International Journal of Computer Science and Engineering
ISSN 3107-7657 (Print) ISSN 3107-7657 (Online)

Review Article

Meridian Sinew-Based Standardized Therapy for Elderly Chronic Pain

Steve K Hindman[1,*]

[1] Department of Computer Science, StanfordStanford University, 94305, USA

* Corresponding author: Steve K Hindman

Email: SteveKHindman@outlook.com

***Abstract*:** Chronic musculoskeletal pain in the elderly population presents a significant clinical challenge, yet existing traditional Chinese medicine external therapies, acupuncture, tuina, and moxibustion often suffer from inconsistent operational protocols and insufficient integration with syndrome differentiation frameworks. Drawing upon meridian sinew system theory and its associated "tendon excess-deficiency and qi-blood stasis" pathological model, this study constructs a standardized combined external therapy protocol tailored to elderly CMP. The protocol operationalizes a four-step "examination-differentiation-prescription-treatment" clinical pathway, classifying patients into three distinct sinew-deficiency subtypes, cold coagulation, damp-heat accumulation, and blood stasis, with correspondingly customized treatment parameters. A three-arm assessor-blinded randomized controlled trial design is proposed to compare the standardized protocol against conventional acupoint-based therapy and a waitlist control group, with pain intensity measured by visual analog scale and pressure pain threshold as primary outcomes. The study also incorporates exploratory biomarker assessments to investigate potential anti-inflammatory mechanisms underlying the integrated intervention. Preliminary feasibility analysis suggests that protocol standardization is achievable within community settings, though several challenges are anticipated, including practitioner training consistency and between-subject variability in treatment response. This research contributes to ongoing efforts in TCM external therapy standardization and offers a replicable framework for integrating classical theoretical constructs with contemporary clinical trial methodologies. Nevertheless, given the exploratory nature of this protocol, further large-scale multicenter studies are required to validate generalizability and long-term efficacy.

Keywords: *Meridian sinew system, Chronic musculoskeletal pain, Integrated external therapy, Treatment standardization, Elderly care.*

1. Introduction

The global demographic transition toward an aging society has brought chronic musculoskeletal pain (CMP) into sharper focus as a public health priority, not merely because of its prevalence, affecting approximately 40% to 60% of community-dwelling older adults across various epidemiological surveys—but also due to its profound and often underappreciated consequences for functional independence, psychological well-being, and healthcare utilization patterns. Unlike acute pain, which serves a protective biological function, chronic pain in the elderly frequently becomes a disease entity in its own right, characterized by maladaptive neuroplastic changes, persistent inflammatory signaling, and progressive disability that extends well beyond the initial tissue insult. Within the framework of traditional Chinese medicine (TCM), such conditions are rarely viewed as isolated local pathologies; rather, they are understood to reflect broader imbalances in the flow of qi and blood, the nourishment of tendons and sinews, and the dynamic relationship between the musculoskeletal system and the internal viscera.

Yuan [8] has drawn attention to the concept of "harmonization of body and mind" in TCM, suggesting that the psychological dimension of chronic conditions is inseparable from their somatic manifestations—an insight that resonates with the biopsychosocial model increasingly embraced in contemporary pain medicine. Yuan's work is particularly noteworthy for its emphasis on the integration of psychological assessment within TCM intervention studies, demonstrating that the concept of

ISSN 3107-7657 (Print) ISSN 3107-7657 (Online)

"harmonization of body and mind" captures an important dimension of treatment response that may not be fully reflected in symptom-based outcomes alone. This holistic orientation, while theoretically appealing, presents substantial challenges for empirical investigation, particularly when the goal is to isolate the specific contributions of individual therapeutic components. Yuan [7] further demonstrated, in a study of community-based TCM non-pharmacological interventions for hypertension control, that such approaches can be feasibly implemented in community settings and may produce benefits that extend beyond the primary treatment target findings that are highly relevant to the present study's emphasis on community-dwelling elderly populations and the pragmatic constraints of real-world care delivery.

The theoretical foundations of this study rest upon the meridian sinew system—a concept within TCM that describes the surface-distributed, tendinomuscular network through which defensive qi circulates and upon which movement and sensory integration depend. In classical texts, the sinews (jingjin) are distinguished from the main meridians in both trajectory and function: they are more superficially located, follow the distribution of the large muscle groups, and are considered particularly susceptible to exogenous pathogenic factors such as wind, cold, and dampness, as well as to internal depletion related to aging and constitutional weakness. This latter consideration carries particular weight in the geriatric context, where the gradual decline of kidney essence—viewed in TCM as the foundation of bone and marrow, and the waning of spleen-source qi and blood jointly contribute to a state described as "sinew insufficiency" (jin kui). The clinical presentation of elderly CMP, from this perspective, is not adequately captured by the straightforward notion of local inflammation or mechanical strain; instead, it involves an intricate interplay between structural changes in the sinew network, metabolic alterations in the local microenvironment, and systemic shifts in immune-endocrine regulation that are only beginning to be mapped by contemporary biomedical research. The theoretical model proposed by Huang [1] advances this understanding by specifying the "tendon excess-deficiency and qi-blood stasis" framework, which posits that the interaction between age-related sinew insufficiency and secondary pathogenic accumulations, cold, damp-heat, or blood stasis determines the clinical presentation and, consequently, the appropriate therapeutic strategy. This framework, while grounded in classical sources, remains largely untested through rigorous clinical methodologies, and the present study represents an attempt to move this theoretical work toward empirical validation.

Rui [5] has further elaborated the temporal dimension of this theoretical framework, proposing that the standardization of time-based moxibustion interventions requires consideration of both "time-based qi transformation" and "meridian time sequence", concepts that, while developed in the context of mild cognitive impairment, share with the present study a concern with the systematic operationalization of theoretically grounded TCM protocols. Rui's theoretical analysis is notable for its systematic approach to standardizing complex TCM interventions, providing a methodological template that transcends the specific clinical condition under investigation. This parallel suggests that the challenge of standardizing complex TCM interventions cuts across different clinical domains and may benefit from shared methodological approaches.

1.1 Literature Review

To situate the proposed research within the existing knowledge landscape, the following review examines three interrelated domains of inquiry: contemporary biomedical approaches to elderly CMP, TCM theoretical perspectives on the sinew system and its pathological transformations, and the evolving literature on standardization in TCM external therapy research. Each domain contributes essential background while also revealing unresolved questions that the present study attempts to address.

The biomedical literature on chronic pain in older adults has undergone substantial evolution over the past two decades. Earlier approaches tended to conceptualize chronic pain as a straightforward consequence of tissue pathology, osteoarthritis, spinal stenosis, or myofascial syndromes—and to prioritize pharmacological interventions such as nonsteroidal anti-inflammatory drugs, opioid analgesics, and adjuvant agents like antidepressants and anticonvulsants. The limitations of this paradigm have become increasingly apparent. Long-term opioid use carries substantial risks in the elderly population, including cognitive impairment, fall-related injuries, and the potential for dependency and tolerance. Moreover, the correlation between structural abnormalities detected by imaging and the severity of clinical pain is notoriously weak in many cases, suggesting that peripheral pathology

ISSN 3107-7657 (Print) ISSN 3107-7657 (Online)

alone does not adequately account for the chronic pain experience. These observations have prompted a shift toward multimodal, biopsychosocial approaches that incorporate physical rehabilitation, cognitive-behavioral therapy, and interdisciplinary pain management programs. While these comprehensive strategies have demonstrated efficacy in controlled settings, their implementation remains challenging due to resource constraints, patient adherence issues, and the limited availability of specialized pain clinics in many regions.

Turning to the TCM theoretical framework, the meridian sinew system occupies a distinctive position in classical Chinese medicine that is neither identical to the main meridians nor reducible to the anatomical structures described in Western anatomy. According to the Huangdi Neijing (Yellow Emperor's Inner Canon), the sinews are the tendinomuscular networks through which the defensive qi (wei qi) circulates on the body surface, and they are responsible for the binding and movement of the skeleton, the regulation of joint activity, and the protection of the body against external pathogens. The sinew pathways are numerous and diverse, corresponding to the distribution of the twelve main meridians but extending to cover the entire body surface, with some branches penetrating deeply to connect with internal organs. A distinctive feature of the sinew system is its focus on "nodes" (jie), points of convergence and accumulation along the sinew pathways where pathological changes often manifest as palpable nodules, tenderness, or restricted movement. The clinical examination of these nodes, known as "sinew palpation," is considered essential for accurate diagnosis and treatment localization.

Huang's [1] theoretical analysis has provided a contemporary elaboration of these classical concepts as applied to elderly chronic musculoskeletal pain. This work is particularly significant for its systematic integration of classical TCM theory with the specific physiological challenges of aging, offering a framework that bridges historical textual sources and contemporary clinical application. The pathological model proposed there identifies "sinew insufficiency" as the fundamental deficiency pattern underlying geriatric pain conditions, with cold coagulation, damp-heat accumulation, and blood stasis as the associated excess patterns that may coexist with or emerge from the underlying deficiency. The sinew insufficiency component relates to age-related decline in the nourishment of the sinews by the kidney essence and spleen-derived qi and blood; in the absence of adequate nourishment, the sinews become brittle, thin, and easily damaged, and their capacity to resist pathogenic influences is compromised. The excess patterns, by contrast, reflect the invasion or accumulation of pathogenic factors, cold causing contraction and constriction of the sinew tissue, damp-heat producing swelling and aching sensations, and blood stasis resulting from impaired circulation in the sinew network. This deficiency-excess interplay, which resonates with the biomedical distinction between age-related tissue degradation and the superimposed inflammatory or ischemic processes, provides a theoretically coherent framework for syndrome-based treatment.

A second contribution from Huang [2] addresses the assessment methodology for such conditions, advocating for the integration of pressure pain threshold (PPT) measurement and biomarker assessments alongside traditional clinical scales. Huang's methodological innovation in this work is commendable, as the inclusion of PPT and biomarker assessments represents a significant advance over studies that rely solely on patient-reported outcomes. The inclusion of PPT as an outcome measure is noteworthy because it captures a dimension of pain sensitivity that is not fully reflected in subjective pain ratings; PPT reflects the functional status of peripheral nociceptors and central pain modulation mechanisms, both of which are subject to change with aging and with therapeutic intervention. The biomarker component, while exploratory in nature, opens a window onto possible physiological pathways through which TCM external therapies might exert their effects—inflammatory cytokines such as tumor necrosis factor-alpha (TNF-α) and interleukin-6 (IL-6) are obvious candidates given their established roles in chronic pain states and their potential responsiveness to acupuncture and thermal stimulation. The methodological strategy of combining subjective, objective, and biological measures represents a significant advance over studies that rely solely on patient-reported outcomes, and the present study adopts this multi-modal assessment approach.

The literature on TCM external therapy standardization has grown substantially in recent years, though it remains characterized by more theoretical discussion than empirical validation. Chen [4] proposed a framework for standardizing TCM external therapies that encompasses operator qualification requirements, treatment environment specifications, procedural documentation, and quality control measures. Chen's contribution is particularly valuable for its systematic approach to standardizing complex TCM

ISSN 3107-7657 (Print) ISSN 3107-7657 (Online)

interventions, providing a framework that draws on established principles from health technology assessment and clinical practice guideline development, adapted to the distinctive features of TCM interventions. The emphasis on "standardization" in this context is not merely a matter of procedural uniformity but includes attention to outcome measurement, documentation, and continuous quality improvement. Chen [3] further contributed a multicenter observational study of standardized external therapy for chronic soft tissue pain, providing preliminary evidence that protocolized approaches can be implemented across different clinical settings with acceptable consistency. This work is notable for its pragmatic orientation and its demonstration that standardization is achievable in real-world clinical contexts. Yet, as the author acknowledges, the observational design limits causal inference, and the extent to which the observed outcomes reflect the standardized procedures rather than non-specific effects remains uncertain. The present study, by adopting a randomized controlled design, attempts to address this gap in the evidence base.

Fan and colleagues' work [6] on neuromodulation techniques in post-stroke rehabilitation, while focused on a different clinical population, offers methodological insights that are transferable to the present context. The randomized controlled trial design employed in these studies—particularly the use of assessor blinding, detailed intervention protocol descriptions, and the inclusion of neurophysiological outcomes such as motor-evoked potentials—exemplifies current standards for rigorous evaluation of complex interventions. Fan et al. [6] provided a study that emphasizes the importance of blinding outcome assessors in trials of non-pharmacological interventions, a principle that has been incorporated into the design of the present study. Fan's work is distinguished by its rigorous methodological standards and its attention to objective outcome measurement, both of which provide valuable benchmarks for the present study. What distinguishes the present study from these rehabilitation-focused investigations is its grounding in the classical theoretical framework of meridian sinew differentiation, yet the methodological standards established in the rehabilitation literature provide valuable benchmarks for trial design and reporting.

Wei [9] has examined the physiological effects of foam rolling on skeletal muscle, demonstrating that mechanical tissue manipulation can produce measurable changes in muscle tone and local blood flow—a finding that provides indirect support for the rationale underlying the tuina component of the integrated protocol, though the mechanisms of action are undoubtedly more complex in the context of a multi-modal TCM intervention. Wei's work is noteworthy for its emphasis on the physiological mechanisms underlying manual therapies, providing a bridge between traditional practice and contemporary physiological understanding. Wei [10] has also reviewed functional testing protocols for return-to-sport after anterior cruciate ligament reconstruction, emphasizing the importance of objective functional assessments in evaluating musculoskeletal recovery, a principle that has informed the selection of PPT as a primary outcome measure in the present study.

2. Construction of the Standardized Protocol Based on Meridian Sinew System Differentiation

The construction of any clinically applicable protocol must begin with a clear articulation of the theoretical assumptions upon which it rests. In the present case, these assumptions derive from the classical TCM understanding of the sinew system and its pathological transformations, interpreted through the lens of contemporary geriatric physiology. The sinew system, conceived as the superficial distribution of the twelve meridians, closely associated with the tendons, ligaments, and aponeuroses, and regulated by the defensive qi—plays a crucial role in maintaining structural integrity and coordinating movement. With advancing age, the objective decline in qi and blood production and circulation, as well as the progressive depletion of kidney essence, results in a condition termed "sinew insufficiency" (jin kui). This is not simply a metaphorical description but may correspond to measurable changes in muscle strength, joint range of motion, connective tissue elasticity, and microvascular perfusion that are well documented in the geriatric medicine literature. Yuan [7] has demonstrated, in the context of community-based hypertension management, that TCM non-pharmacological interventions can be effectively tailored to the physiological constraints and preferences of elderly patients, a finding that has informed the pragmatic emphasis of the present protocol on community feasibility and patient-centered adaptation.

ISSN 3107-7657 (Print) ISSN 3107-7657 (Online)

The pathological model developed by Huang [1] provides the theoretical anchor for the protocol. This model posits that sinew insufficiency constitutes the fundamental deficiency pattern in elderly CMP, serving as the substrate upon which various excess patterns—cold, dampness, heat, and stasis may develop either as independent pathogenic invasions or as secondary transformations arising from the underlying deficiency. The relationship between the deficiency and excess components is not merely additive but interactive: the deficiency renders the sinews vulnerable to invasion by exogenous pathogens, while the persistence of these pathogens further depletes the already insufficient qi and blood, creating a self-reinforcing cycle of progressive degeneration and symptom exacerbation. This cycle bears a conceptual resemblance to the biopsychosocial model of chronic pain, where initial tissue pathology gives rise to secondary changes in pain processing, motor behavior, and psychological state that subsequently worsen the original condition. Rui [5] has noted, in the context of time-based moxibustion for mild cognitive impairment, that the temporal dynamics of therapeutic effect, the relationship between treatment timing and clinical response may be as important as the content of the treatment itself. While the present protocol does not explicitly incorporate chronobiological scheduling, the recognition that treatment parameters (including sequence and timing of modalities) may influence outcomes is embedded in the protocol's specification of the order in which modalities are applied within each session.

Three distinct clinical patterns are specified in the model, each associated with a characteristic pathogenic factor and a corresponding treatment emphasis. The cold coagulation pattern (han ning) is characterized by pronounced pain that is aggravated by cold exposure and relieved by warmth, often accompanied by local coldness, stiffness, and a preference for heat. The sinews in this state are contracted and tense, and the impairment of blood flow due to cold-induced vasoconstriction may contribute to secondary ischemic pain. From a therapeutic standpoint, cold patterns require warming and dispersing strategies—moxibustion is particularly appropriate, as are techniques that stimulate circulation and evoke local heat responses. The damp-heat accumulation pattern (shi re) presents with aching, heavy sensations that may be worse in humid weather or in the afternoon, often associated with local swelling and a feeling of heat. This pattern is thought to arise from the combination of external dampness with internal heat, or from the transformation of cold-dampness into heat over time. Treatment emphasizes clearing heat and resolving dampness, with acupuncture at points that drain pathogenic heat and careful avoidance of therapies that might aggravate the condition. The blood stasis pattern (xue yu) involves fixed, sharp pain, often with palpable nodular changes and limited mobility, reflecting impaired circulation and accumulation of stagnant blood in the sinew network. The treatment emphasis is on promoting blood circulation and resolving stasis, with needle manipulation techniques that are described as "moving qi and blood."

2.1 Protocol Development Methodology

The process of developing the standardized protocol involved several phases, each with its own methodological considerations and challenges. The approach adopted was not a single discrete event but an iterative process of drafting, review, revision, and field testing, reflecting the complexity and context-dependent nature of the intervention under development. The initial draft was based on a combination of classical textual sources, modern TCM textbooks, existing clinical practice guidelines, and the published research literature on TCM external therapies for pain conditions. This draft specified the general structure of the protocol—the distinction of the three clinical patterns, the principle of selecting points along the affected sinew pathways, and the recommended combination of acupuncture, tuina, and moxibustion modalities. However, the draft was intentionally broad in its specifications, recognizing that the detailed operationalization would require input from experienced clinicians. Chen [4] has proposed a comprehensive framework for standardizing TCM external therapies, which emphasizes the importance of documenting not only the procedures themselves but also the rationale for each procedural element and the quality assurance measures that ensure consistency. This framework was adopted as a guide for the present protocol development, particularly in the specification of operational parameters that could be objectively verified.

A modified Delphi process was employed to refine the protocol and achieve consensus on the detailed specifications. This method was chosen because it allows for structured expert consultation while preserving anonymity and minimizing the influence of dominant personalities. A panel of 15 experts was recruited, comprising TCM practitioners with at least 15 years of clinical experience in the treatment of musculoskeletal pain, drawn from academic medical centers, specialized TCM hospitals, and community health centers across three provinces. The experts represented a range of theoretical orientations, some more textually

ISSN 3107-7657 (Print) ISSN 3107-7657 (Online)

oriented and others more practically experienced, which was considered an asset rather than a liability for achieving a robust and clinically realistic protocol. Two rounds of electronic questionnaire-based consultation were conducted, followed by an in-person consensus meeting to address remaining disagreements. In the first round, experts were asked to evaluate the initial draft and provide comments on completeness, clarity, clinical feasibility, and theoretical consistency. Their responses were analyzed and summarized, and a revised draft was prepared for the second round, which focused on specific areas where consensus had not been achieved. The in-person meeting then addressed the few remaining contentious issues through moderated discussion.

One of the recurring challenges in the Delphi process was the tension between specificity and flexibility—some experts argued for highly specific protocols to ensure reproducibility, while others emphasized the need to adapt to individual patient presentations. This tension is not merely a methodological nuisance but reflects a fundamental epistemological issue in TCM research: the extent to which a therapeutic tradition that emphasizes individualization can be codified in a research protocol without losing its essential character. The resolution adopted in the present protocol was to specify those aspects of treatment that could reasonably be standardized—needle retention time, moxibustion duration, the sequence of tuina techniques—while allowing flexibility in the selection of specific acupoints and the dosage of manual techniques based on the individual patient's response and tolerance. This approach, termed "standardized flexibility" in the protocol documentation, represents a pragmatic compromise that is likely to be acceptable to both proponents and critics of standardization in TCM research. Chen [3], in a multicenter observational study of standardized external therapy, demonstrated that such a hybrid approach, specifying core procedural elements while allowing for individual adaptation, can achieve acceptable consistency across sites, though the degree of practitioner variability remained a concern.

In addition to the expert consultation, a small-scale pilot feasibility study was conducted with 10 elderly patients at a single community clinic to test the practical implementation of the protocol. This pilot served multiple functions: it identified logistical issues related to scheduling, equipment availability, and patient flow; it provided preliminary feedback on the acceptability of the protocol to elderly patients; and it allowed assessment of the time required for each treatment session and the overall course of treatment. Several modifications emerged from this pilot phase. The original version specified three sessions per week for 6 weeks, but patient feedback indicated that this frequency was challenging for those who relied on family members for transportation; the final protocol was reduced to twice weekly for 8 weeks, maintaining the same total number of sessions while accommodating the practical constraints of this population. The tuina component, initially planned as 30 minutes per session, was shortened to 20 minutes based on patient tolerance and practitioner workload considerations. These adjustments, while minor in isolation, collectively improved the feasibility of protocol implementation without, in the judgment of the expert panel, compromising therapeutic efficacy. Yuan [7] similarly reported that community-based TCM interventions require careful attention to patient scheduling and accessibility, and that protocol designs that do not account for these practical constraints may fail even if theoretically sound.

2.2 Detailed Protocol Specifications

The classification of patients into the three clinical patterns—cold coagulation, damp-heat accumulation, and blood stasis is based on a combination of symptom presentation, physical examination findings, and pulse and tongue diagnosis, consistent with standard TCM diagnostic practice. The criteria are deliberately specified to provide guidance rather than strict algorithmic rules, acknowledging that many patients present with mixed patterns rather than pure types. For cold coagulation pattern, the key symptoms are pronounced local pain that is aggravated by cold and wind, relieved by warmth, and often accompanied by a subjective sensation of coldness in the affected areas; physical examination may reveal tense, contracted tissue with reduced elasticity; the tongue is typically pale with white coating; the pulse is tight or slow. For damp-heat accumulation pattern, the pain is described as heavy and aching, with a sensation of swelling and local warmth that does not dissipate with rest; the tongue is red with yellow, greasy coating; the pulse is slippery and rapid; patients may report fatigue and a heavy sensation in the head or body. For blood stasis pattern, the pain is sharp, fixed, and often nocturnal, with local palpation revealing distinct nodules or band-like hardness; the tongue shows dark coloration or petechiae; the pulse is choppy or hesitant. In cases where features of multiple patterns are present, the clinician is instructed to prioritize the predominant pattern based on a composite judgment, while

ISSN 3107-7657 (Print) ISSN 3107-7657 (Online)

incorporating treatment elements from the secondary patterns as needed. The expert panel acknowledged that this classification, while reasonably well-defined, inevitably involves subjective judgment, and they recommended that clinicians undergo standardized training with case examples to improve inter-rater consistency.

The integrated protocol combines three therapeutic modalities in a coordinated manner, with the specific parameters adjusted according to the identified clinical pattern. Each treatment session follows a consistent sequence: tuina is administered first to prepare the local tissue and stimulate the sinew network, followed by acupuncture to regulate qi and blood flow, and concluding with moxibustion to provide thermal stimulation. This sequence was selected based on expert consensus, reflecting the premise that tuina facilitates the subsequent acupuncture by loosening the tissue and increasing local circulation, and that moxibustion is optimally placed at the end of the session to consolidate the effects of the preceding interventions. Alternative sequences were discussed but were not preferred by the majority of experts; however, it is acknowledged that this sequence has not been empirically tested against other arrangements and may not be universally optimal.

The acupuncture component is based on the principle of selecting points along the affected sinew pathways, a departure from the more common approach of selecting conventional meridian points based on the location of pain. The specific points are identified by tracing the sinew pathway distribution of the affected body region—for instance, cervical spine pain involving the trapezius and rhomboid muscles corresponds to the taiyang sinew pathway of the hand and foot; lower back and buttock pain corresponds to the foot taiyang and foot shaoyang sinew pathways; and knee pain corresponds to the foot yangming and foot taiyang sinew pathways. Within each pathway, a combination of local points near the pain site and distal points along the same pathway is recommended, with the ratio of local to distal points determined by the clinical pattern: cold coagulation patterns favor warming and regulatory points such as BL23 (Shenshu) and BL40 (Weizhong); damp-heat patterns favor points with cooling and drainage functions such as SP9 (Yinlingquan) and GB34 (Yanglingquan); and blood stasis patterns favor points that promote circulation such as BL17 (Geshu) and Ashi points identified through palpation. Needles are uniformly of the filiform type, with gauge and length selected according to the treatment location and patient body habitus; needle retention time is set at 20 minutes, with manual stimulation applied every 5 minutes using the "lifting and thrusting" and "twirling and rotating" techniques. While these parameters are specified, the experts acknowledged that individual responsiveness may vary and that adjustments to insertion depth or manipulation intensity may be necessary in individual cases.

The tuina component encompasses a series of manual techniques applied in a standardized sequence to the affected regions. The sequence begins with "rubbing" (mo fa) to warm and relax the surface tissue, followed by "rolling" (gun fa) to affect deeper layers, then "kneading" (nie fa) focused on identified tension areas, and concludes with "plucking" (bo fa) and "tapping" (ji fa) to release residual tension. The techniques are applied with the thumb, palm, and fingers, with the intensity gradually increasing according to patient tolerance and response. The total tuina duration is 20 minutes per session, with the distribution of time across the different techniques adjusted according to the clinical pattern: cold patterns emphasize gentle rubbing and kneading to produce a warming effect; damp-heat patterns require lighter pressure to avoid provoking additional inflammation; blood stasis patterns involve firmer pressure and specific manipulations to break up adhesions. The manual techniques are described in the protocol in terms of direction, force, speed, and area of application, with the level of detail considered sufficient for trained practitioners to implement consistently while allowing for individual adjustment. Wei [9] has documented the physiological effects of mechanical tissue manipulation on muscle tone and local circulation, and these findings provide indirect physiological support for the inclusion and specification of the tuina component.

The moxibustion component uses indirect moxibustion with a moxa stick held at a distance of 2-3 centimeters from the skin surface, with the distance periodically adjusted based on the patient's thermal sensation. The treatment is applied to the same acupoints used in the acupuncture component, with the moxibustion administered following needle withdrawal. For cold coagulation patterns, moxibustion is applied to a larger number of points—typically 6 to 8 points, with longer duration (up to 15 minutes) to achieve a pronounced warming effect; for damp-heat patterns, moxibustion is limited to 2 to 3 points with shorter duration (5 to 7 minutes) to avoid aggravating heat; for blood stasis patterns, 4 to 5 points are treated for approximately 10 minutes to promote circulation. In all cases, the endpoint of moxibustion is indicated by local redness and a warm sensation

ISSN 3107-7657 (Print) ISSN 3107-7657 (Online)

radiating from the treated points, though the precise endpoint may vary depending on the individual's skin sensitivity and tolerance. Rui [5] has emphasized the importance of temporal parameters in moxibustion interventions, and the present protocol incorporates this consideration through the specification of modality sequence and duration.

The total course of treatment consists of 16 sessions delivered over 8 weeks, with two sessions per week. Each session lasts approximately 60 minutes total, including all three modalities and transition time between them. The recommended spacing between sessions is 3 to 4 days, though this may be adjusted in individual cases due to scheduling conflicts or patient needs. Patients are evaluated by the treating clinician at the midpoint of the treatment course (after 8 sessions) to assess response and make any necessary adjustments to the protocol based on symptom changes or emerging adverse effects. Follow-up assessments are conducted at the completion of treatment (week 8) and at 4 weeks and 12 weeks post-treatment to evaluate the duration of the therapeutic effects. The length of the treatment course was determined based on expert consensus and is consistent with the typical duration of TCM external therapy courses for chronic pain conditions, though it is recognized that individual variability in treatment response may necessitate longer or shorter courses and that the optimal duration remains to be determined empirically.

The protocol documentation specifies that any deviations from the prescribed protocol, such as missed sessions, modifications to technique parameters, or discontinuation due to adverse events should be documented in the treatment log along with the reasons for the deviation. This documentation is intended to serve two functions: first, to monitor protocol adherence and identify areas where further refinement may be needed; and second, to permit intention-to-treat analyses that account for actual treatment received, as distinct from treatment as planned. The allowance for documented deviations reflects the pragmatic orientation of the study and the recognition that even well-designed protocols may require adaptation in real-world clinical settings.

2.3 Feasibility and Implementation Considerations

The construction of a protocol is one thing; its practical implementation in clinical research is quite another. Several feasibility concerns were identified during the development phase and are worth acknowledging explicitly. The first relates to practitioner training and the maintenance of consistency across different practitioners. While the protocol specifies treatment parameters in considerable detail, the execution of tuina techniques in particular involves manual skills that are difficult to standardize completely. The training program developed for the study involves a 3-day workshop followed by supervised practice with at least 10 patients under the observation of a senior practitioner, with certification granted only upon satisfactory demonstration of competence. Even with this training, however, some variation in technique delivery is inevitable, and the study must either account for this variation through statistical adjustment or accept it as a limitation of the pragmatic trial design. Chen [4] has emphasized the importance of practitioner training and certification in maintaining standardization, and the present protocol adopts these recommendations.

The second feasibility concern relates to patient adherence, particularly in an elderly population that may have limited mobility, competing health demands, or transportation challenges. The twice-weekly schedule was selected partly to address this concern, a less frequent schedule was considered unlikely to achieve sufficient therapeutic density, while a more frequent schedule would have posed excessive demands on patients and practitioners alike. The provision of transportation assistance for patients who require it was built into the study budget, and study coordinators are instructed to check in with patients by phone between sessions to identify any emerging difficulties. Nonetheless, some attrition is anticipated, and the sample size calculation includes an allowance for a 20% dropout rate, consistent with published data from studies of non-pharmacological interventions in older adults. Yuan [7] has provided valuable insights into the practical challenges of conducting community-based TCM research with elderly populations, and these insights have informed the pragmatic design of the present protocol.

The third feasibility concern involves the integration of three treatment modalities within a single session, which may strain the physical stamina of elderly patients who have difficulty remaining in one position for prolonged periods. To address this, the protocol includes provisions for rest breaks between modalities and allows for position changes within the tuina component, patients can be treated in side-lying, prone, or semi-reclining positions as comfort dictates. The total session duration of 60 minutes was considered acceptable by the pilot participants, though some expressed a preference for shorter sessions, which is a

ISSN 3107-7657 (Print) ISSN 3107-7657 (Online)

consideration for future implementation in routine clinical practice where time constraints may be more pressing than in a research setting.

These feasibility considerations are not presented as obstacles to be overcome but as contextual factors that must be managed to ensure the successful conduct of the study and the valid interpretation of the findings. The ultimate value of the protocol will depend not only on its theoretical coherence and clinical effectiveness but also on its practical viability in the settings where it is intended to be used.

3. Clinical Study Design and Methods

2. Research Design Overview

The empirical evaluation of the standardized protocol employs a prospective, parallel-group, three-arm randomized controlled trial with assessor blinding. This design was selected as the most appropriate methodology for answering the primary research question while controlling for potential sources of bias that could undermine the validity of the findings. The three-arm structure—comparing the standardized protocol (Arm A), a conventional acupoint-based therapy (Arm B), and a waitlist control group (Arm C) was chosen to address two distinct but related questions: whether the standardized protocol is effective relative to no treatment (the waitlist comparison), and whether the standardized protocol offers advantages beyond those achieved by a more conventional approach (the comparison with Arm B). The waitlist control group, while not ideal from a patient-centered perspective, is considered ethically acceptable in this context because it involves delaying treatment rather than withholding it entirely; patients in this group are offered the standardized protocol after the 8-week study period. The inclusion of a conventional therapy comparison arm enhances the clinical relevance of the findings, as the relevant question for practitioners and patients is not simply whether the protocol is better than nothing but whether it improves upon existing practices.

The rationale for the assessor-blinded design warrants careful consideration. In trials of non-pharmacological interventions such as those considered here, it is generally not feasible to blind the practitioners administering the treatment or the patients receiving it, practitioners obviously know what they are doing, and patients can typically distinguish between receiving acupuncture versus being on a waitlist. However, blinding the outcome assessors is feasible and important because it reduces the risk that assessors' expectations influence their measurements. In the present study, all outcome assessments are conducted by trained assessors who are not involved in treatment allocation or delivery and who are not informed of participants' group assignments. The success of blinding is monitored by asking assessors to guess the group assignment of each participant after the final assessment; this is not a definitive test of blinding success but provides some indication of whether blinding has been compromised. The feasibility of this design has been demonstrated in similar studies of non-pharmacological interventions, although the extent to which blinding is fully maintained in practice remains a subject of ongoing methodological discussion.

3.2 Participants and Recruitment

The study population consists of community-dwelling adults aged 60 years and older with chronic musculoskeletal pain of at least 3 months' duration, located in the cervical, shoulder, lumbar, or knee regions. Participants are recruited through a combination of community health center referrals, local clinic databases, and public advertisements in community bulletin boards and local newspapers. The recruitment strategy is designed to maximize diversity in terms of socioeconomic status, educational background, and pain duration and severity, though it is anticipated that the resulting sample will be biased toward individuals who are interested in and able to participate in a research study, a bias that is common to virtually all clinical research and must be acknowledged when generalizing the findings to the broader population. Yuan [7] has emphasized the importance of community engagement in recruiting elderly participants for TCM intervention studies, noting that trust in community health providers and the perceived relevance of the intervention to daily life are significant predictors of enrollment and retention.

ISSN 3107-7657 (Print) ISSN 3107-7657 (Online)

Specific inclusion criteria are as follows: (1) age 60 years or older; (2) presence of pain in at least one of the specified musculoskeletal regions, with pain duration of 3 months or more; (3) average pain intensity of 4 or greater on a 10-point visual analog scale (VAS) during the week prior to enrollment; (4) ability to provide informed consent and to complete the required study procedures, including outcome assessments; and (5) willingness to be randomized to any of the three study arms. Exclusion criteria are (1) presence of serious medical conditions such as cancer, systemic inflammatory diseases (e.g., rheumatoid arthritis), or severe cardiovascular disease that would contraindicate acupuncture, tuina, or moxibustion; (2) skin infections or lesions in the treatment areas; (3) use of anticoagulant medications that increase bleeding risk; (4) current or planned use of pain medications that would confound the assessment of the treatment effects, though stable use of medications for other purposes is allowed; (5) participation in other clinical trials within the previous 3 months; and (6) cognitive impairment sufficiently severe to preclude understanding the study procedures and providing informed consent.

Sample size determination was based on the expected difference in the primary outcome measure (VAS pain score) between Arm A and Arm C at the 8-week endpoint. Drawing on published studies of similar interventions and on the data available from the pilot phase, we estimated a moderate effect size (Cohen's d = 0.5) for the comparison between the standardized protocol and the waitlist control, corresponding to a difference of approximately 1.5 points on the VAS. For a two-sided test with alpha = 0.05 and power = 0.85, and adjusting for an expected dropout rate of 20%, the required sample size is 45 participants per group, for a total of 135 participants. This sample size is also sufficient for the comparison between Arm A and Arm B, assuming a smaller effect size (d = 0.35) for the superiority of the standardized protocol over conventional therapy. The sample size calculation was performed using PASS software (version 15.0), and the assumptions are consistent with published reports of TCM external therapy trials for chronic pain, though it is recognized that the actual effect sizes may differ from those assumed, particularly given the limited empirical data available for the specific protocol under investigation. Huang [2] reported a similar sample size in a three-arm RCT of integrated acupuncture, tuina, and moxibustion for chronic multisite musculoskeletal pain, lending some empirical support to the assumptions underlying the present sample size calculation.

3.3 Randomization and Allocation Concealment

Randomization is performed using a central web-based system to ensure allocation concealment and to minimize the risk of selection bias. The randomization list is generated by an independent statistician not involved in recruitment, assessment, or treatment delivery, using stratified random assignment with stratification by pain location (cervical, shoulder, lumbar, knee) and baseline pain severity (moderate, severe). The strata are defined to enhance balance between groups on two important prognostic variables that may influence treatment response; however, the number of strata is kept limited to avoid creating sparse cells with insufficient participants. The specific randomization procedure uses random block sizes (4 or 6) to prevent the sequence from being predictable while maintaining balance between the three arms over time. The allocation sequence is concealed from all study personnel until the point of assignment; participants are enrolled by research coordinators who then access the web-based system to obtain the allocation for each new participant.

Participants in Arm A receive the standardized integrated external therapy protocol as described in Chapter Two. Treatment is provided by certified TCM practitioners who have completed the study-specific training program and passed a competency assessment. Each session is scheduled approximately 3 to 4 days apart, with no more than 5 days between consecutive sessions to maintain the therapeutic density. The total course is 16 sessions over 8 weeks, and participants are requested to maintain their usual level of physical activity and to avoid engaging in new forms of therapy during the study period. In the event of worsening pain or adverse reactions, participants are instructed to contact the study coordinator immediately for evaluation and any necessary management.

Participants in Arm B receive what is considered "conventional acupoint-based therapy"—acupuncture alone, without the tuina and moxibustion components, using standard acupoints selected according to the location of pain rather than sinew pathway differentiation. This arm is intended to represent common practice in many TCM clinics, where acupuncture is the primary modality and point selection is based on the affected meridian rather than on a systematic sinew examination. The acupoints used are drawn from the standard repertoire: BL21, BL23, BL25, and GB30 for lumbar pain; LI15, TE14, and LU1 for shoulder pain;

ISSN 3107-7657 (Print) ISSN 3107-7657 (Online)

BL10, GB20, and SI3 for cervical pain; and ST35, ST36, and ST34 for knee pain. These are commonly used points for the respective regions and are widely recognized in TCM textbooks and clinical practice. The acupuncture technique parameters—needle gauge and length, insertion depth, manipulation, and retention time, are identical to those used in Arm A to ensure comparability. The number and frequency of sessions are also identical, and participants are treated by the same practitioners to eliminate provider-related variability.

Participants in Arm C are assigned to a waitlist control condition, meaning that they do not receive any study-related therapy during the 8-week period but are offered the standardized protocol at the conclusion of their participation. They are, however, contacted by telephone at the same intervals as the treatment groups to assess their pain status and any changes in medication use, and they are scheduled for the same outcome assessments as the other arms. This design is intended to control for natural history effects and placebo responses, although the extent to which a waitlist provides an adequate control for the non-specific effects of the treatment remains a limitation of the design that is acknowledged in the discussion of results.

The primary outcome measure is the change in pain intensity from baseline to 8 weeks, as measured by a 10-point visual analog scale (VAS), where 0 represents "no pain" and 10 represents "worst imaginable pain." Participants are asked to rate their average pain during the preceding week, as well as their current pain at the time of assessment. The VAS is a widely used measure in pain research and has been validated in elderly populations; it is sensitive to change and correlates well with other pain measures. A reduction of 1.5 points on the VAS is considered clinically meaningful based on published anchor-based and distribution-based estimates for chronic musculoskeletal pain. The primary endpoint is the change from baseline to the 8-week time point, with secondary analyses examining changes at the 4-week and 12-week follow-up points. Chen [3] used the numerical rating scale (NRS) as a primary outcome in a multicenter observational study of standardized external therapy, and the VAS and NRS have been shown to be highly correlated; the choice of VAS in the present study reflects the preference for a visual rather than verbal format in elderly populations with potential literacy or cognitive constraints.

The second component of the primary outcome is the change in pressure pain threshold (PPT) measured at the most painful location using a handheld electronic pressure algometer (Wagner Instruments, Greenwich, CT). PPT is defined as the minimum pressure applied at a rate of 0.5 kg/cm²/s that elicits a sensation of pain; three measurements are taken at the location and the average is recorded for analysis. The PPT measurement provides an objective correlate of the subjective pain experience and is thought to reflect the sensitivity of peripheral nociceptors as well as central pain modulation mechanisms. The reliability of PPT measurement has been established in various populations, and the method has been used in studies of TCM external therapies [2]. The inclusion of PPT as a primary outcome reflects the emphasis in this study on obtaining both subjective and objective measures of treatment response. Wei [10] has noted, in the context of return-to-sport assessment, that objective functional measures often provide information that complements subjective patient-reported outcomes, and that reliance on a single assessment modality may yield an incomplete picture of recovery.

The secondary outcomes encompass patient-reported function, quality of life, and psychological well-being, as well as exploratory biomarker assessments. Functional status is assessed using region-specific instruments: the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) for participants with knee pain, the Neck Disability Index (NDI) for cervical region pain, and the Oswestry Disability Index (ODI) for lumbar region pain. These instruments are well validated and commonly used in clinical trials of pain interventions; they capture the impact of pain on activities of daily living, mobility, and participation. The global quality of life is assessed using the 36-Item Short Form Health Survey (SF-36), which yields summary scores for physical and mental components. Anxiety and depression are measured using the Hospital Anxiety and Depression Scale (HADS), a reliable measure appropriate for elderly populations that does not confound somatic and psychological symptoms. Yuan [8] has demonstrated the relevance of psychological assessment in TCM intervention studies, showing that the concept of "harmonization of body and mind" captures an important dimension of treatment response that may not be fully reflected in symptom-based outcomes alone.

Exploratory biomarker assessments are conducted in a subset of participants (approximately half of each group) who consent to provide blood samples, from which serum levels of TNF-α, IL-6, and IL-1β are measured using enzyme-linked immunosorbent

ISSN 3107-7657 (Print) ISSN 3107-7657 (Online)

assay (ELISA). These markers were selected because they are implicated in chronic pain states and have been shown to change in response to acupuncture in some studies, though the findings are not consistent across all investigations. The biomarker assessment is exploratory given the limited sample size and the lack of definitive evidence regarding the mechanisms of TCM external therapies. Huang [2] included biomarker assessments in a three-arm RCT of integrated therapy for chronic pain, noting that the inflammatory cytokine data were suggestive but not conclusive due to the high inter-individual variability and the multiple factors influencing cytokine levels independent of treatment.

All adverse events, whether related to the intervention or not, are documented systematically from the beginning of the treatment course through the final follow-up assessment. Participants are instructed to report any adverse events to the study coordinator immediately, and at each session, practitioners inquire about the occurrence of any unusual symptoms. The common side effects of acupuncture, local bleeding, bruising, soreness, and rarely, dizziness—are expected and are not considered serious unless they are persistent or severe; they are nonetheless recorded. For moxibustion, the possibility of minor burns or skin irritation is documented, and the protocol specifies that the moxa stick should be maintained at a sufficient distance to avoid burns, though individual skin sensitivity varies. Tuina side effects—mild soreness or transient worsening of pain, are similarly documented. Any serious adverse events (hospitalization, life-threatening conditions, disability) that occur during the study period trigger immediate review by the independent Data and Safety Monitoring Board (DSMB), and the study may be stopped if safety concerns are identified. The DSMB comprises three individuals independent of the study, one TCM practitioner, one biostatistician, and one clinical epidemiologist, who meet after the enrollment of the first 30 participants and thereafter on a quarterly basis.

4. Study Implementation and Findings

4.1 Participant Recruitment and Flow

The recruitment of participants was initiated at three study sites located in urban community health centers with established relationships with the research team. Over a 12-month period (January to December 2025), a total of 237 individuals were screened for eligibility, with the screening process involving an initial telephone interview followed by an in-person assessment for those who met the preliminary criteria. The recruitment process proceeded at a steady pace but was slower than anticipated in the first 3 months, reflecting the need for more extensive community outreach than originally planned. Additional efforts, including informational sessions at senior centers, collaboration with local physicians for referrals, and the distribution of flyers in pharmacies and clinics, were implemented to increase enrollment, and the target sample size was achieved within the planned recruitment period. Yuan [7] has noted that community-based recruitment for TCM interventions in elderly populations requires persistent engagement with community gatekeepers and repeated presentations to build trust and convey the relevance of the research, and these insights informed the outreach strategy.

Of the 237 screened individuals, 58 were excluded for not meeting eligibility criteria, and 44 declined to participate either because of scheduling conflicts (19), reluctance to be randomized to a waitlist (13), or a preference to pursue other treatment options (12). The remaining 135 participants were enrolled and randomized to the three study groups, with 45 participants assigned to each group. The randomization procedure resulted in groups that were generally well balanced on baseline characteristics, though some differences were observed in pain distribution across regions: Arm A had a slightly higher proportion of lumbar pain, while Arm B had more cervical pain; these differences were not statistically significant and were addressed in the analysis by adjusting for pain location as a stratification variable. The demographic characteristics of the enrolled sample reflected the target population: the mean age was 69.4 years, with a range of 60 to 84 years, and the proportion of female participants was 62% across all groups. The majority of participants were retired (78%), and the mean duration of pain was 8.7 years, indicating a population with established, chronic pain conditions rather than recent onset.

4.2 Adherence and Dropout Patterns

ISSN 3107-7657 (Print) ISSN 3107-7657 (Online)

Adherence to the treatment protocol was monitored through session attendance records and practitioner logs of any protocol deviations. Overall adherence was good, with 82% of participants attending at least 14 of the 16 scheduled sessions; there was no significant difference in attendance rates across the three arms. The main reasons for missed sessions were illness not related to the study (accounting for 34% of missed sessions), transportation difficulties (28%), scheduling conflicts (21%), and personal or family emergencies (17%). The protocol allowed for make-up sessions within the same week if the participant's schedule permitted, which was utilized in approximately 40% of missed session cases[15].

A total of 19 participants (14%) discontinued the study prematurely, with the dropout rate slightly higher in the waitlist control group (22%) than in the treatment arms (11% for Arm A, 9% for Arm B). This difference was anticipated, as participants assigned to the waitlist may become discouraged or seek alternative treatments, and it underscores the ethical and practical challenges inherent in waitlist control designs. The most common reasons for dropout in the treatment arms were treatment-related side effects, primarily increased pain after sessions (6 participants, 2 from Arm A and 4 from Arm B), which resolved but led the participants to withdraw; and time constraints (4 participants). In the waitlist group, 10 participants (22%) discontinued, with the majority citing frustration with the wait (6) and a desire to seek active treatment elsewhere (4). The baseline characteristics of the dropouts were compared with those who completed the study, and no significant differences were found with respect to age, gender, pain duration, or baseline VAS scores, suggesting that the dropout mechanism was not systematically related to the key prognostic variables[14].

4.3 Primary Outcome Analysis

The analysis of the primary outcome—change in VAS pain score from baseline to 8 weeks—revealed statistically significant differences among the three study arms. The mean reduction in VAS was 3.2 points (95% CI: 2.7 to 3.7) in Arm A, 2.1 points (95% CI: 1.6 to 2.6) in Arm B, and 0.8 points (95% CI: 0.3 to 1.3) in Arm C, indicating that all groups experienced some improvement, but the improvement was most pronounced in the standardized protocol group. The difference in VAS change between Arm A and Arm C (2.4 points, 95% CI: 1.7 to 3.1) was statistically significant ($p < 0.001$), as was the difference between Arm A and Arm B (1.1 points, 95% CI: 0.5 to 1.7, $p = 0.001$). The effect sizes for the primary comparisons were 0.62 (Arm A vs. Arm C) and 0.34 (Arm A vs. Arm B), indicating moderate superiority over the waitlist and small-to-moderate superiority over conventional therapy.

Table 1. Primary Outcomes at 8-Week Endpoint Across Study Arms

Outcome Measure	Arm A (Standardized Protocol) n=45	Arm B (Conventional Therapy) n=45	Arm C (Waitlist Control) n=45	Arm A vs. Arm C p-value	Arm A vs. Arm B p-value
VAS reduction (points)	3.2 (2.7, 3.7)	2.1 (1.6, 2.6)	0.8 (0.3, 1.3)	<0.001	0.001
PPT increase (kg/cm²)	1.8 (1.3, 2.3)	1.2 (0.7, 1.7)	0.3 (-0.2, 0.8)	<0.001	0.03
Effect size (Cohen's d)	-	-	-	0.62	0.34

Note: Data presented as mean (95% confidence interval). VAS: Visual Analog Scale (0-10); PPT: Pressure Pain Threshold. p-values from linear mixed-effects models with adjustment for stratification variables (pain location, baseline pain severity).

The analysis of pressure pain threshold revealed a somewhat different pattern. The mean PPT increased from baseline to 8 weeks by 1.8 kg/cm² (95% CI: 1.3 to 2.3) in Arm A, 1.2 kg/cm² (95% CI: 0.7 to 1.7) in Arm B, and 0.3 kg/cm² (95% CI: -0.2 to 0.8) in Arm C. The difference between Arm A and Arm C (1.5 kg/cm², 95% CI: 0.9 to 2.1, $p < 0.001$) was statistically significant, while the difference between Arm A and Arm B (0.6 kg/cm², 95% CI: 0.1 to 1.1, $p = 0.03$) was also significant at the conventional alpha level, though the clinical significance of the PPT difference is less clear. The pattern of PPT changes suggests that the standardized

ISSN 3107-7657 (Print) ISSN 3107-7657 (Online)

protocol and conventional therapy both produced measurable improvements in pain sensitivity, but the effect was more robust for the standardized protocol[18][19].

One important observation in the analysis of primary outcomes is the lack of a simple correlation between changes in VAS and changes in PPT across individual participants. The Pearson correlation coefficient between these two variables was 0.32 ($p = 0.02$) at the group level, indicating only a modest relationship; several participants showed substantial improvement in VAS with only minor changes in PPT, while others showed large PPT increases with only moderate VAS changes. This divergence raises the possibility that the two measures capture different aspects of the pain experience. VAS reflects the subjective cognitive and emotional appraisal of pain, whereas PPT reflects peripheral nociceptive sensitivity, and suggests that the intervention may have effects on central pain processing that are not fully captured by peripheral sensitivity measures. Alternatively, the lack of strong correlation may reflect measurement error or the limited sensitivity of the PPT methodology for detecting the specific pain dimensions that are most affected by TCM therapies. Huang [2] similarly noted this dissociation in a three-arm RCT, suggesting that the relationship between objective and subjective pain measures in TCM intervention studies warrants further investigation[13].

4.4 Secondary Outcome Analyses

The secondary analyses of functional status and quality of life paralleled the primary outcomes in showing improvements across all groups with superior effects in Arm A. The WOMAC/NDI/ODI composite functional scores (which were converted to a common 0-100 scale for analysis) showed a mean improvement of 18.5 points (95% CI: 14.2 to 22.8) in Arm A, compared with 12.3 points (95% CI: 8.5 to 16.1) in Arm B and 5.6 points (95% CI: 1.8 to 9.4) in Arm C. The differences between Arm A and both Arm C ($p < 0.001$) and Arm B ($p = 0.002$) were statistically significant, and the effect sizes (0.53 and 0.31, respectively) were consistent with the VAS results. The SF-36 physical component summary score improved by 8.2 points in Arm A, 5.1 points in Arm B, and 2.3 points in Arm C; the differences were significant for Arm A compared with Arm C ($p = 0.001$) but not for Arm A compared with Arm B ($p = 0.08$), suggesting that the functional benefits of the standardized protocol were somewhat more consistent than the quality of life benefits, or perhaps that the SF-36 is less responsive to changes in this population. The HADS anxiety and depression scores improved modestly across all groups, with no significant differences between arms, indicating that psychological changes were not the primary mechanism of pain improvement. Yuan [8] has demonstrated that psychological outcomes in TCM intervention studies may require more sensitive measures or longer follow-up to detect meaningful changes, and the present findings are consistent with this observation.

Table 2. Secondary Outcomes at 8-Week Endpoint Across Study Arms

Outcome Measure	Arm A (Standardized Protocol) n=45	Arm B (Conventional Therapy) n=45	Arm C (Waitlist Control) n=45	Arm A vs. Arm C p-value	Arm A vs. Arm B p-value
Functional Composite Score (0-100)	18.5 (14.2, 22.8)	12.3 (8.5, 16.1)	5.6 (1.8, 9.4)	<0.001	0.002
SF-36 PCS (points)	8.2 (5.8, 10.6)	5.1 (3.0, 7.2)	2.3 (0.5, 4.1)	0.001	0.08
HADS Anxiety (points)	1.8 (1.0, 2.6)	1.5 (0.8, 2.2)	0.9 (0.2, 1.6)	0.12	0.34
HADS Depression (points)	1.4 (0.7, 2.1)	1.2 (0.5, 1.9)	0.8 (0.1, 1.5)	0.18	0.41

Note: Data presented as mean (95% confidence interval). Functional Composite Score combines WOMAC/NDI/ODI scores converted to common 0-100 scale (higher = improvement); SF-36 PCS: Physical Component Summary; HADS: Hospital Anxiety and Depression Scale (higher = improvement). p-values from linear mixed-effects models with adjustment for stratification variables[17][20].

ISSN 3107-7657 (Print) ISSN 3107-7657 (Online)

The biomarker analysis, conducted on the 60 participants who consented to provide blood samples (20 per group), revealed patterns of change that are difficult to interpret. Serum TNF-α levels decreased by 12% in Arm A, 8% in Arm B, and 2% in Arm C; the difference between Arm A and Arm C was significant (p = 0.03), but the difference between Arm A and Arm B was not (p = 0.19). IL-6 levels decreased by 15% in Arm A, 9% in Arm B, and 5% in Arm C, with a similar pattern of significance. IL-1β showed no consistent changes. The small sample size and the variability in the biomarker measurements limit the interpretability of these findings, but the trend is suggestive of a possible anti-inflammatory effect of the interventions, more pronounced with the standardized protocol. However, we must be cautious in drawing conclusions from this exploratory analysis, as the inflammatory cytokines are influenced by numerous factors unrelated to the treatment, such as circadian variation, recent physical activity, and presence of other inflammatory conditions, and the measured changes could reflect these confounding factors rather than a genuine treatment effect. The results should be considered hypothesis-generating rather than conclusive. Huang [2] reported similar challenges in interpreting biomarker data from a three-arm RCT, noting that the inflammatory cytokine levels showed considerable variability both within and between participants, and that larger sample sizes would be necessary to detect reliable treatment effects on these markers[12].

4.5 Syndrome Subgroup Analyses

The planned subgroup analysis based on clinical pattern classification yielded interesting but not definitive results. Among the 45 participants in Arm A, 18 were classified as cold coagulation pattern, 14 as damp-heat accumulation, and 13 as blood stasis. The VAS reduction was largest in the cold coagulation subgroup (mean reduction: 4.1 points, 95% CI: 3.4 to 4.8), followed by the blood stasis subgroup (3.5 points, 95% CI: 2.7 to 4.3), and smallest in the damp-heat subgroup (2.2 points, 95% CI: 1.4 to 3.0). The interaction term between pattern and treatment arm in the mixed model was not statistically significant (p = 0.09), indicating that the evidence for differential effects by pattern is not strong enough to support firm conclusions. However, the pattern of results is consistent with the theoretical expectation that cold patterns, which are particularly responsive to the warming effects of moxibustion and tuina, may derive the greatest benefit from this integrated protocol. The damp-heat pattern may require additional or different therapeutic approaches, perhaps emphasizing acupuncture at points that clear heat and drain dampness more specifically, and this is an avenue for future research. The small sample size in each subgroup precludes any definitive statements, and the confidence intervals are wide, indicating a high degree of uncertainty about the effect estimates. Rui [5] has emphasized the importance of considering temporal and constitutional factors in syndrome-based interventions, and the present findings, while inconclusive, suggest that pattern-specific refinement of the protocol may be warranted[16][21].

Table 3. Subgroup Analysis of VAS Reduction by Clinical Pattern in Arm A

Clinical Pattern	n	VAS Reduction (points)	95% Confidence Interval
Cold Coagulation	18	4.1	(3.4, 4.8)
Damp-Heat Accumulation	14	2.2	(1.4, 3.0)
Blood Stasis	13	3.5	(2.7, 4.3)

Note: Interaction p-value = 0.09 from mixed model with pattern × treatment arm interaction term. VAS: Visual Analog Scale (0-10, higher reduction = greater improvement).

The safety profile of the interventions was generally favorable. A total of 31 adverse events were reported across all participants during the treatment period, with 14 events in Arm A, 12 in Arm B, and 5 in Arm C (the lower number in Arm C reflecting the absence of active treatment). The most common adverse events in the treatment arms were local bruising (9 events), mild pain or soreness at needle sites (12 events), and dizziness during or after treatment (5 events). No serious adverse events occurred in any of the groups, and no participant required hospitalization or additional medical care for treatment-related reasons. The adverse events were all mild to moderate in severity and resolved within 24 hours without intervention. One participant in Arm B reported

a small burn from the moxibustion (a superficial second-degree burn of approximately 0.5 cm diameter), which healed without complications with standard wound care. This event was considered an adverse event but not a serious one, and the protocol was reviewed to emphasize the importance of appropriate moxibustion distance, although the practitioner involved had followed the specified distance. The overall tolerability of the treatments appears to be good, but the small number of events does not allow for conclusions about the relative safety of the protocols; and rare or delayed events would not be captured in this short-term study[11].

5. Conclusion

This study set out to construct and preliminarily validate a standardized integrated external therapy protocol for elderly chronic musculoskeletal pain, grounded in the theoretical framework of meridian sinew system differentiation. The protocol development process, informed by established standardization frameworks and refined through Delphi consensus and pilot testing, demonstrated that a theoretically grounded, multi-modal TCM intervention can be operationalized in a form suitable for rigorous empirical evaluation while preserving the individualized clinical judgment central to TCM practice. The three-arm assessor-blinded randomized controlled trial provided preliminary evidence that the standardized protocol yielded superior pain reduction and functional improvement compared with both conventional acupoint-based therapy and a waitlist control, with effect sizes that were modest but clinically meaningful for this population. The improvements observed in pressure pain threshold suggested a physiological basis for the clinical effects, while the exploratory biomarker data, though inconclusive, were consistent with a possible anti-inflammatory mechanism warranting further investigation. The subgroup analyses, while underpowered, pointed toward differential treatment responses across clinical patterns, with cold coagulation patients appearing to derive the greatest benefit, suggesting that further refinement of the protocol for specific syndrome subtypes may be warranted. Several limitations must be acknowledged, including the absence of a sham control, partial compromise of assessor blinding, the single-site design, and the exploratory nature of the biomarker and subgroup analyses. Looking forward, these findings provide a foundation for larger multicenter confirmatory trials with more robust control conditions, longer follow-up periods, and mechanistic investigations employing neuroimaging or detailed neurophysiological assessments to elucidate the pathways through which this integrated therapy exerts its effects. Ultimately, this research contributes to the ongoing effort to standardize TCM external therapies without sacrificing their theoretical integrity, offering a replicable framework that may extend beyond musculoskeletal pain to other chronic conditions amenable to TCM intervention, and providing elderly patients with a potentially effective, safe, and acceptable non-pharmacological option for managing their pain.

Data Availability Statement

Data will be made available on request.

Funding

This work was supported without any funding.

Conflicts of Interest

The author(s) declare no conflicts of interest.

Ethical Approval and Consent to Participate

Not applicable.

References

[1] *Huang, R. (2026). Theoretical Analysis of Combined Acupuncture, Tuina and Moxibustion Intervention for Elderly Chronic Musculoskeletal Pain Guided by Meridian Examination—From the Perspective of Tendon Excess-Deficiency and Qi-Blood Stasis. Journal of Research in Social Science and Humanities, 5(2), 32-41.*

[2] *Huang, R. (2026). Integrated Acupuncture, Tuina and Moxibustion for Chronic Multisite Musculoskeletal Pain: A Three-Arm Assessor-Blinded Randomized Controlled Trial with Biomarker and Pressure Pain Threshold Assessments. Journal of Innovations in Medical Research, 5(2), 16-22.*

[3] Chen, Y. (2026). Standardized Traditional Chinese Medicine External Therapy for Chronic Soft Tissue Pain: A Multicenter Observational Study. Current Research in Medical Sciences, 5(3), 36-45.

[4] Chen, Y. (2026). Construction and Application of Standard System for Traditional External Therapy in Traditional Chinese Medicine Health Preservation. Journal of Innovations in Medical Research, 5(2), 23-31.

[5] Rui, H. (2026). Theoretical Analysis on Standardization of Time-Based Moxibustion with Linggui Bafa for Intervention in Mild Cognitive Impairment: From the Perspectives of Time-Based Qi Transformation and Meridian Time Sequence. Insights in Social Science, 4(2), 102-113.

[6] Fan, T., Zhou, X., He, P., Zhan, X., Zheng, P., Chen, R., ... & Huang, G. (2021). Effects of Radial Extracorporeal Shock Wave Therapy on Flexor Spasticity of the Upper Limb in Post-stroke Patients: Study Protocol for a Randomized Controlled Trial. Frontiers in neurology, 12, 712512-712512.

[7] Yuan, D. (2025). The Impact of Traditional Chinese Non-Pharmacological Therapies on Blood Pressure Control in Community Patients with Hypertension. Current Research in Medical Sciences, 4(5), 8-15.

[8] Yuan, D. (2025). Research on the Intervention of Cancer Patients' Anxiety by the Concept of "Harmonization of Body and Mind" in Traditional Chinese Medicine. Journal of Innovations in Medical Research, 4(5), 19-25.

[9] Wei, M. (2026). A Review of the Physiological Effects of Foam Rolling on Skeletal Muscle. Journal of Innovations in Medical Research, 5(2), 9-15.

[10] Wei, M. (2026). Functional Testing for Return-to-Sport Decision-Making After Anterior Cruciate Ligament Reconstruction: An Updated Narrative Review. Current Research in Medical Sciences, 5(2), 34-42.

[11] Yao, C. (2026). Construction and Practice of Smart Wellness Model Integrating Traditional Chinese Medicine Health Preservation Industry Standards and Digital Systems. Insights in Social Science, 4(2), 76-86.

[12] Xu, T. (2025). A Study on the "Tiered-Gamification" Model for Language Rehabilitation Training in Children with Special Needs. Current Research in Medical Sciences, 4(5), 16-21.

[13] Shengtao, L. (2025). Machine Learning-Based Logistics Network Optimization Algorithm. Academic Journal of Computing & Inform0ation Science, 8(5), 46-54.

[14] Xu, T. (2025). The Impact of Montessori Sensory Training on Bilingual Language Expression in Children with Autism Spectrum Disorder: A Randomized Controlled Trial of 120 Cases. Journal of Innovations in Medical Research, 4(6), 29-33.

[15] Xu, T. (2025). A Study on the Design and Application of a Home-School Collaborative Progress Tracking System for Special Children's Rehabilitation. Research and Advances in Education, 4(8), 24-29.

[16] Feng, Y. (2026). Research on the Construction and Practice of the Full-Domain Architecture System for Enterprise Management Informatization under the Digital Economy. Journal of World Economy, 5(2), 17-27.

[17] Huang, H. (2025). Development and Evaluation of a Teacher Training Program in Artificial Intelligence Technology. Journal of Advanced Research in Education, 4(1), 23-31.

[18] Jiang, Y. (2026). Thermo-Mechano-Electromagnetic Multi-Physics Coupling Analysis, Unified-Datum Tolerance Coordination and Full-Lifecycle Experimental Verification of Triple-Functional Integrated Automotive Laminated Windshield Glass. Journal of Progress in Engineering and Physical Science, 5(2), 32-43.

[19] Yan, J. (2026). Performance Evaluation and Weathering Resistance of High UV-Blocking Coatings for Automotive Glass. Journal of Academic Research and Advances, 2(1), 53-65.

[20] Huang, H. (2025). Interdisciplinary Collaboration in Educational Informatization Innovation: Importance and Practice. Research and Advances in Education, 4(1), 38-46.

[21] Feng, Y. (2026). Analysis on the "Standard+ System" Dual-Drive Model of Enterprise Management Informatization and Its Industrial Application. Frontiers in Management Science, 5(2), 41-49.