am.* 2012;94(3):227–233. doi:10.2106/JBJS.J.00739
8. Longo UG, Carnevale A, Piergentili I, et al. Retear rates after rotator cuff surgery: a systematic review and meta-analysis. *BMC Musculoskeletal Disord.* 2021;22(1):749. doi:10.1186/s12891-021-04634-6
9. PROSPECT Working Group collaborators; Toma O, Persoons B, Pogatzki-Zahn E, et al. PROSPECT guideline for rotator cuff repair surgery: systematic review and procedure-specific postoperative pain management recommendations. *Anaesthesia.* 2019;74(10):1320–1331. doi:10.1111/anae.14796
10. Chiamonte R, Bonfiglio M, Chisari S. A significant relationship between personality traits and adhesive capsulitis. *Rev Assoc Med Bras.* 2020;66(2):166–173. doi:10.1590/1806-9282.66.2.166
11. Kehleth H, Jensen TS, Woolf CJ. Persistent postsurgical pain: risk factors and prevention. *Lancet.* 2006;367(9522):1618–1625. doi:10.1016/S0140-6736(06)68700-X
12. Novoa-Boldo A, Gulotta LV. Expectations following rotator cuff surgery. *Curr Rev Musculoskelet Med.* 2018;11(1):162–166. doi:10.1007/s12178-018-9470-7
13. Sgroi TA, Cilenti M. Rotator cuff repair: post-operative rehabilitation concepts. *Curr Rev Musculoskelet Med.* 2018;11(1):86–91. doi:10.1007/s12178-018-9462-7
14. Schwenk ES, Mariano ER. Designing the ideal perioperative pain management plan starts with multimodal analgesia. *Korean J Anesthesiol.* 2018;71(5):345–352. doi:10.4097/kja.d.18.00217
15. Guity MR, Sobhani Eraghi A, Hosseini-Baharanchi FS. Early postoperative pain as a risk factor of shoulder stiffness after arthroscopic rotator cuff repair. *J Orthop Traumatol.* 2021;22(1):25. doi:10.1186/s10195-021-00585-9
16. Green S, Buchbinder R, Hetrick SE, et al. Physiotherapy interventions for shoulder pain. *Cochrane Database Syst Rev.* 1996;2013. doi:10.1002/14651858.CD004258
17. China Association of Chinese Medicine. Guidelines for INTEGRATED TCM WM diagnosis and treatment of rotator cuff injuries (2023 edition). *J Trad Chin Orthop Trauma.* 2024;36(01):1–9.
18. Zijlstra FJ, Ineke B, Huygen F, et al. Anti-inflammatory actions of acupuncture. *Mediators Inflammation.* 2003;12(2):59–69. doi:10.1080/0962935031000114943
19. Zhang R, Lao L, Ren K, et al. Mechanisms of acupuncture-electroacupuncture on persistent pain. *Anesthesiology.* 2014;120(2):482–501. doi:10.1097/ALN.000000000000101
20. Heo JW, Jo JH, Lee JJ, et al. Electroacupuncture for the treatment of frozen shoulder: a systematic review and meta-analysis. *Front Med Lausanne.* 2022;9:928823. doi:10.3389/fmed.2022.928823
21. Pirri C, Manocchio N, Sorbino A, Pirri N, Foti C. Percutaneous electrolysis for musculoskeletal disorders management in rehabilitation settings: a systematic review. *Healthcare.* 2025;13(15):1793. doi:10.3390/healthcare13151793
22. Zheng Z, Gibson S, Helme RD, et al. Effects of electroacupuncture on opioid consumption in patients with chronic musculoskeletal pain: a multicenter randomized controlled trial. *Pain Med.* 2019;20(2):397–410. doi:10.1093/pm/pny113
23. Mao JJ, Liou KT, Baser RE, et al. Effectiveness of electroacupuncture or auricular acupuncture vs usual care for chronic musculoskeletal pain among cancer survivors: the PEACE randomized clinical trial. *JAMA Oncol.* 2021;7(5):720–727. doi:10.1001/jamaoncol.2021.0310
24. Shah S, Godhardt L, Spofford C. Acupuncture and postoperative pain reduction. *Curr Pain Headache Rep.* 2022;26(6):453–458. doi:10.1007/s11916-022-01048-4
25. Hopewell S, Chan AW, Collins GS, et al. CONSORT 2025 statement: updated guideline for reporting randomised trials. *BMJ.* 2025;389:e081123. doi:10.1136/bmj-2024-081123
26. Chan AW, Boutron I, Hopewell S, et al. SPIRIT 2025 statement: updated guideline for protocols of randomised trials. *BMJ.* 2025;389:e081477. doi:10.1136/bmj-2024-081477
27. American Academy of Orthopaedic Surgeons. Management of rotator cuff injuries clinical practice guideline. Available from: <https://www.aaos.org/rotatorcuffinjuriesepg>. Accessed March 11, 2019.
28. Ellman H. Diagnosis and treatment of incomplete rotator cuff tears. *Clin Orthop Relat Res.* 1990;254:64–74. doi:10.1097/00003086-199005000-00010
29. Witt CM. Clinical research on acupuncture - Concepts and guidance on efficacy and effectiveness research. *Chin J Integr Med.* 2011;17(3):166–172. doi:10.1007/s11655-011-0662-x
30. Scott J, Huskisson EC. Graphic representation of pain. *Pain.* 1976;2(2):175–184. doi:10.1016/0304-3959(76)90113-5
31. Li L, Liu X, Herr K. Postoperative pain intensity assessment: a comparison of four scales in Chinese adults. *Pain Med.* 2007;8(3):223–234. doi:10.1111/j.1526-4637.2007.00296.x
32. He L, Li Y, Liao X, et al. Effects of evidence-based nursing combined with enhanced recovery after surgery on shoulder joint function and neurological function after arthroscopic rotator cuff injury repair. *Medicine.* 2021;100(47):e27951. doi:10.1097/MD.00000000000027951
33. Yue H, Yao F, Yin X, et al. Electroacupuncture for pain relief after endoscopic sinus surgery: a randomized controlled trial. *J Pain.* 2023;24(11):2014–2023. doi:10.1016/j.jpain.2023.06.010
34. Song B, Li Y, Teng X, et al. Comparison of morning and evening operation under general anesthesia on intraoperative anesthetic requirement, postoperative sleep quality, and pain: a randomized controlled trial. *Nat Sci Sleep.* 2020;12:467–475. doi:10.2147/NSS.S257896
35. Tan C, Wang J, Cao G, et al. Reliability and validity of the Chinese version of the Athens insomnia scale for non-clinical application in Chinese athletes. *Front Psychol.* 2023;14:1183919. doi:10.3389/fpsyg.2023.1183919

36. Lao L, Bergman S, Hamilton GR, et al. Evaluation of acupuncture for pain control after oral surgery: a placebo-controlled trial. *Arch Otolaryngol Head Neck Surg.* 1999;125(5):567–572. doi:10.1001/archotol.125.5.567
37. Yi D, Lim H, Yim J. Effect of microcurrent stimulation on pain, shoulder function, and grip strength in early post-operative phase after rotator cuff repair. *Medicina.* 2021;57(5):491. doi:10.3390/medicina57050491
38. Ratte-Larouche M, Szekeres M, Sadi J, et al. Rotator cuff tendon surgery and postoperative therapy. *J Hand Ther.* 2017;30(2):147–157. doi:10.1016/j.jht.2017.05.008
39. Chen X, Lyu W, Kang L, et al. Comparative study on acupoint local effects between manual acupuncture and electro-acupuncture. *J Clin Acupuncture Moxibustion.* 2022;38(07):6–9. doi:10.19917/j.cnki.1005-0779.022125
40. Liu S, Wang Z, Su Y, et al. A neuroanatomical basis for electroacupuncture to drive the vagal-adrenal axis. *Nature.* 2021;598(7882):641–645. doi:10.1038/s41586-021-04001-4
41. Chen Y, Yang H. Bioelectric phenomena in electroacupuncture analgesia. *Zhong Guo Zhen Jiu.* 2024;44(01):89–93. doi:10.13703/j.0255-2930.20230413-0001
42. Chen T, Zhang WW, Chu YX, Wang YQ. Acupuncture for pain management: molecular mechanisms of action. *Am J Chin Med.* 2020;48(4):793–811. doi:10.1142/S0192415X20500408
43. Guo Y, Dong Y, Yang Y, et al. Clinical study on the effects of electro-acupuncture in postoperative rehabilitation of motor function of rotator cuff repair. *China J Tradition Chinese Med Pharm.* 2020;35(02):1010–1014.
44. Ning Y, Sun FF, Tong PJ. Application of electroacupuncture and rehabilitation exercises to postoperative rehabilitation of rotator cuff injuries. *J Trad Chin Orthop Trauma.* 2018;30(01):29–31. doi:10.3969/j.issn.1001-6015.2018.01.006
45. Wu MS, Chen KH, Chen IF, et al. The efficacy of acupuncture in post-operative pain management: a systematic review and meta-analysis. *PLoS One.* 2016;11(3):e0150367. doi:10.1371/journal.pone.0150367
46. Lam WL, Wang J, Yeung WF, et al. A combination of electroacupuncture and auricular acupuncture for postoperative pain after abdominal surgery for gynaecological diseases: a randomized controlled trial. *Phytomedicine.* 2022;104:154292. doi:10.1016/j.phymed.2022.154292
47. Pei L, Wang G, Yang S, et al. Electroacupuncture reduces duration of postoperative ileus after laparoscopic gastrectomy for gastric cancer: a multicenter randomized trial. *Gastroenterology.* 2025;169(1):73–84. doi:10.1053/j.gastro.2025.02.006
48. Martínez-Pozas O, Sánchez-Romero EA, Beltran-Alacreu H, et al. Effects of orthopedic manual therapy on pain sensitization in patients with chronic musculoskeletal pain: an umbrella review with meta-meta-analysis. *Am J Phys Med Rehabil.* 2023;102(10):879–885. doi:10.1097/PHM.0000000000002239
49. Meléndez-Oliva E, Martínez-Pozas O, Sinatti P, et al. Relationship between the gut microbiome, tryptophan-derived metabolites, and osteoarthritis-related pain: a systematic review with meta-analysis. *Nutrients.* 2025;17(2):264. doi:10.3390/nu17020264
50. Gonzalez-Alvarez ME, Sanchez-Romero EA, Turróni S, Fernandez-Carnero J, Villafañe JH. Correlation between the altered gut microbiome and lifestyle interventions in chronic widespread pain patients: a systematic review. *Medicina.* 2023;59(2):256. doi:10.3390/medicina59020256
51. Cuenca-Zaldívar JN, Del Corral-Villar C, García-Torres S, et al. Fourteen-year retrospective cohort study on the impact of climatic factors on chronic musculoskeletal pain: a Spanish primary care analysis. *Int J Rheum Dis.* 2025;28(3):e70125. doi:10.1111/1756-185X.70125
52. Sánchez Romero EA, Lim T, Villafañe JH, et al. The influence of verbal suggestion on post-needling soreness and pain processing after dry needling treatment: an experimental study. *Int J Environ Res Public Health.* 2021;18(8):4206. doi:10.3390/ijerph18084206
53. Xiong ZY, Liu XY, Ma PH, et al. Placebo response among different types of sham acupuncture for low back pain: a systematic review and meta-analysis of randomized controlled trials. *Chin J Integr Med.* 2023;29(10):941–950. doi:10.1007/s11655-023-3608-1
54. Torres SF, de Macedo ACB, Sakai RY, et al. Effect of different frequencies of electroacupuncture on chronic low back pain in older adults: a triple-blind, placebo-controlled, randomized clinical trial. *Pain Physician.* 2023;26(2):161–173. doi:10.36076/ppj.2023.26.161
55. Kong JT, Puetz C, Tian L, et al. Effect of electroacupuncture vs sham treatment on change in pain severity among adults with chronic low back pain: a randomized clinical trial. *JAMA Network Open.* 2020;3(10):e2022787. doi:10.1001/jamanetworkopen.2020.22787

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