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Pain-reducing effects of auricular acupuncture in cold-damp-type knee osteoarthritis: A randomized controlled trial

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Abstract

Background: Effective, low-risk adjuncts for knee osteoarthritis (KOA) are needed. We evaluated whether adjunctive auricular acupuncture (AA) improves pain and function in patients with cold-damp-type KOA.

Methods: In a single-center, randomized, single-blind, controlled trial, 124 adults (≥40 years) with radiographic primary KOA and baseline VAS ≥6 were randomized 1:1 to receive standard care (electroacupuncture, shortwave diathermy, and Duhuo Jisheng decoction tablets) with either weekly AA at Shenmen, Sympathetic, and Knee auricular points for 4 weeks (n=62) or sham auricular patches (n=62). Co-primary outcomes were change in VAS (0-10) and proportion achieving pain-free status (VAS ≤1) at week 4; secondary outcomes included WOMAC subscales and responder thresholds (≥30% and ≥50% WOMAC reduction).

Results: Mean VAS reduction was greater in the AA group than control (-4.84 ±0.22 vs -3.43 ±0.16; between-group p=0.009). Mean total WOMAC change favored AA (-42.64 ±1.74 vs -26.39 ±1.28; p=0.009). Pain-free status at week 4 occurred in 15/62 (24.2%) AA versus 3/62 (4.8%) control (RR 4.8; 95% CI 1.4-16.2; p=0.002). Clinically meaningful functional response (≥50% WOMAC) was 37/62 (59.7%) versus 7/62 (11.3%) (RR 5.3; 95% CI 2.5-11.2; p<0.001). No intervention-related adverse events were reported.

Conclusions: Weekly AA added to standard therapy produced greater short-term pain relief and functional gains with excellent safety. Confirmatory multicenter trials with longer follow-up are warranted.

Keywords: knee osteoarthritis, auricular acupuncture, VAS, WOMAC.

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1. INTRODUCTION

1.1. Background on knee osteoarthritis

Knee osteoarthritis (KOA) is a common, progressive joint disease characterized by articular cartilage loss, subchondral bone remodelling and periarticular soft-tissue changes that cause pain, stiffness and functional impairment. Population-based estimates indicate a substantial global and regional burden of KOA [1]. Globally, knee osteoarthritis affects approximately 16.0% (95% CI: 14.3%-17.8%) of individuals aged 15 years and older, with prevalence increasing to 22.9% (95% CI: 19.8%-26.1%) in adults over 40 years [1]. In 2021, osteoarthritis knee accounted for 374.74 million prevalence cases and 12.02 million disability-adjusted life years globally, with age-standardized rates continuing to rise [1]. In Vietnam, though national epidemiology is lacking, a study in Ho Chi Minh City found a radiographic KOA prevalence of 34.2% among adults aged ≥40 years [2]. Furthermore, within

Traditional Medicine (TM), KOA often manifests as the "cold-damp obstruction" syndrome. Patients characteristically experience joint pain aggravated by cold or wind, absence of local heat and redness, movement-induced pain exacerbation, aversion to wind and cold, and a pale tongue body with a wiry or tight pulse [3, 4].

1.2. Current treatments & gaps

Standard management of KOA includes NSAIDs, physical therapy modalities, and intra-articular injections (e.g., corticosteroids, hyaluronic acid). While these approaches can provide symptomatic relief, chronic NSAID use carries risks of gastrointestinal, renal, and cardiovascular adverse effects; physical modalities often require prolonged engagement; and intra-articular injections may offer only transient benefit [5,6]. In clinical care for knee osteoarthritis, acupuncture and tailored exercise programs are supported by recent evidence, and non-pharmacologic rehabilitation interventions are considered core, patient-centered, drug-sparing strategies [5,6].

1.3. Mechanism of auricular acupuncture from traditional medicine theory to modern medical application

In TM theory, auricular acupuncture is understood as stimulation of a somatic microsystem in which specific auricular points correspond to zang-fu organs and meridian pathways; targeted needling (e.g. "knee", Shenmen, sympathetic-related points) is intended to regulate Qi and Blood, dispel dampness and stasis, and restore systemic and local balance-actions that, within the TM framework, relieve pain by unblocking channels and improving local circulation in the affected joint [3].

In modern biomedical terms, auricular stimulation activates auricular afferents (including the auricular branch of the vagus and other cranial/cervical nerves) projecting to the nucleus tractus solitarius and connected brainstem and forebrain nuclei; this engagement modulates autonomic tone, recruits the cholinergic anti-inflammatory reflex to lower proinflammatory cytokines, and activates descending analgesic systems (PAG–RVM and endogenous opioid mechanisms), collectively reducing peripheral nociception, central sensitisation and inflammatory maintenance of musculoskeletal pain such as knee osteoarthritis [3].

Auricular acupuncture (AA) has been studied as a complementary therapy for KOA pain, with evidence of reduced pain and analgesic use without major side effects [7]. AA targets specific points on the auricle that correspond to somatic and autonomic innervation. The auricle's richly innervated cartilage and skin receive branches of the great auricular nerve, lesser occipital nerve, trigeminal nerve, vagus nerve, and cervical sympathetic fibers, making it a nexus for modulating pain and autonomic function. Stimulating auricular points such as Shenmen, Sympathetic, and the Knee point adheres to TM principles of selecting points by disease correspondence and functional indication; these points have been associated with endogenous opioid release, spinal "gate control" inhibition of C-fiber transmission, and supraspinal modulation of nociceptive processing.

1.4. Literature review

Recent systematic review and meta-analysis indicate durable benefits of acupuncture for KOA up to several months post-treatment [5]. Randomized and controlled trials of AA in KOA remain limited. In auricular-specific interventions, a randomized, sham-controlled trial by Zhang and colleagues (2022) reported that auricular acupressure applied at the knee, Shenmen, subcortex, and Sympathetic points produced significantly lower pain scores and reduced use of nonsteroidal

anti-inflammatory drugs in patients with early knee osteoarthritis ($p<0.05$) [7]. A comprehensive meta-analysis by Chen et al. (2024) confirmed the durability of acupuncture effects for knee osteoarthritis, with treatment benefits persisting 12-24 weeks post-intervention, supporting its long-term clinical utility [5]. Despite promising findings, evidence is constrained by small sample sizes, single-center designs, and variable blinding and follow-up durations.

1.5. Objective

This randomized controlled trial was conducted at the Ho Chi Minh City Traditional Medicine Hospital to determine whether adjunctive AA at Shenmen, Sympathetic, and Knee points enhances pain relief (VAS) and functional improvement (WOMAC) over standard therapy alone in patients with cold-damp KOA. The primary hypothesis was that the AA group would demonstrate greater reductions in VAS pain scores after four weeks of treatment compared with controls.

2. METHODS

2.1. Study design and setting

This study was a randomized, single-blind, controlled trial. Patients were recruited from both the outpatient and inpatient departments of the Traditional Medicine Hospital in Ho Chi Minh City between June 2023 and April 2024.

2.2. Participants

2.2.1. Inclusion criteria

- Age ≥ 40 years.
- Diagnosis of primary KOA according to the 1991 ACR criteria (pain, osteophytes on radiograph, synovial fluid characteristics).
- Chronic knee pain lasting >3 months.
  - TM syndrome of Wind-Cold-Damp Bi with all seven TM symptoms: knee pain, absence of redness/heat, pain aggravated by movement, wind and cold aversion, pale red tongue body.
- Baseline visual analog scale (VAS) pain ≥6/10.
- Failure of at least two prior therapies (paracetamol, NSAIDs, physical therapy, orthotic devices, lifestyle modification).
- Discontinuation of NSAIDs ≥1 week prior to enrollment.
- Radiographic Kellgren-Lawrence stage I-III.
- Written informed consent.

2.2.2. Exclusion criteria

- Systemic inflammatory arthritis (e.g., rheumatoid arthritis), coagulopathy, cardiac pacemaker, severe cardiovascular disease, active infection, malignancy, immunodeficiency.
- Current knee joint swelling, redness, or heat.
- Platelet count <150,000/mm³.
- Pregnancy.
- Intra-articular corticosteroid or hyaluronic acid injection within 6 weeks.
- Prior knee surgery (including arthroscopy) or joint infection.
- Radiographic stage IV KOA.

2.3. Randomization and blinding

A random number table of 124 unique identifiers was generated and random allocation in a 1:1 ratio using sealed, opaque envelopes. Patients were blinded to the AA procedure.

2.4. Interventions

2.4.1. Intervention group

- **AA** was administered weekly at Shenmen (F4), Sympathetic (AH6), and Knee (AH4) points on the affected side, with needles retained for 7 days and replaced weekly over 4 sessions.
- **Electroacupuncture:** Two 10-day courses, stimulation mode targeting standard knee acupoint.
- **Shortwave diathermy:** Two 10-day courses, at the knee joint.

- **Herbal medicine:** DJD tablets, oral, twice daily for 4 weeks.

2.4.2. Control group

- **Sham AA:** Participants in this group received a non-penetrating sham intervention. We used the same adhesive patches as the intervention group, but **the embedded intradermal needles were manually removed prior to application**. These needle-free patches were applied to the **same auricular points** (Shenmen, Sympathetic, and Knee) to maintain visual identity and ensure single-blinding. Since the patches contained only adhesive tape without a needle or a hard object (such as a seed), they provided no skin penetration and minimal acupressure, thereby avoiding significant neurophysiological stimulation or vagal reflexes.
- **Electroacupuncture, shortwave diathermy, and herbal medicine:** Identical protocol to intervention group.

2.5. Outcome measures

2.5.1. Primary outcome

- **Pain intensity:** Change in VAS score (0-10 cm) from baseline (T0) to 4 weeks (T4). Proportion of patients achieving VAS ≤1 at T4.

2.5.2. Secondary outcomes

- **Functional status:** Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) subscales (pain, stiffness, function) and total score, with ≥50% improvement defined as treatment success.
- **Safety:** Adverse events related to the intervention and vital signs were recorded at each visit.

2.6. Sample size calculation

Based on preliminary data indicating a 50% success rate in the control group and hypothesizing a 70% success rate in the intervention group for VAS pain relief at 4 weeks, with α=0.05, power=90% (β=0.10), the required sample size per group was calculated as 56 patients. Allowing for a 10% attrition rate, 62 patients were enrolled per arm (total n=124).

2.7. Statistical analysis

Statistical analyses were performed using IBM SPSS. Between-group comparisons: independent t-test for continuous data, paired t-test for within-group changes, chi-square or Fisher's exact test for categorical data. Repeated measures ANOVA assessed trends over time. Relative risk (RR) calculated for dichotomous outcomes. Risk ratios were calculated with 95% confidence intervals for binary outcomes, including pain-free status (VAS ≤ 1) and functional response (≥50% WOMAC improvement). Number needed to treat was derived from absolute risk reduction for clinically relevant endpoints. A p-value <0.05 was considered statistically significant.

2.8. Ethical considerations

The study protocol was approved by the Ethics Review Board of the Ho Chi Minh City Hospital of Traditional Medicine on July 3, 2023 (No. 2301/YHCT-HDDD). All patients provided written informed consent. The trial was conducted in accordance with the Declaration of Helsinki and relevant national regulations.

3. RESULTS

3.1. Participant flow

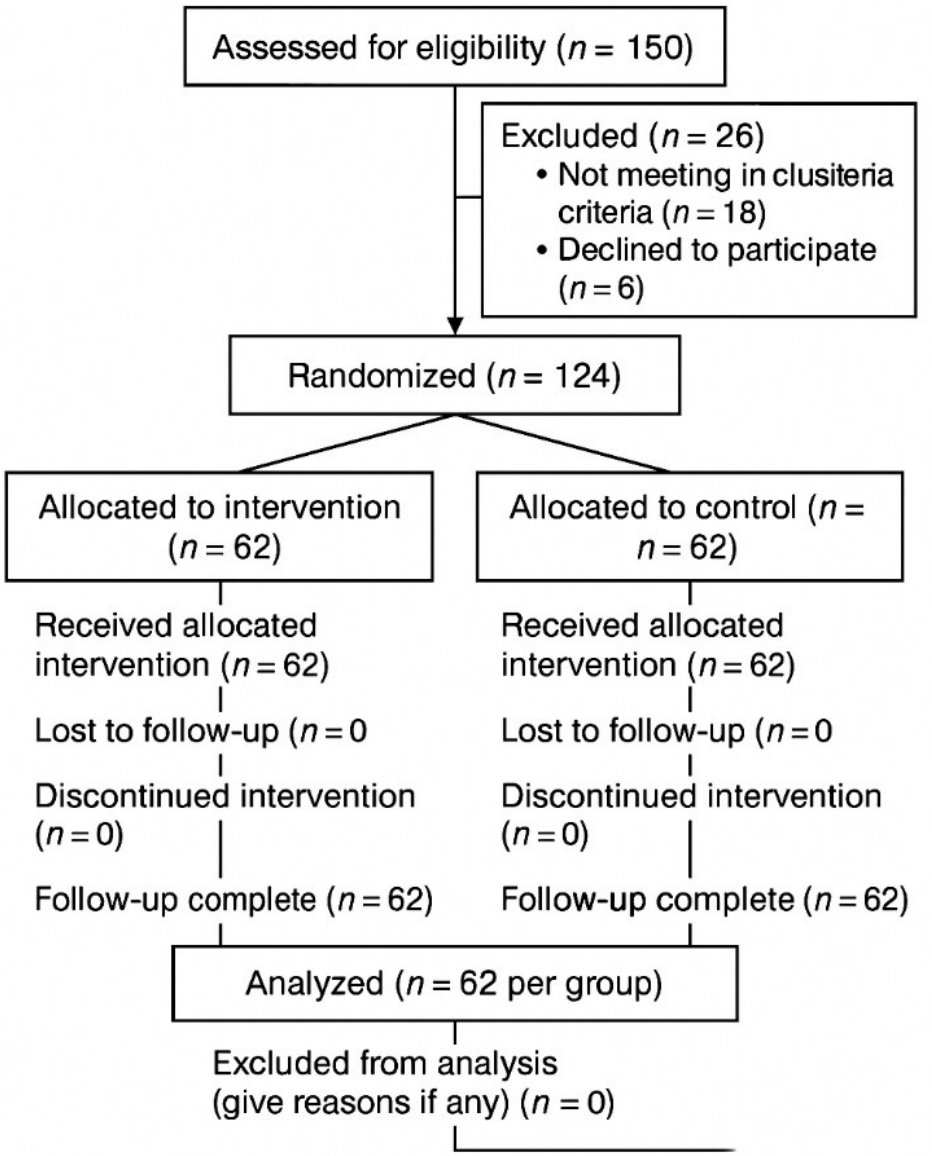

Figure 1. CONSORT flow diagram of participant screening, randomization, follow-up, and analysis.

As outlined in the Methods, 124 participants were enrolled and randomized (n=62 per group). All randomized participants completed the 4-week study protocol and were included in the per-protocol analyses (Figure 1).

3.2. Baseline characteristics

Table 1. Baseline demographic and clinical characteristics of study participants.

Characteristic	Intervention group (n=62)	Control group (n=62)	Total (n=124)	P-value
Age group, n(%)				0.45
40-59 years	14 (22.6%)	19 (30.6%)	33 (26.6%)	
60-69 years	28 (45.2%)	23 (37.1%)	51 (41.1%)	
≥70 years	20 (32.2%)	20 (32.2%)	40 (32.2%)	
Gender (female), n(%)	52 (83.9%)	49 (79.0%)	101 (81.5%)	0.49
BMI category (kg/m²), n(%)				0.24
Normal (<23.0)	13 (21.0%)	12 (19.4%)	25 (20.2%)	
Overweight/obese (≥23.0)	49 (79.0%)	50 (80.6%)	99 (79.8%)	
Disease duration, n(%)				0.35
3-6 months	19 (30.6%)	22 (35.5%)	41 (33.1%)	
	43 (69.4%)	40 (64.5%)	83 (66.9%)	
Kellgren-Lawrence grade, n(%)				0.33
Grade 1	2 (3.2%)	0 (0%)	2 (1.6%)	
Grade 2	36 (58.1%)	35 (56.5%)	71 (57.3%)	
Grade 3	24 (38.7%)	27 (43.5%)	51 (41.1%)	
Baseline scores, Mean ±SD				
VAS (0-10)	7.69 ±0.92	8.29 ±1.13	-	0.95
WOMAC total (0-96)	65.95 ±1.83	74.87 ±1.85	-	0.54

Note: BMI categorized according to Asian criteria. SD: Standard deviation.

Baseline demographic and clinical characteristics were comparable between groups (all p>0.05; Table 1).

3.3. Primary and secondary outcomes

3.3.1. Pain intensity (VAS)

Table 2. Clinical outcomes at baseline and week 4.

Outcome (score range)	Group	Baseline (Mean ±SD)	Week 4 (Mean ±SD)	Change from Baseline (Mean ±SD)	P-value (Between groups)
VAS (0-10)	Intervention	7.69 ±0.92	2.85 ±0.19	-4.84 ±0.22	**0.009**
	Control	8.29 ±1.13	4.85 ±0.23	-3.43 ±0.16	
WOMAC pain (0-20)	Intervention	13.73 ±0.34	4.92 ±0.42	-8.69 ±0.43	**0.0005**
	Control	15.95 ±0.39	10.64 ±0.39	-5.75 ±0.28	
WOMAC stiffness (0-8)	Intervention	5.63 ±0.14	2.86 ±0.20	-2.56 ±0.17	**0.002**
	Control	5.53 ±0.14	4.90 ±0.13	-0.87 ±0.15	
WOMAC function (0-68)	Intervention	47.63 ±1.28	16.84 ±1.53	-31.39 ±1.35	**0.01**
	Control	53.39 ±1.38	34.82 ±1.39	-19.76 ±1.01	
WOMAC total (0-96)	Intervention	65.95 ±1.83	28.42 ±2.38	-42.64 ±1.74	**0.009**
	Control	74.87 ±1.85	46.87 ±2.04	-26.39 ±1.28	

At week 4, the intervention group demonstrated a significantly greater mean reduction in VAS pain score compared with the control group (−4.84 ±0.22 vs −3.43 ±0.16; between-group p=0.009; Table 2). Explanations related to the WOMAC score will be presented in the next section.

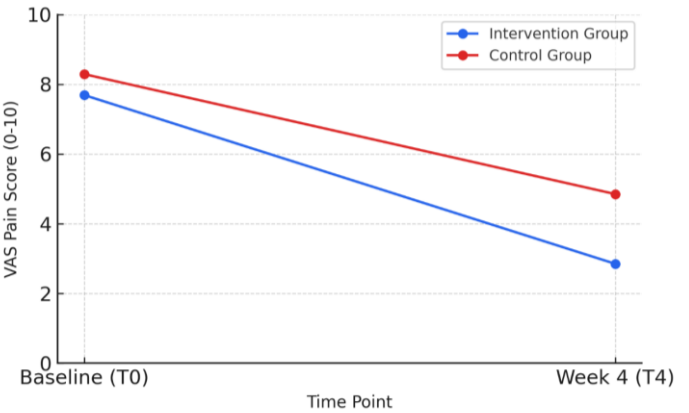

Figure 2. Depicts the change in mean VAS scores at time points T0 (baseline) and T4 (after 4 weeks) for both groups.

Figure 2 illustrates the steeper decline in pain intensity in the intervention arm across time points.

3.3.2. Functional status (WOMAC)

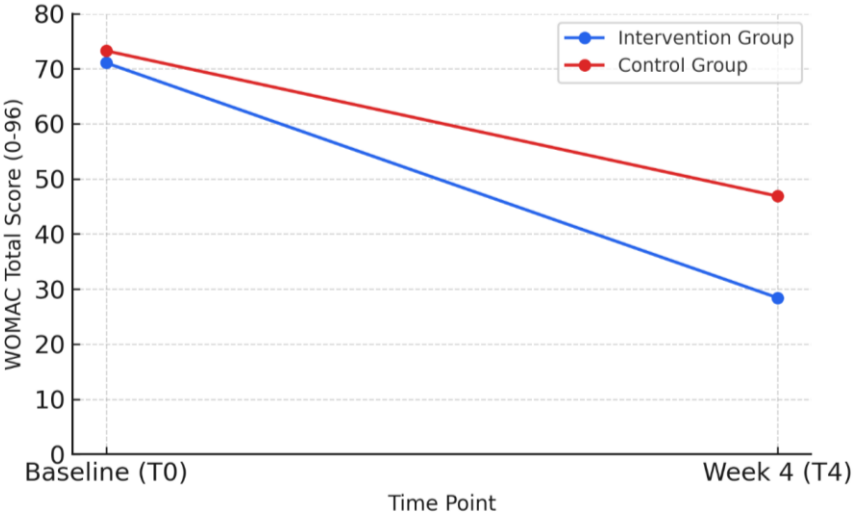

Figure 3. Illustrates the change in mean total WOMAC scores at time points T0 and T4 for both groups.

Significant improvements favoring the intervention group were observed across all WOMAC domains, including pain (p=0.0005), stiffness (p=0.002), and physical function (p=0.01). The total WOMAC score improved by −42.64 ±1.74 in the intervention group versus −26.39 ±1.28 in controls (p=0.009; Table 2; Figure 3).

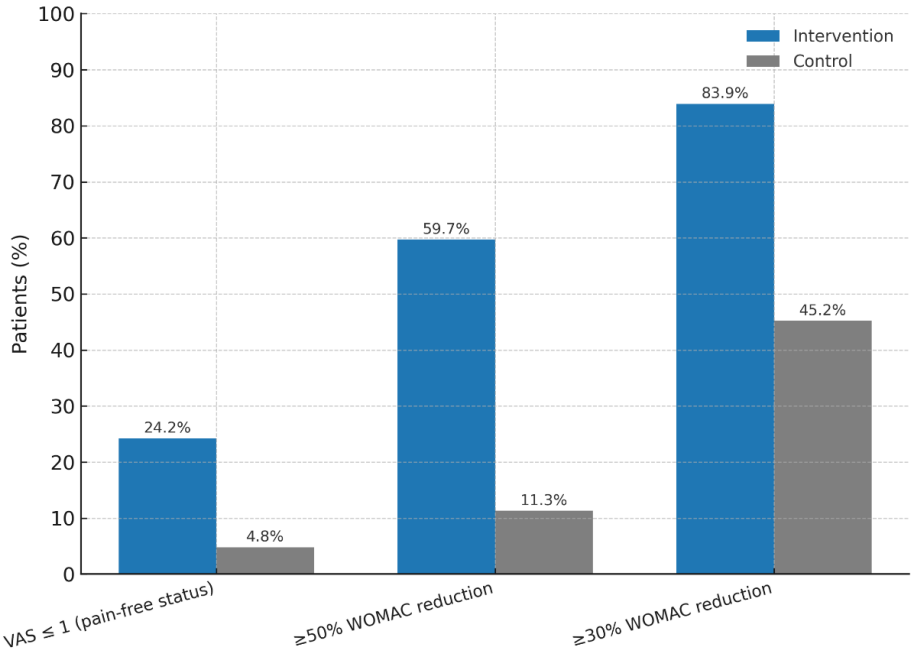

Figure 4. Proportion of patients achieving clinically meaningful improvement in pain and function at week 4.

Figure 4 compares the proportion of patients in the intervention and control groups achieving clinically meaningful improvements in pain and function at week 4, based on standardized outcome measures (VAS and WOMAC). The intervention group demonstrated consistently higher improvement rates across all domains compared with controls.

3.3.3. Categorical response rates

Table 3. Treatment response rates and relative risk estimates

Outcome measure	Intervention, n(%)	Control, n(%)	Risk ratio (95% CI)	P-value
VAS pain response				
VAS ≤ 1 (pain-free status)	15 (24.2%)	3 (4.8%)	4.8 (1.4-16.2)	0.002*
WOMAC Functional Response				
≥50% WOMAC reduction	37 (59.7%)	7 (11.3%)	5.3 (2.5-11.2)	<0.001*
≥30% WOMAC reduction	52 (83.9%)	28 (45.2%)	1.9 (1.4-2.5)	<0.001*

**Statistical significance: p<0.05*

A higher proportion of intervention patients achieved pain-free status (VAS≤1) at week 4 (24.2% vs 4.8%; RR=4.8; 95% CI 1.4-16.2; p=0.002) and clinically meaningful functional improvement (≥50% WOMAC reduction: 59.7% vs 11.3%; RR=5.3; 95% CI 2.5-11.2; p<0.001). Rates for ≥30% WOMAC improvement were also superior in the intervention group (83.9% vs 45.2%; RR=1.9; 95% CI 1.4-2.5; p<0.001) (Table 3).

3.3.4. Protocol adherence

All participants attended ≥95% of scheduled treatment sessions. No deviations from the study protocol occurred.

3.3.5. Adverse events

No adverse events, including nausea, vomiting, bleeding, vasovagal reaction, local pain at the needling site, or skin allergies, were reported in either group during the study period. Vital signs remained stable throughout the trial.

4. DISCUSSION

4.1. Characteristics of the study sample

The 124 per-protocol participants were well matched across key demographic and clinical variables, supporting the internal validity of the trial. The cohort's profile (predominantly older females with KL grade 2-3) is consistent with the general population of KOA patients targeted in this clinical setting, allowing for generalizability to similar TM hospital populations.

4.2. Analgesic efficacy by VAS

We deliberately enrolled participants with baseline pain ≥ 6/10 to ensure a sample with at least moderate-to-severe symptomatic burden and therefore sufficient "room to improve," increasing assay sensitivity to detect clinically meaningful analgesic effects. Published categorizations of 0–100 mm VAS commonly place moderate pain beginning near 45 mm (≈4.5/10) and severe pain above ~75 mm, so a 6/10 threshold selectively recruits patients above the conventional moderate range and closer to the severe range used in many pain trials [8].

Selecting this higher threshold reduces the risk of a floor effect (participants with low baseline pain who cannot demonstrate large absolute decreases) and increases the likelihood that observed absolute changes exceed published minimal clinically important differences (MCID) for knee pain (typically ≈0.8–1.5 cm on a 10-cm VAS), thus improving clinical interpretability

of treatment effects [9].

Moreover, individual-patient data syntheses in osteoarthritis research indicate that participants with greater baseline pain tend to show larger absolute improvements, which enhances statistical power for absolute-change endpoints while remaining clinically relevant to the subset of patients most likely to seek adjunctive therapies [10].

AA elicited a pronounced and rapid decrease in pain intensity, surpassing control throughout the 4-week course. This degree of analgesia aligns closely with Thuy's findings using electroacupuncture plus DJD, yet our sharper decline may reflect the synergistic modulation of meridian Qi and local anti-inflammatory effects unique to ear-acupuncture in TM theory.

Moreover, complete resolution of knee pain (VAS=0) occurred in 24% of patients receiving AA compared to only 5% of controls ($p<0.05$), a differential that underscores the clinical relevance of this modality for achieving symptom-free status within one month. A 4-week endpoint is commonly used as an early efficacy timepoint in RCTs of non-pharmacological KOA interventions (including acupuncture) [6], our results substantiate AA as a potent adjunct for rapid pain control in chronic knee osteoarthritis.

Regarding the standard care regimen (Electroacupuncture, Shortwave diathermy, and Duhuo Jisheng Decoction), it is important to clarify that the Control group achieved a substantial mean VAS reduction of 3.43 cm (41.4%) after 4 weeks. This improvement far exceeds the minimal clinically important difference (MCID) for knee osteoarthritis pain (typically 1.37-1.75 cm), confirming that the comprehensive background regimen was indeed effective.

The perceived "poor" outcome in the Control group (final VAS ≈ 4.8) is primarily attributable to the high baseline severity (initial VAS ≈ 8.3) rather than a lack of treatment efficacy. In fact, the absolute reduction in our Control group was comparable to or even greater than that reported in similar trials using standard TCM care. Therefore, the significant between-group difference observed favors the specific additive effect of Auricular Acupuncture-potentially via central pain modulation mechanisms-rather than an underperformance of the standard therapy.

4.3. Symptom and functional gains by WOMAC

Improvements were observed across all WOMAC domains in the auricular acupuncture arm compared with control (see Table 2). These benefits encompassed pain relief, reduced stiffness, and enhanced physical function, indicating a broad therapeutic effect that extends beyond isolated analgesia. Notably, the symptomatic gains in pain and stiffness appeared to translate into meaningful improvements in daily activities, supporting the intervention's functional relevance in this population. Potential mechanisms may include central modulation of nociceptive signalling alongside peripheral effects such as improved local microcirculation, but the present trial was not designed to establish causal pathways. (See Table 2 for detailed outcome values.)

4.4. Responder analysis

Responder analysis demonstrated substantially greater clinical benefit in the auricular acupuncture arm: 60% (37/62) achieved ≥50% reduction in total WOMAC versus 11% (7/62) in controls (RR for ≥50% WOMAC 5.3, 95% CI 2.5–11.2), and RR for pain-free status (VAS ≤1) was 4.8 (95% CI 1.4–16.2). These results are concordant with recent pooled evidence indicating clinically meaningful and durable benefits of acupuncture for

knee osteoarthritis [5]. Likely contributors to our higher responder proportion include greater baseline pain (larger absolute change possible), use of AA as an adjunct within a multimodal protocol, differences in auricular technique, and a later assessment timepoint (4 weeks).

4.5. Safety profile

No treatment-related adverse events (e.g., bleeding, infection, or persistent local discomfort) were reported, supporting a favourable safety profile for auricular needling in this multimorbid population. Overall, the findings support auricular acupuncture as an effective and well-tolerated adjunct to standard care for symptomatic KOA.

4.6. Proposed mechanisms

Auricular stimulation engages multi-level neurophysiological and neuro-immune pathways that plausibly account for the rapid and clinically meaningful analgesia observed in our trial. Mechanistic syntheses by Guo et al. indicate that auricular afferents (including the auricular branch of the vagus and other cranial/cervical nerves) project to brainstem nuclei (e.g., NTS) and thence to supraspinal centres, allowing simultaneous recruitment of (i) the cholinergic anti-inflammatory reflex with downstream suppression of pro-inflammatory cytokines, and (ii) descending analgesic circuits (PAG–RVM) and endogenous opioid release that reduce spinal nociceptive transmission and central sensitisation. These converging pathways can-without implying measured biomarker change in this trial-explain both the early reduction in VAS pain and the concurrent improvements in WOMAC domains by decreasing peripheral nociceptive drive (synovitis-associated nociception) and lowering central pain amplification [3].

From the TM viewpoint synthesized in Guo et al., auricular points function as a somatic microsystem: Shenmen, Sympathetic and the Knee point were selected to “disperse cold-damp,” invigorate local circulation and harmonize systemic Qi–Blood. When interpreted translationally, these TM actions overlap with the biomedical effects above-improved microcirculation, modulation of autonomic balance, and resolution of local stagnation—which may synergize with concurrent electroacupuncture to amplify symptomatic and functional gains. Thus, the point selection and weekly retention strategy used here are consistent with both TM rationale and modern neuro-immunologic mechanisms described by Guo et al. (2024) [3]. Specifically, regarding the 'Cold-Damp' pattern in Traditional Medicine, the selection of points was strategic. The 'Sympathetic' (AH6) point regulates autonomic function, promoting vasodilation and improving microcirculation, which corresponds to the 'warming' action required to dispel Cold. The 'Knee' (AH4) point directs Qi and blood flow specifically to the affected joint to resolve local stagnation (Dampness). Furthermore, we propose a synergistic neurophysiological interaction between the two modalities. While local electroacupuncture primarily activates segmental spinal mechanisms (Gate Control) and local release of endogenous opioids, auricular acupuncture stimulates the auricular branch of the vagus nerve, engaging supraspinal descending inhibitory pathways (PAG–RVM) and systemic anti-inflammatory reflexes. This combination creates a dual 'bottom-up' (spinal) and 'top-down' (supraspinal) modulation, likely producing a cumulative analgesic effect that is superior to local stimulation alone.

Key limitations of mechanistic inference from this trial are that autonomic and inflammatory mediators (e.g., HRV,

serum/synovial TNF-α, IL-6, or neuroimaging markers of descending inhibition) were not measured; therefore causal links remain hypothetical. Future trials should prospectively incorporate predefined mechanistic endpoints (autonomic indices, peripheral/synovial cytokines, and, where feasible, imaging or opioid-system biomarkers) and stratify by TM phenotypes (e.g., cold-damp) to test whether the clinical benefits demonstrated here correspond to the putative vagal, anti-inflammatory and microcirculatory mechanisms articulated by Guo et al. [3] and reflected in our clinical outcomes.

4.7. Strengths

This study's randomized, per-protocol design with blinded outcome assessors, standardized auricular point selection, and rigorous sterile technique underpin its internal validity. The inclusion of both subjective (VAS/WOMAC) and objective (shortwave diathermy settings) measures further bolsters methodological robustness.

4.8. Limitations and future directions

Although our randomized trial demonstrates short-term symptomatic benefit of adjunctive auricular acupuncture, several limitations constrain causal and external inference. First, the single-center design and modest sample (n=124) limit generalisability and the ability to detect rare or delayed adverse events; second, the short follow-up (4 weeks) precludes assessment of durability of effect and potential structural disease modification; third, the trial used single-blind masking of patients (while outcome assessment was blinded), leaving therapists unblinded and introducing potential performance bias; and fourth, mechanistic inference is limited because autonomic and inflammatory biomarkers (e.g., HRV, serum/synovial TNF-α/IL-6, imaging or opioid-system markers) and longer-term functional/ structural measures were not collected.

To address these issues we recommend the following in future research: (1) larger, multicentre RCTs to improve external validity and permit robust safety and subgroup analyses; (2) extended follow-up (≥3-6 months, ideally 12 months) with prespecified post-treatment assessments to determine durability and potential disease-modifying signals; (3) strengthened blinding using validated sham auricular devices and separation of treatment providers from outcome assessors to minimise performance and detection bias; (4) incorporation of prespecified mechanistic endpoints (autonomic indices, peripheral and synovial cytokines, standardized imaging and, where feasible, neuroimaging or opioid-system biomarkers) to test vagal, anti-inflammatory and central-modulatory hypotheses; (5) stratification or preplanned subgroup analyses by Traditional Medicine phenotypes (e.g., cold-damp vs other patterns) to evaluate whether TM diagnosis modifies response; and (6) inclusion of pragmatic and cost-effectiveness evaluations and multicondition cohorts to determine real-world applicability and scalability. Collectively, these methodological enhancements will permit stronger causal inference regarding mechanisms and broader recommendations for integration of auricular acupuncture into KOA care pathways.

5. CONCLUSION

In this randomized trial, auricular acupuncture as an adjunct to standard care demonstrated superior efficacy in reducing pain intensity and improving physical function compared to standard care alone. The intervention significantly increased the likelihood of patients achieving meaningful clinical responses, including pain-free status and substantial functional recovery. Furthermore, auricular acupuncture

was safe and well-tolerated, with no serious adverse events reported. These findings support the use of auricular acupuncture as an effective, low-risk, non-pharmacological adjunctive therapy for managing symptoms in patients with cold-damp type knee osteoarthritis.

LIST OF ABBREVIATIONS USED

AA: Auricular acupuncture
DJD: Duhuo Jisheng Decoction
KOA: Knee osteoarthritis
RCT: Randomized Controlled Trial
TM: Traditional Medicine
VAS: visual analog scale
WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index.

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