Journal of Pain Research

Dovepress

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STUDY PROTOCOL

The Impact of Fu's Subcutaneous Needling on Lower Limb Muscle Stiffness in Knee Osteoarthritis Patients: Study Protocol for a Pilot Randomized Controlled Trial

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Background: Knee osteoarthritis (OA) is a leading cause of disability worldwide, with clinicians often observing increased muscle stiffness associated with joint pain and dysfunction. This study examines the impact of Fu's Subcutaneous Needling (FSN), a non-pharmacological technique, on muscle stiffness in the lower limbs of individuals with knee OA.

Materials and Methods: This study protocol is a pilot, single-center, randomized controlled trial. Sixty knee OA patients will be allocated equally for FSN or electroacupuncture (EA) treatments. Interventions will be applied thrice weekly for the first two weeks and twice weekly for the subsequent two weeks for a total of ten sessions. Assessments will be conducted at baseline, post-initial session, after four weeks of intervention, and at the end of a four-week follow-up. The primary outcome will be the muscle stiffness in the lower extremities, as measured by shear wave elastography (SWE). Secondary outcomes include response rate, a reduction in the mean pain intensity on the Numerical Rating Scale (NRS) by at least two points and on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) function subscale by six points at week four compared with baseline. Weekly monitoring of the NRS and WOMAC scores will determine the rapidity of pain alleviation and functional improvement, along with 12-item short-form (SF-12) score changes from baseline to week four.

Results: This is the first standardized protocol examining the effects of FSN on lower limb muscle stiffness in patients with knee OA by SWE. We hypothesize that FSN could outperform EA in alleviating lower limb stiffness associated with knee OA. Findings will contribute to the body of knowledge regarding the efficacy of acupuncture-derived interventions in managing muscle stiffness and may guide future research directions.

Study Registration: The trial has been registered on the Chinese Clinical Trial Registry (Registered number: ChiCTR2300073615). Registered 17 July 2023.

Keywords: Fu's subcutaneous needling, electroacupuncture, muscle stiffness, knee osteoarthritis, shear wave elastography

Introduction

Knee Osteoarthritis (OA), afflicting approximately 20% of adults, emerges as a predominant cause of chronic disability among China's aging citizens,[1] whereas the estimated lifetime risk of symptomatic knee OA was up to 13.83% in the

Received: 10 June 2024
Accepted: 1 October 2024
Published: 9 October 2024

United States.[2] Knee OA is a major cause of chronic disability, leading to physical debilitation, reduced quality of life, and decreased longevity in seniors.[3,4] Economically, knee OA is burdensome, with annual costs in the US anticipated to be $185 billion.[5] Therefore, discovering effective treatment for knee OA is of paramount importance.

Extensive researches[6–9] have linked lower limb muscular deficiencies to the emergence and progression of knee OA. Diagnostic modalities such as isokinetic dynamometry, bioelectrical impedance, computed tomography (CT), dual-energy X-ray absorptiometry (DXA), and magnetic resonance imaging (MRI) assess muscular health and composition. However, these methods are encumbered by high costs, long durations, and contraindications, restricting their clinical application.[10] In contrast, shear wave elastography (SWE) presents as an affordable, non-invasive method for assessing muscle elasticity and is gaining traction for musculoskeletal evaluations.[11–14] Empirical evidence often correlates musculoskeletal discomfort with increased muscular stiffness. Studies such as those by Huang[15] and Huseyin Botanlioglu[16] have highlighted the presence of increased lateral femoris rigidity and significant weakness in the vastus medialis obliquus muscles in knee OA and patellofemoral pain syndrome patients, respectively. Initial study[17] also indicates a significant rise in the shear modulus of hamstrings in those with knee OA, correlating moderately with the Western Ontario and McMaster Universities Arthritis Index (WOMAC) scores. Furthermore, Gökşen A[18] observed a positive correlation between biceps femoris muscle stiffness and WOMAC stiffness scores, despite no stiffness differences in rectus femoris muscles between OA patients and healthy individuals.

The chief aim of OA treatment is to alleviate pain, enhance joint function, and improve the patient's quality of life.[19] Although treatment modalities have been advancements, existing therapies present numerous limitations. As a result, attention has shifted to non-pharmacological and non-surgical strategies. Acupuncture, recognized for its effectiveness in diminishing pain and improving joint mobility, has become a favored complementary therapy for knee OA.[20–22] Current research supports the prolonged benefits of an 8-week electroacupuncture protocol, which persists up to 26 weeks after treatment.[23]

Fu's subcutaneous needling (FSN), a contemporary derivative of acupuncture, is acclaimed for its simplicity, fewer needle insertions, absence of discomfort, and compatibility with patients' daily activities.[24–27] FSN treatment quickly and effectively reduces pain due to knee OA without any noticeable side effects.[28–30] Our preliminary findings[29] suggest that FSN may reduce the quadriceps' muscular rigidity after intervention. However, the confounding influence of the subcutaneous fat layer calls for further examination to ensure the accuracy of our results. Thus, our forthcoming study, utilizing SWE, seeks to meticulously examine the effect of FSN on muscular stiffness in the lower limbs of individuals with knee OA. Over four weeks, we plan to measure the impact of FSN versus electroacupuncture (EA) on pain relief and functional recovery by tracking changes in the Numeric Rating Scale (NRS) and WOMAC functional subscale scores weekly. This study will provide insights into the potential mechanisms of FSN in treating knee OA, particularly its effects on muscle, and offer a direct comparison of FSN and EA, which could inform clinical decision-making and future research directions stiffness.

Method and Analysis

Study Design

We present a single-center, randomized, evaluator-blinded pilot study protocol to assess the therapeutic efficacy of Fu's subcutaneous needling versus electroacupuncture in patients with knee OA. This study is registered with the Chinese Clinical Trial Registry (ChiCTR2300073615) and has received approval from the ethics committee (No. KYLL-2023047), adhering to the Declaration of Helsinki's tenets. A sample of sixty eligible patients will be evenly divided into FSN or EA treatment arms, with four-week interventions and a subsequent month of follow-up observation. We illustrate the trial's chronology and methods in Table 1. Participant recruitment was initiated in December 2023, and the study's framework and dissemination are guided by the CONSORT and SPIRIT recommendations.

Recruitment

The study is hosted at the Shandong Provincial Third Hospital, projected to run from 2023 to 2025. Recruitment commenced in December 2023, with a target end date of June 2025. Patient enrollment, aimed at thirty individuals per

Table 1 The Schedule of Enrollment, Interventions, and Assessments

	Enrolment//baseline	Allocation	Treatment						Follow-up
Timepoint	−1w	0	BFT	AFT	1w	2w	3w	4w	8w
Eligibility screen	X								
Informed consent	X								
Inclusion/Exclusion criteria	X								
Basic information	X								
Medical history	X								
Physical examination	X								
Randomization		X							
Interventions									
FSN group (n=30)			3 sessions			3 sessions	2 sessions	2 sessions	
EA group (n=30)			3 sessions			3 sessions	2 sessions	2 sessions	
Assessments									
Shear wave elastography			X	X				X	
Response rate					X	X	X	X	
Numeric Rating Scale	X				X	X	X	X	X
WOMAC	X				X	X	X	X	X
SF-12	X							X	X
Compliance of participants								X	X
The use of Tylenol				X		X	X	X	
Adverse events				X		X	X	X	

Abbreviations: w, week; BFT, before first treatment; AFT, after first treatment; FSN, Fu's subcutaneous needling; EA, Electroacupuncture; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index; SF-12, 12-item Short-Form Survey.

arm, utilizes hospital outpatient services, digital platforms such as WeChat, and traditional print media supplemented by partnerships with community health service establishments. Potential candidates are briefed extensively on study particulars and screened preliminarily through WeChat or telephone before providing informed consent.

Inclusion Criteria

1. Aged from 45 to 75 years, male or female.
2. Diagnosed with unilateral or bilateral knee OA according to the American College of Rheumatology criteria[31] for symptomatic knee OA.
3. Chronic knee pain for more than 3 months. The most painful side will be measured, or the dominant side in case of equal symptoms.
4. The knee pain, NRS > 3 on the most painful side in the last week.[32]
5. X-ray confirmation of knee osteoarthritis (Kellgren and Lawrence grade[33] II or III within 6 months).
6. Tightened muscle[29] can be palpated in the lower limb muscles on the most knee pain side.

Exclusion Criteria

1. History of lower extremity trauma or surgery.
2. Intra-articular steroid or intra-articular hyaluronic acid injections in the past 6 months or arthroscopy within 1 year.
3. Knee pain from other causes (immune system diseases, malignant tumors, infection, fracture, joint loose bodies, severe effusion of joint cavity, hip joint disease, lumbar spine diseases, gout, etc).
4. History of peripheral neuropathy, central nervous system diseases, or peripheral neuropathy.
5. History of taking medication that may affect muscle tone (ie, muscle relaxants).
6. History of receiving acupuncture therapy within 2 weeks or participating in another clinical study in the previous 3 months.
7. Pregnant or lactating women.

Randomization and Blinding

Patients will be randomly assigned in a 1:1 ratio to the FSN or EA groups. The randomization sequence was computer-generated using SPSS software by an independent statistician who was not involved in the later implementation or statistical analysis. Group assignments will be veiled within sealed, opaque, sequentially numbered envelopes, which will be opened only after participant enrollment and baseline assessment. Given the nature of acupuncture studies, while patient and practitioner masking is unfeasible, evaluators, statisticians, and sonographers will remain blind to group distribution. A single sonographer (CCY) will perform all imaging assessments using standardized equipment to ensure uniformity.

Interventions

FSN Group

The procedure of FSN is illustrated as the following:

1. Needle insertion: According to our previous study,[29] and after the discussion of FSN experts, three insertion points have been chosen for the FSN treatment (Figure 1): (A) the upper one-third spot of the line joining the anterior superior iliac spine and superior edge of the patella; (B) the midpoint of the line joining the inferior aspect of the patella to the lateral malleolus; (C) the midpoint of the popliteal fossa and the heel. The participant lies supine with the knee extended and pelvis centered to access points (A) and (B). For point (C), the participant assumes a prone position, keeping the knee straight. Using the left middle finger, lift the skin at the insertion point. Position the insertion device at a 15°-20° angle using the right hand and depress the trigger to insert the needle swiftly into the subcutaneous tissue, avoiding deeper penetration. Ensure the needle remains within the subcutaneous layer by monitoring for any pain sensations reported by the participant. Confirm placement and retract the needle core into the protective sheath.

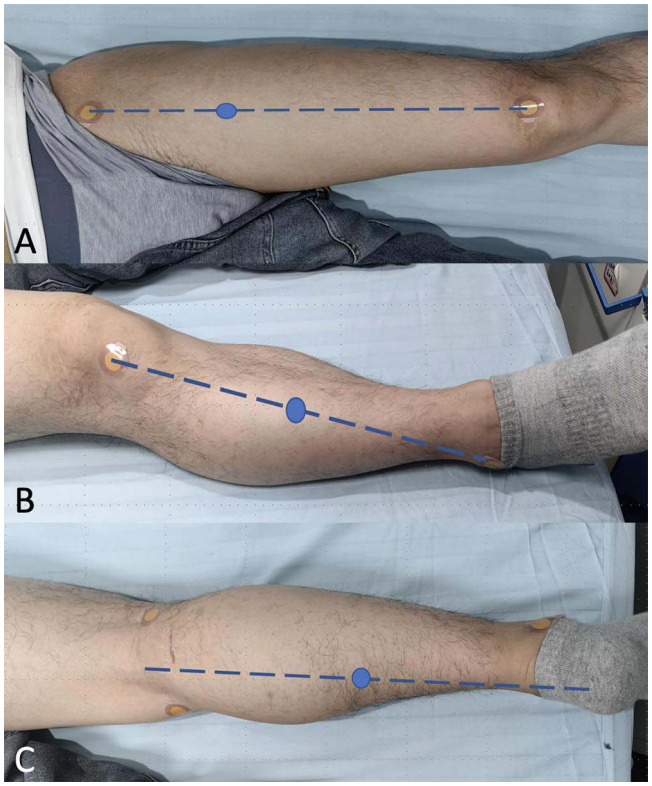

Figure 1 Locations of insertion points used in the FSN group. (**A**) The blue dashed line connects the anterior superior iliac spine and the superior edge of the patella; the blue circle indicates the insertion point at the upper one-third of this line. (**B**) The blue dashed line connects the inferior edge of the patella and the lateral malleolus; the blue circle indicates the insertion point at the midpoint of this line. (**C**) The blue dashed line connects the popliteal fossa and the heel; the blue circle indicates the insertion point at the midpoint of this line.

2. Swaying Movement: After the FSN needle has been inserted into the subcutaneous layer, perform the swaying movement. Support the FSN handle with the thumb as a pivot point, while the index, middle, and ring fingers are positioned on the opposite side of the FSN needle handle. Specifically, the middle finger and thumb should hold the needle on opposite sides of the handle, with the index and ring fingers moving alternately in a back-and-forth motion.

3. Reperfusion Approach (RA): This technique complements the swaying movement with specific exercises targeting the treated muscles, Point A: Focuses on the quadriceps muscle group. Participants perform knee flexion and extension for one minute, alternating with 10 seconds of exercise followed by a 10-second rest. Point B: Targets the tibialis anterior and related muscle groups, involving a one-minute cycle of ankle dorsal flexion. Point C: Concentrates on the gastrocnemius and soleus muscles, crucial for knee flexion and ankle plantarflexion. The swaying movement and the reperfusion approach will be performed as described in the previous studies.[29,30]

EA Group

The selection and manipulation of acupoints derives from the Acupuncture Therapeutics textbook used by Chinese medicine colleges and universities in China. *Dubi* (ST35), *Neixiyan* (EX-LE5), *Liang qiu* (ST34), *Yang ling quan* (GB34), *Xuehai* (SP10), *Yinlingquan* (SP9) and *Ashi point* are selected (Table 2). Sterilized, single-use needles of 0.25–0.30 mm in diameter and 40 mm in length (Hwato Needles, made in Suzhou, China) will be used for acupuncture. All needles will be inserted 15–30 mm in depth and twirling lifting, and thrusting (needle manipulation) will be performed for at least 10 seconds to produce a characteristic sensation known as *Deqi* (a sensation of soreness, numbness, distention, or heaviness that indicates effective needling). Electronic acupuncture apparatus (Hwato, SDZ-II, Suzhou Medical Appliance) will be attached to the two pairs of needles longitudinally for each side of ST35 and ST34, SP10, and EX-LE5. The EA device administers a 30-minute session of 2 hz continuous wave stimulation, with intensity levels tailored to patient comfort, ranging from 0.1 to 1 mA.[34]

For bilateral symptoms, treatment is applied to both knees, though assessments are concentrated on the joint exhibiting more severe symptoms. Both treatment modalities are scheduled thrice weekly for the first two weeks, followed by twice weekly sessions, totaling ten sessions. Tylenol is reserved for intolerable pain and will be documented if used. Patients are precluded from receiving additional treatments, such as injections or moxibustion, to preserve the study's validity.

To ensure consistency in treatment delivery, all FSN and EA treatments will be performed by acupuncturists with over 5 years of experience in their respective techniques. The acupuncturists will undergo standardized training before the study to ensure uniform application of the protocols. They will not be involved in participant assessment or data analysis to maintain blinding.

To control for potential differences in practitioner-patient interactions, FSN and EA sessions will follow a standardized script for communication with participants. This approach aims to minimize any bias arising from differences in verbal or non-verbal cues between the two interventions.

Table 2 Acupoints Will Be Used in the Electroacupuncture Group

Acupoint	Location
Dubi (ST35)	On the anterior aspect of the knee, in the depression lateral to the patellar ligament
Neixiyan (EX-LE5)	On the anterior aspect of the knee, in the depression medial to the patellar ligament
Liang qiu (ST34)	On the anterolateral aspect of the thigh, between the vastus lateralis muscle and the lateral border of the rectus femoris tendon, 2 cun superior to the base of the patella
Yang ling quan (GB34)	On the fibular aspect of the leg, in the depression anterior and distal to the head of the fibula
Xuehai (SP10)	On the anteromedial aspect of the thigh, on the bulge of the vastus medialis muscle, 2 cun superior to the medial end of the base of the patella
Yinlingquan (SP9)	On the tibial aspect of the leg, in the depression between the inferior border of the medial condyle of the tibia and the medial border of the tibia

Outcome Measurements

In unilateral cases, the affected knee is solely evaluated. In bilateral instances, the knee experiencing more severe pain will be assessed.

Primary Outcome - Ultrasound Imaging Acquisition Protocol

The primary outcome will be revealed as lower limb muscle stiffness, measured at three intervals: pre-first treatment, immediately post-first treatment, and after the 4-week treatment. Imaging occurs in a controlled hospital environment, ensuring participant calmness and temperature consistency. Patients are instructed to rest for five minutes before scanning to normalize muscle tone. The more symptomatic or dominant side is scanned in cases of bilateral symptoms. Participants are to abstain from physical exercise 24 hours prior to the ultrasound examination and remain motionless with regular breathing during the scan. The technician operates a Mindray ultrasound system with an L18 probe, set to a frequency of 5–18 MHz, adhering to established 2-D SWE musculoskeletal protocol[35] and previous research.[36] The probe will be positioned parallel to the muscle fibers with minimal pressure to avoid tissue deformation. The angle of incidence will be kept as close to 90 degrees as possible to ensure optimal shear wave propagation. Gain settings will be adjusted to achieve clear visualization of muscle fascicles while avoiding signal saturation.

To ensure consistency, all measurements will be taken by the same experienced sonographer (CCY) with over five years of experience in musculoskeletal ultrasonography. The sonographer will undergo specific training on the standardized protocol before the study commences. Additionally, we will conduct regular quality control checks throughout the study to maintain consistency in image acquisition.

Four specific lower limb muscles are imaged (Figure 2): (A) Rectus femoris (RF): the midpoint of the line joining the anterior superior iliac spine and superior edge of the patella; (B) Vastus lateralis (VL): the midpoint between the head of the great trochanter and superior edge of the patella; (C) Tibialis anterior(TA), one-third between the inferior aspect of the patella to the lateral malleolus; and (D) Gastrocnemius: Medial gastrocnemius (MG), one-third between the medial popliteal fossa and the lateral malleolus, lateral gastrocnemius (LG), one-third between the lateral popliteal fossa and the medial malleolus. The areas were chosen based on previous studies.[37–39]

A gel pad is employed to prevent distortion from probe pressure. B-mode is utilized initially for anatomical clarity, followed by SWE mode preset for muscle stiffness measurement. A 5-second interval precedes capturing three consecutive images per target area, with probe repositioning in between.[40] A uniform 1.5 cm² color window is maintained for image consistency, with ROI placement avoiding the window's perimeter. To reduce the effects of the depth of the measurements and artifacts in the circular ROIs on the results, based on our pre-test and other studies,[17,40] nine circular regions of interest (5 mm diameter) will be placed covering as much of the muscle as possible for each given square SWE color map (Figure 3).

The ultrasound software computes the shear modulus from shear wave velocities, considering the density of soft tissue. An average is derived from twenty-seven readings for each muscle region. The shear modulus (μ) was calculated from the recorded shear wave velocities (V_s) ($\mu = \rho \times V_s^2$)[20] based on a density (ρ) of 1000 kg/m^3, which is generally assumed for soft tissue.[41,42] Blinded analysis of the images will be performed independently by two investigators (CCY and JM), following the data collection and consistent with established review protocols.

Secondary Outcomes

1. ***The response rate***: The response rate is defined as the proportion of participants exhibiting a minimum two-point reduction on the NRS for pain, coupled with a six-point improvement on the WOMAC function subscale score by the end of week four, benchmarked against initial evaluations.[43] Furthermore, we will track weekly changes in NRS and WOMAC function scores from baseline during the first three weeks to evaluate the promptness of symptomatic and functional improvements attributable to each therapy. The NRS ranges from no pain (0) to the most intense pain conceivable (10). With its seventeen-item questionnaire, the WOMAC function subscale assesses daily functional capabilities, where higher scores indicate increased knee OA-related functional impairment.[44]
2. ***Quality of Life Assessment***: Utilizing the 12-item short-form (SF-12) survey,[45] which quantifies mental and physical health components on a 0 to 100 scale, participants' quality of life will be appraised. Here, higher scores correlate with improved health status. The SF-12 assessments will be administered at baseline, week four, and week eight.

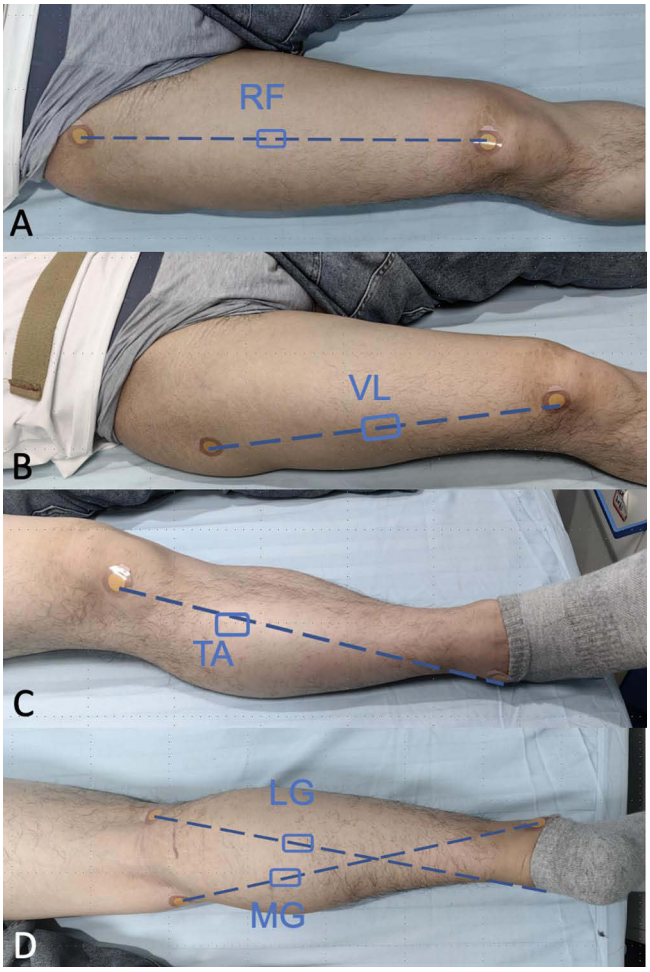

Figure 2 Ultrasound probe placement locations for muscle stiffness measurements. (**A**) Rectus femoris (RF): The blue dashed line connects the anterior superior iliac spine and the superior edge of the patella; the blue box indicates the probe placement at the midpoint. (**B**) Vastus lateralis (VL): The blue dashed line connects the top of the great trochanter and the superior edge of the patella; the blue box indicates the probe placement at the midpoint. (**C**) Tibialis anterior (TA): The blue dashed line connects the inferior edge of the patella and the lateral malleolus; the blue box indicates the probe placement at one-third the distance from the patella. (**D**) Gastrocnemius: Medial gastrocnemius (MG): The blue dashed line connects the medial side of the popliteal fossa and the lateral malleolus; the blue box indicates the probe placement at the upper one-third of this line. Lateral gastrocnemius (LG): The blue dashed line connects the lateral side of the popliteal fossa and the medial malleolus; the blue box indicates the probe placement at the upper one-third of this line.

Safety Assessment

Any adverse events (AEs), whether reported spontaneously by the participant or identified by the clinical team, will be reported to the ethics committee within 24 hours of occurrence. AEs related to acupuncture, such as persistent needle pain, lightheadedness, bruising, or infection, will be diligently recorded at each visit and weekly throughout the study. This data will be included in our final results and discussed in terms of the overall risk-benefit profile of each intervention.

Feasibility Outcomes

We will monitor patient adherence by tracking the number of attended sessions. Reasons for withdrawal or dropout will be systematically documented, with adherence rates below 80% at the fourth week marked as suboptimal.

Data Collection and Management

Data from participants will be systematically collected using a standardized Case Report Form (CRF). Considering the low-risk profile of FSN and EA, the establishment of a formal Data Safety Monitoring Board is not anticipated. Regular data oversight will be conducted by the research team.

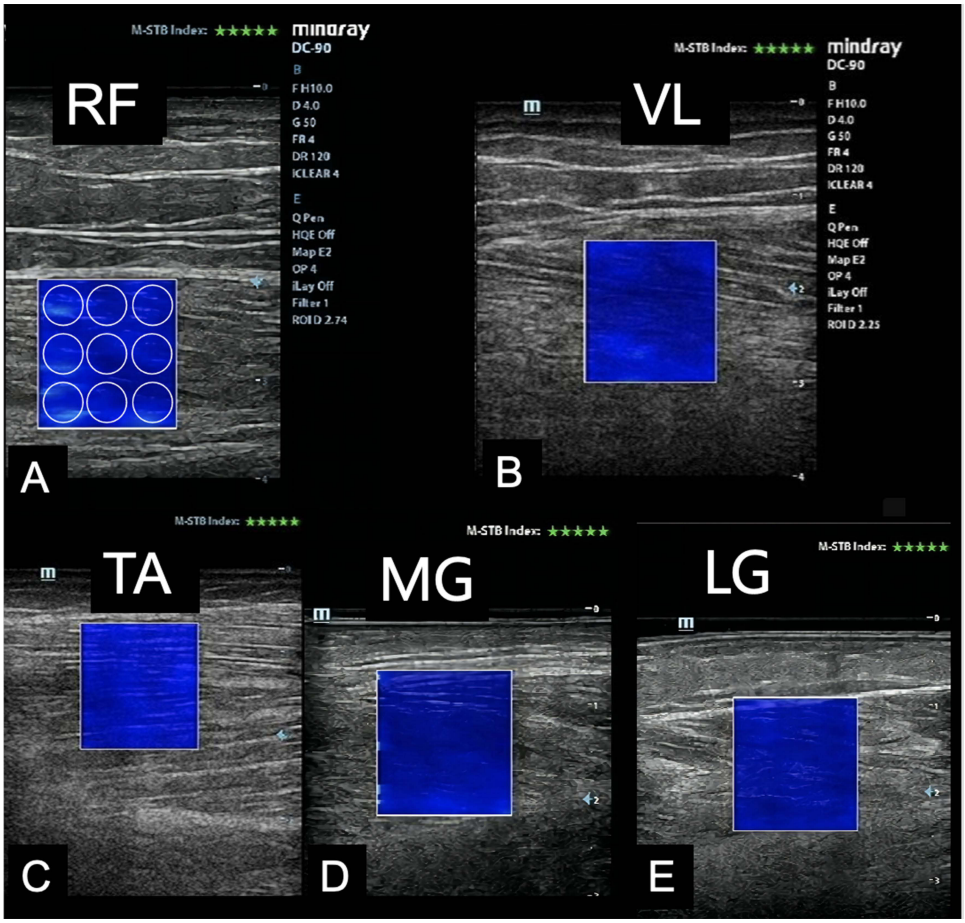

Figure 3 Elastography data collection: 9 circular regions of interest (5 mm diameter) will be manually placed, covering as much of the muscle as possible for each given square SWE color map. For example, (**A**) shows an elastography image of RF and the positions of the Q boxes for the RF. (**B, C, D,** and **E**) are elastography images of the VL, TA, MG, and LG, respectively. An average is derived from twenty-seven measurements (9 ROIs for each slice and 3 slices total) for each muscle region. The blue boxes represent the shear wave elastography color maps for each muscle.

Sample Size

This pilot study is designed to assess the effect of acupuncture therapy on lower limb muscle stiffness using ultrasound SWE. There was no previous study on which to establish a sample size. The study's exploratory nature does not necessarily require a precise sample size calculation. Therefore, a sample size of sixty participants (30 for each group) will be recruited to achieve the practical purpose of the trial based on expert opinion and similar acupuncture studies.[46–52]

Statistical Analysis

We will adhere to an intention-to-treat principle, where all individuals who have received at least one treatment session will be included in the analysis. Statistical significance is set at a p-value below 0.05. Demographics and baseline characteristics will be descriptively summarized by the treatment arm. Outcome data presentation will respect distribution properties, with categorical data presented as proportions. For our primary outcome (muscle stiffness measured by SWE), we will use a linear mixed-effects model to account for repeated measures and potential confounding factors. This model will include the treatment group, time point, and their interaction as fixed effects and participant as a random effect. Baseline SWE measurements and relevant demographic factors will be included as covariates. For secondary outcomes with repeated measures (NRS and WOMAC scores), we will also employ linear mixed-effects models. These models can handle missing data more effectively than traditional repeated measures ANOVA and provide a more nuanced understanding of treatment effects over time. For the response rate analysis, we will use logistic regression to

compare the odds of response between the two groups, adjusting for relevant baseline characteristics. Data on dropouts will be analyzed using the last observation carried forward method.

Ethics and Dissemination

Approval for this trial has been obtained from the Ethical Committee of the Shandong Provincial Third Hospital, with registration details (ChiCTR2300073615) the compliant with CONSORT and SPIRIT recommendations. Data from participants will be anonymized and encrypted, accessible solely to designated research personnel. Results will be disseminated through scholarly journals, and findings will be presented at scientific forums and conferences.

Discussion

This investigation endeavors to elucidate the impact of FSN on the stiffness of lower limb muscles in patients with knee OA, as measured by SWE. This is the first to use shear wave elastography to assess the effects of FSN on lower limb muscle stiffness in knee OA patients. It compares FSN with EA, two acupuncture-derived techniques that have not been directly compared before. Recognizing the pivotal role of muscular function in KOA's pathogenesis and management, our focus aligns with the growing body of research[53–55] that interrogates the interplay between KOA and muscular dysfunction. Our prior research[29] indicates that the location of pain in patients with knee OA does not necessarily correspond to the site of the underlying lesion. Instead, the source of symptoms in other areas of the body and muscle belly suggests that subjective pain in these patients may be attributed to muscular factors, specifically dysfunction in myofascial trigger points (MTrPs). This dysfunction is believed to be the primary contributor to knee pain in individuals with knee OA. Moreover, research[56] shows that FSN treatment can enhance the morphological structure and function of mitochondria in tightened muscles, increasing mitochondrial creatine synthase and Complex II levels and boosting the active expression of cytochrome c oxidase (COX-I) protein in muscle tissues. Our prior research[57] suggests that FSN therapy can significantly alleviate neuropathic pain by reducing inflammation and endoplasmic reticulum stress, making it a promising treatment for peripheral nerve injuries, knee OA, and associated muscular issues.

The utilization of ultrasonography (US) for musculoskeletal assessment has gained traction for its noninvasive and diagnostic prowess, offering insights into treatment efficacy.[58–60] Research has examined the impact of acupuncture therapy on muscle stiffness using SWE. Sanchez-Infante[61] observed that a single session of dry needling (DN) intervention in latent trigger points of the upper trapezius muscle resulted in decreased muscle stiffness and increased pressure pain threshold compared to sham DN. However, these findings contradict those of Juan Antonio,[62] who reported that a single session of DN or sham DN on active MTrPs in the upper trapezius muscle did not lead to noticeable changes in stiffness at the MTrP or control sites. The contrasting findings on acupuncture's effect on muscle stiffness underscore the need for further inquiry, particularly regarding FSN, a modality with burgeoning use in managing musculoskeletal pain. Our preliminary data suggests FSN's capability to marginally attenuate quadriceps muscle hardness, hinting at a potential mechanism tied to the MTrP resolution. This study will contribute to a nuanced understanding of acupuncture's therapeutic effects on muscle stiffness in knee OA.

Given the significant implications of knee pain in impairing mobility and quality of life among the elderly, strategies for pain mitigation in KOA are crucial.[63] While acupuncture's benefits for pain relief and joint function enhancement are documented,[22,23] the immediate analgesic effects of various acupuncture techniques remain underexplored. Through the NRS and WOMAC assessments, this study aspires to discern which modality affords more expedient symptomatic and functional improvements, thereby offering references for efficacious pain management in knee OA.

However, our study may have limitations. The four-week follow-up period, while providing initial insights, may not be sufficient to capture the long-term effects of the interventions. Future research should consider extending the follow-up duration to better assess the sustainability of treatment benefits. Conducting the study at a single center may limit the generalizability of our findings. Multi-center trials would provide more robust and generalizable results. While we have taken steps to blind assessors and participants to group allocation, complete blinding is challenging in acupuncture trials due to the nature of the interventions. Particularly, the inherent nature of FSN and EA interventions impedes the implementation of a blinded methodology. Additionally, the size of our sample may restrict the power of our statistical analyses, particularly in detecting small effect sizes. Consequently, we will interpret our findings with caution and utilize

them to inform effect size estimates and power calculations for future, more extensive trials. Both FSN and EA may induce placebo effects, which could influence our results. Future studies might consider including a sham acupuncture arm to control for these effects. Additionally, the three junctures of SWE measurements, as opposed to a more frequent schedule, may impede our ability to track dynamic shifts in muscle stiffness, marking a potential area for future study refinement.

Conclusion

This single-center, assessor-blinded, randomized controlled trial is poised to compare the effects of FSN against EA on muscle stiffness in patients with knee OA. Additionally, offering a direct comparison of FSN and EA, the forthcoming results are anticipated to ascertain the relative efficacy of these two modalities in providing swift pain alleviation, which could inform clinical decision-making and future research directions. By doing so, we aim to lay a clinical groundwork to inform large-scale, multifaceted clinical trials and enhance evidence-based practices for knee OA management. Furthermore, it seeks to standardize the protocol for assessing muscle stiffness in knee OA patients using SWE. This standardization could prove invaluable for future investigations in the field, paving the way for more definitive conclusions and therapeutic advancements.

Disclosure

All authors reported no conflicts of interest in this work and declared that there was no financial or otherwise support and no other relationships or activities could appear to have influenced the submitted work.

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