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STUDY PROTOCOL

Effects of Massage on Pain, Muscle Co-Contraction, and Knee Loading in Medial Knee Osteoarthritis: A Randomized Controlled Trial Protocol

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Background: Increased joint loading and muscle co-contraction during gait contribute to the progression of knee osteoarthritis (OA). Although massage benefits for knee OA are documented, evidence based on objective biomechanical outcomes remains limited. This study aims to investigate the effects of massage on pain, muscle co-contraction and joint loading after a 12-week intervention in patients with medial knee OA.

Methods/Design: This parallel, two-arm randomized controlled trial will enroll 56 participants with medial knee OA. Participants will be randomly assigned to either a Massage group or a Healthcare Education group for a 12-week intervention delivered twice weekly. The massage protocol will use standardized Shi's manual therapy techniques targeting periarticular knee soft tissues, including the quadriceps, hamstrings, and surrounding structures. The primary outcome is the pain subscale of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). Secondary outcomes include WOMAC stiffness and function, antagonist muscle co-contraction, knee kinetics and kinematics (including the external knee adduction moment [EKAM]), and temporospatial gait parameters. Outcomes will be assessed at baseline and after the 12-week intervention.

Discussion: This is the first randomized controlled trial to simultaneously evaluate the midterm (12-week) effects of massage on pain, muscle co-contraction and EKAM. The findings may provide novel evidence on the biomechanical mechanisms of massage beyond traditional subjective assessments and have important implications for developing individualized, mechanism-oriented rehabilitation strategies.

Trial Registration: International Traditional Medicine Clinical Trial Registry: ITMCTR2025001524.

Keywords: knee osteoarthritis, muscle co-contraction, knee loading, massage, randomized controlled trial

Introduction

Knee osteoarthritis (OA) is a prevalent, painful, and disabling condition that affects millions of individuals worldwide.[1] Epidemiological evidence from large cohort studies indicates that the prevalence of symptomatic knee OA ranges from 11% to 18% in women and from 6% to 13% in men.[2,3] In China, more than 8% of the retired population has been reported to suffer from symptomatic knee OA, making it a leading cause of disability.[4] With the progressive aging of the

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population and the increasing prevalence of obesity, the societal and economic burden attributable to knee OA is expected to escalate substantially.[5]

The loading at the knee during gait has been proven to be related to pain, structural deterioration, and disease severity in individuals with knee OA.[6–8] Although direct quantification of in vivo knee loading remains technically challenging, the external knee adduction moment (EKAM) is widely regarded as a valid surrogate indicator of medial compartment loading.[9,10] Longitudinal evidence has demonstrated that each unit increase in EKAM is associated with a sixfold higher risk of OA progression,[6] underscoring its prognostic utility. Accordingly, some biomechanical and rehabilitative interventions have been developed with the objective of alleviating symptoms by attenuating peak EKAM.[10,11]

Nevertheless, it has been reported that reductions in EKAM do not invariably translate into corresponding decreases in actual knee joint loading,[12] highlighting the complexity of underlying load-distribution mechanisms. In addition, neuromuscular factors, particularly knee antagonist muscle co-contraction, are recognized as primary contributors to joint loading.[13] Individuals with knee OA frequently demonstrate elevated knee muscle co-contraction during gait.[14] Although such adaptations may confer short-term joint stabilization, they paradoxically increase compressive loading across the joint.[15] Given the robust association between excessive knee loading and both symptomatic and structural progression of OA, the reduction of knee joint loading remains a central objective in the development of therapeutic strategies.

Massage is a common intervention for musculoskeletal disorders[16] and has demonstrated efficacy in reducing pain and improving function in individuals with knee OA.[17–19] A recent meta-analysis confirmed its short-term benefits in pain, stiffness, and physical function.[20] Nevertheless, the majority of previous investigations have primarily relied on subjective questionnaires rather than objective biomechanical assessments. Cruz-Montecinos et al (2016)[21] examined the immediate effects of massage on muscle co-contraction during stair descent in patients with knee OA; however, neither the EKAM nor the knee adduction angular impulse (KAAI) was reported, leaving the influence of massage on knee loading during level walking unresolved.

More recently, Zhang et al (2024)[22] demonstrated that a six-week massage intervention yielded clinically meaningful improvements. Furthermore, the results indicated that the observed pain reduction was associated with decreased antagonist muscle co-contraction during gait. These findings suggest that the potential mechanism underlying the effects of massage in the management of knee OA may involve modulation of antagonist muscle co-contraction. Previous study indicated that massage could reduce muscle stiffness and neurological excitability,[23] which may enhance knee joint stability and, in turn, reduce antagonist muscle co-contraction during gait. Consequently, the reduction in co-contraction may ultimately decrease mechanical knee loading, thereby alleviating pain during movement.[13] Nevertheless, that study was limited by its short intervention period, small sample size, and lack of a control group, thereby introducing a potential risk of bias.

To our knowledge, this is the first randomized controlled trial (RCT) to simultaneously evaluate the midterm (12-week) effects of massage on pain, muscle co-contraction, and EKAM. To ensure a rigorous comparison, health education will be used as an attention-matched control condition to account for non-specific effects such as time and participant engagement, thereby enabling a clearer evaluation of the specific effects of massage. Accordingly, the primary aim of this study is to examine the effect of massage on pain, with secondary outcomes including knee antagonist muscle co-contraction, EKAM during gait, and other biomechanical parameters. We hypothesize that a 12-week massage intervention will significantly reduce pain, knee antagonist muscle co-contraction, and EKAM, while producing clinically meaningful improvements in knee kinetics and kinematics compared with health education. These findings may provide novel insights into the biomechanical mechanisms underlying massage beyond conventional subjective assessments and hold important implications for the development of individualized, mechanism-based rehabilitation strategies.

Methods

Study Design

This study is a single-center, two-arm (1:1 allocation ratio), parallel-group, assessor-blinded RCT conducted at Henan Provincial Hospital of Traditional Chinese Medicine (Second Affiliated Hospital of Henan University of Traditional

Chinese Medicine). The study protocol has been registered with the International Traditional Medicine Clinical Trial Registry (No. ITMCTR2025001524). The protocol is developed in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement,[24] and the trial will be reported following the Consolidated Standards of Reporting Trials (CONSORT) guidelines.[25]

Recruitment and Informed Consent Process

Participants will be recruited via posters, social media platforms (eg, WeChat Moments), and local hospitals. Individuals expressing interest and providing written informed consent will undergo a screening assessment conducted by a designated physician to verify eligibility. The study protocol flowchart is presented in Figure 1.

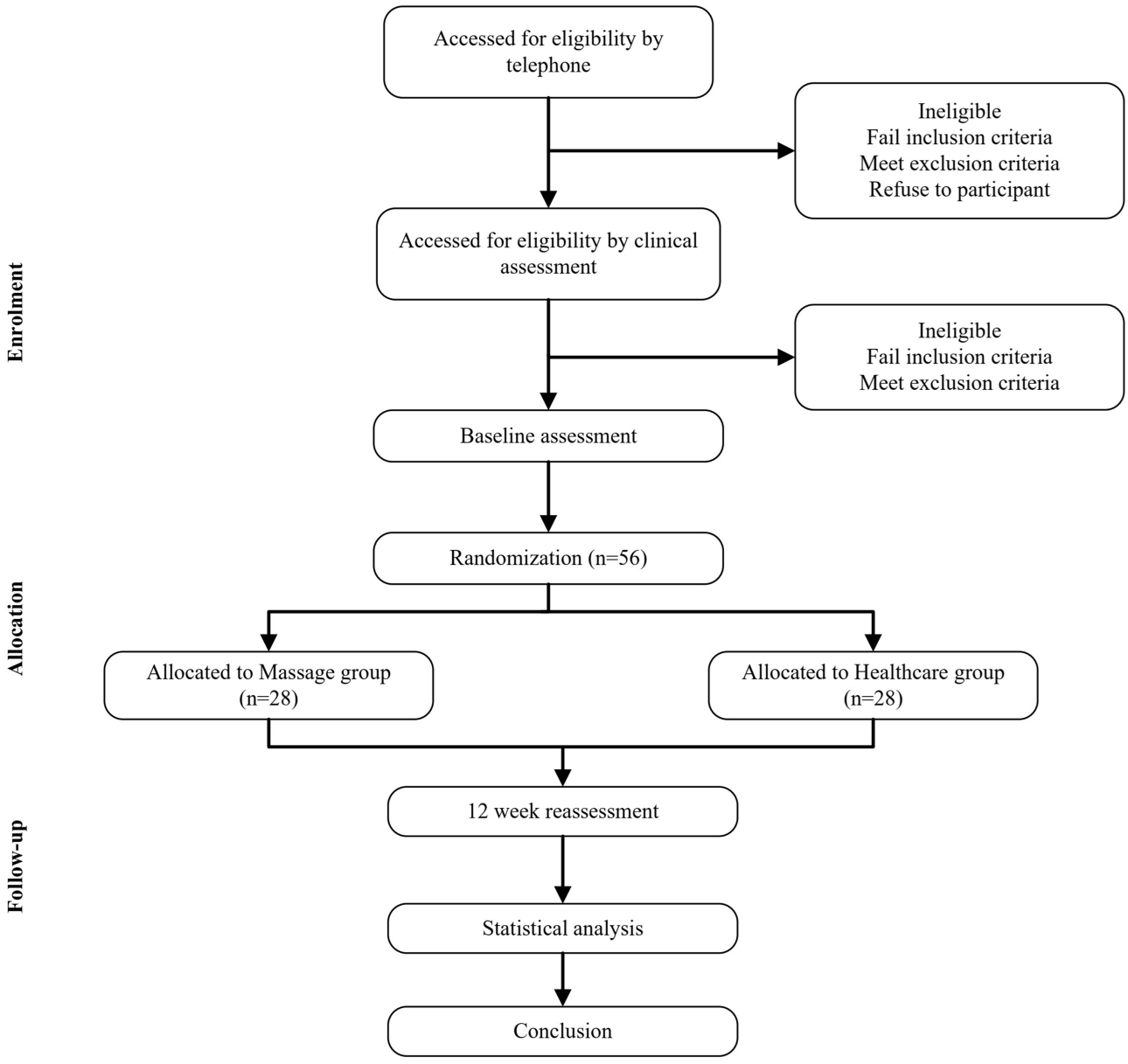

Figure 1 Flow diagram of study protocol.

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Eligibility Criteria

Inclusion Criteria

Participants will be eligible if they meet the following criteria: (1) aged 50–70 years; (2) body mass index (BMI) $\leq$ 40.0 kg/m^2; (3) diagnosis of medial knee OA according to the American College of Rheumatology criteria,[26] with radiographic confirmation of Kellgren–Lawrence (KL) grade 2–3 in the affected knee;[27] (4) knee pain on most days with an intensity $\geq$3 on a 0–10 numeric rating scale (NRS); (5) ability to provide written informed consent; and (6) ability to walk independently for at least 20 consecutive minutes without assistance.

Exclusion Criteria

Participants will be excluded if they: (1) fail to meet the inclusion criteria; (2) have a neurological disorder affecting gait; (3) present with skin lesions or dermatological conditions at the treatment site; (4) have received other treatments for knee OA within the preceding four weeks; (5) have participated in another clinical trial within the preceding two months; or (6) have a history of knee surgery or are currently on a waiting list for knee surgery.

Sample Size

The sample size was calculated using G*Power (Version 3.1.9.6, University of Kiel, Kiel, Germany). The calculation was based on previously reported effects of massage on the pain subscale of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) in patients with knee OA, as described by Perlman et al (2006).[28] That study investigated a massage intervention in patients with knee OA comparable to the present trial in terms of clinical characteristics and treatment duration, providing a relevant basis for estimating the expected treatment effect.

Therefore, an effect size of 0.86 was assumed, with a two-sided alpha level of 0.05 and statistical power of 0.80, indicating that 23 participants per group would be required. To account for an anticipated dropout rate of 20%, the target sample size was increased to 28 participants per group, resulting in a total planned recruitment of 56 participants.

Randomization

Eligible participants will be randomized to either the massage or healthcare education group in a 1:1 allocation ratio. An independent researcher will generate the random sequence using a computerized random number table Allocation will be concealed in opaque, sealed envelopes, from which participants will randomly select one. A duplicate copy of the randomization code will be securely retained by the research supervisor and will remain confidential until study completion. Two members of the research team will serve as outcome assessors for pre- and post-intervention evaluations and will remain blinded to group assignments and statistical analyses. Participants will be explicitly instructed not to disclose their group allocation to the assessors.

Blinding

Given the nature of massage and health education interventions, blinding of participants and treating researchers will not be feasible. To reduce the risk of bias, outcome assessors (research assistants) and statisticians will remain blinded to group allocation during both outcome assessments and data analysis. Furthermore, evaluators will not be granted access to study data until the completion of all data collection.

Interventions

Massage

All massage interventions will be performed strictly in accordance with Shi's manual therapy protocols.[29] Interventions will be administered by a physician from Henan Provincial Hospital of Traditional Chinese Medicine, who has over five years of clinical experience in massage therapy. This ensures consistency and fidelity of the intervention across all participants.

Participants will be positioned supine on the treatment bed in a relaxed state, and the skin over the affected knee will be exposed. Rolling manipulation will first be applied from the quadriceps femoris to the patella using moderate pressure (technique intensity will be adjusted within a tolerable range according to participant comfort), at a rhythmic frequency

of 40–60 cycles per minute, moving in a proximal-to-distal direction for 10 minutes. This will be followed by pressing and kneading on both sides of the patella using moderate, tolerable pressure, delivered at a frequency of approximately 30–50 compressions per minute with circular multidirectional movements for 10 minutes. Subsequently, the physician will place the inner edge of the palm over the treatment area with the knuckles slightly flexed. By extending the elbow and wrist to move forward, and slightly flexing the elbow while extending the wrist to move backward, combined with inward and outward rotation of the forearm, the edge of the palm will be repeatedly moved back and forth across the treatment site using moderate, continuous pressure, at a frequency of 40–60 strokes per minute in an alternating longitudinal direction for 5 minutes. Participants will then be repositioned in the prone position. Rolling manipulation will be applied from the posterior mid-thigh to the upper calf using moderate pressure, at a frequency of 40–60 cycles per minute, progressing in a proximal-to-distal direction for 5 minutes. This will be followed by rubbing along the medial and lateral sides of the knee joint using light-to-moderate pressure, delivered at a frequency of approximately 50–70 strokes per minute with longitudinal and circular movements for an additional 5 minutes [Supplementary Figure S1].

For participants with bilateral medial knee OA, both knees will receive treatment. Massage sessions will be conducted twice weekly over a 12-week period, with technique intensity adjusted within a tolerable range according to participant comfort while maintaining standardized frequency and directional patterns.

Health Education

Participants assigned to the health education group will receive preprinted booklets developed by the research team. These materials cover basic information on knee OA, joint protection and daily activity guidance, nutrition, symptom monitoring, mental health and social support, as well as self-monitoring forms and resources [Supplementary Material 2]. Health education will be delivered by a designated research assistant via telephone, twice weekly throughout the 12-week intervention. During each call, participants will be asked about their symptoms and overall health status.

Outcome Measures

Demographic and clinical characteristics of eligible participants, together with baseline data, will be summarized to assess the comparability of the intervention groups. The efficacy of the interventions will be evaluated by two independent research assistants and a designated statistician, all of whom will remain blinded to group allocation, at both baseline and at the conclusion of the 12-week intervention period. For participants with bilateral knee OA, only the more symptomatic knee will be assessed, although interventions will be permitted on both sides.[30] The schedule of study procedures, assessment time points, and outcome measures is presented in Table 1.

Primary Outcome

The primary outcome will be the change in the WOMAC pain subscale score from baseline to 12 weeks. The WOMAC is a validated and reliable instrument for assessing symptoms in individuals with knee OA.[30,31] It comprises three subscales: pain (5 items), stiffness (2 items), and physical function (17 items). Scores on the pain subscale range from 0 to 20, with higher scores reflecting greater pain experienced during activities of daily living.[30,32]

Secondary Outcome

1. The WOMAC stiffness subscale evaluates the severity of joint stiffness, particularly after waking or following periods of inactivity, with scores ranging from 0 to 8; higher scores indicate greater stiffness. The WOMAC physical function subscale assesses the extent to which OA affects a participant's ability to perform activities of daily living, with scores ranging from 0 to 68; higher scores indicate greater functional impairment.
2. Kinematic data during gait will be collected using a ten-camera, three-dimensional motion analysis system (Version 1.8.5, VICON, Oxford, UK) at a sampling rate of 120 Hz. Ground reaction force (GRF) data will be recorded using integrated force plates (OR6-6, AMTI, Watertown, MA, USA) at a sampling rate of 1000 Hz and synchronized with the cameras. Marker placement will adhere to the calibrated anatomical systems technique (CAST) as described by Cappozzo et al (1995).[33] Retro-reflective markers will be placed on specific anatomical landmarks, including the anterior superior iliac spine (ASIS), posterior superior iliac spine (PSIS), iliac crest,

Table 1 The Specific Time Points, Study Procedures, and Outcome Assessments

	Study Period					
	Enrollment	Allocation	Post-Allocation			
Time point	−7-0 Day	0 Day	1 week	6 week	12 week	After 12 weeks
Enrolment						
Eligibility screen	•					
Informed consent	•					
Randomization and allocation		•				
Interventions:						
Massage group			•	•	•	
Health education group			•	•	•	
Assessments:						
WOMAC		•				•
Knee kinetics		•				•
Knee kinematics		•				•
Knee antagonist muscle co-contraction		•				•
Temporal-spatial variables		•				•

Note: • indicates that the procedure or assessment will be performed at the specified time point.
Abbreviation: WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

greater trochanter, medial and lateral femoral epicondyles, medial and lateral malleoli, the 1st, 2nd, and 5th metatarsal heads, and the calcaneus of both feet. Four additional non-collinear markers, mounted on rigid cluster plates, will be secured to the anterofrontal surfaces of the shanks and thighs, as well as around the pelvis, using elastic bandages (Fabrifoam, USA).[22] Temporal-spatial, kinematic, and kinetic data will be analyzed using Visual3D software (Version 6.01.16, C-Motion, Rockville, MD, USA). Kinematic and analog signals will be filtered using a low-pass Butterworth filter, with cutoff frequencies of 6 Hz for kinematic data and 25 Hz for analog data.[22] Kinetic variables will be calculated using inverse dynamics methods.

Surface electromyography (sEMG) data will be recorded using a 16-channel sEMG system (Noraxon, Scottsdale, AZ, USA) at a sampling rate of 1500 Hz. The muscles monitored will include the vastus lateralis (VL), vastus medialis (VM), biceps femoris (BF), and semitendinosus (ST). Maximum voluntary isometric contraction (MVIC) values will be obtained following the methodology outlined by Zeni et al (2010).[34]

The sEMG signals will be first high-pass filtered at 20 Hz to remove noise and skin motion artifacts, then rectified, and subsequently smoothed using a 6 Hz low-pass Butterworth filter to generate the linear envelope. Co-contraction between the VL/BF and VM/ST muscles will be quantified using the following formula from a previous study:

$$Co-contraction = \frac{sEMG_{Lower}}{sEMG_{Higher}} \times \left(sEMG_{Lower} + sEMG_{Higher}\right)$$

where EMG_Lower and sEMG_Higher represent the sEMG activity of the less active and more active muscle, respectively, of the two antagonistic muscles.[35]

Adverse Event

Participants will be carefully monitored at each visit throughout the intervention period for the occurrence of adverse events. Any adverse events that arise during the treatment will be systematically documented using a dedicated adverse event case report form and will be assessed for both their relation to the intervention and their severity. Furthermore, all adverse events will be reported to the relevant oversight authorities, including the institutional review board.

Data Management and Monitoring

The study data will include randomization records, baseline characteristics, changes in symptoms and signs following the intervention, follow-up results, and statistical analysis outputs. Data entry will be carried out independently by two research assistants using Excel. Following data entry, the assistants will cross-check for discrepancies, verify the accuracy of the original records against the case report forms, lock the dataset, and then proceed with statistical analyses.

This study will be conducted under the supervision and management of the research team from the School of Traumatology and Orthopedics, Henan University of Chinese Medicine. An independent Data Monitoring Committee (DMC) will oversee the trial to ensure participant safety and to evaluate the integrity and reliability of the collected data. All participants' medical records will be securely stored at the research center, and personal information will be encrypted, used solely for research purposes, and strictly protected from disclosure or unauthorized use.

Statistical Analysis

Primary and secondary outcome measures will be compared between treatment groups at baseline and after the 12-week intervention period. Statistical analyses will be conducted using IBM SPSS Statistics for Windows, Version 24.0 (IBM Corp., Armonk, NY, USA). The Shapiro–Wilk test will be used to assess normality. For variables that are not normally distributed, logarithmic transformation will be applied following previously reported methods.[36] Descriptive statistics will be presented as mean ± standard deviation (SD). Between-group differences will be evaluated using independent samples Student's t-tests, and within-group changes over time will be assessed using paired samples Student's t-tests. If baseline imbalances are observed, analysis of covariance (ANCOVA) will be performed with baseline values entered as covariates to provide adjusted between-group comparisons.

For secondary biomechanical outcomes involving multiple indicators (eg, muscle co-contraction index and EKAM), correction for multiple comparisons (eg, Bonferroni adjustment) will be considered to control the risk of type I error. Preplanned subgroup analyses will be conducted to explore potential differential effects across clinically relevant strata, including radiographic severity (eg, K-L grade) and BMI categories. Statistical significance will be defined as $p < 0.05$.

Discussion

This trial is designed to evaluate the effects of massage on pain, antagonist muscle co-contraction, and knee joint loading in patients with medial knee OA. By combining patient reported outcome measures with objective biomechanical measures, the study aims to clarify the pathways through which massage may influence function. Muscle co-contraction is a compensatory strategy that increases medial knee joint loading. Massage may reduce pain and muscle stiffness, improve proprioception, and modulate neuromuscular excitability. These changes could improve muscle coordination and reduce excessive joint loading.[13,23]

It should be noted that participants and therapists cannot be blinded in this study, which may introduce expectancy and performance biases. These biases could particularly affect subjective outcomes such as pain and self-reported function. These potential effects should be carefully considered when interpreting the results.

One limitation of this protocol is that outcomes will be assessed only at baseline and after the 12-week intervention, which limits the ability to examine short-term and the long-term persistence of effects once the intervention ends. Consequently, the temporal pattern of change in pain, muscle co-contraction, and knee joint loading cannot be fully characterized. This is particularly relevant given that biomechanical adaptations may develop gradually and may not be maintained long-term after treatment withdrawal. Biomechanical adaptations, particularly changes in muscle coordination and joint loading, may require longer exposure and continued monitoring to determine whether they stabilize and

translate into sustained functional benefits.[37] Future studies incorporating short-term assessments and long-term (eg. 52-week) follow-up are therefore needed to better understand the trajectory and durability of massage-related effects. The 12-week intervention period is selected because it represents a commonly used and clinically meaningful timeframe in conservative knee OA trials, allowing sufficient opportunity to detect changes in pain and neuromuscular function while maintaining study feasibility and participant adherence. Furthermore, long-term follow-up is not included primarily due to feasibility considerations, including resource constraints and the potential impact on participant retention.

The current trial is the first randomized controlled study to systematically investigate the effects of massage on mid-term pain, muscle co-contraction, and knee loading in patients with medial knee OA. The protocol was developed in accordance with SPIRIT and CONSORT guidelines and has been registered to ensure transparency, reproducibility, and credibility. Overall, the study is expected to provide valuable insights into the mechanisms and therapeutic effects of massage in knee OA, while offering guidance for future conservative treatment strategies and mechanistic research in this field.

Data Sharing Statement

The datasets generated and/or analyzed in this study are not publicly available to protect participant privacy but can be obtained from the corresponding authors, Min Zhang and Shangzeng Wang, upon reasonable request.

Ethics Approval

The study design and procedures were approved by the Ethics Committee of Henan Provincial Hospital of Traditional Chinese Medicine (Second Affiliated Hospital of Henan University of Traditional Chinese Medicine) (Reference number: 1679-01). The trial will be conducted in accordance with the Helsinki Declaration.

Author Contributions

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

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Disclosure

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