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The impact of blood flow restriction training combined with low-load resistance training on the risk of falls in patients with knee osteoarthritis in China: a single-centre, two-arm, single-blind, parallel randomised controlled trial protocol

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ABSTRACT

Introduction Patients with knee osteoarthritis are at a higher risk of falls compared to healthy individuals, thereby increasing the likelihood of accidental injury. Resistance training is an important strategy for managing knee osteoarthritis. Although some studies suggest that blood flow restriction training combined with low-load resistance training (LL-BFRT) is a beneficial treatment approach, its effect on fall risk and balance function in patients with knee osteoarthritis remains unclear. We aim to conduct a randomised controlled trial to assess the effectiveness of combined training in reducing fall risk and improving function in patients with knee osteoarthritis.

Methods and analysis We will conduct a single-blind pilot randomised controlled trial involving patients with knee osteoarthritis. 98 patients will be randomly assigned to either the LL-BFRT group or the low-load resistance training (LL-RT) group, with a 1:1 allocation ratio. Both groups will undergo a 4-week intervention. Follow-up assessments will be conducted at baseline, 4 weeks, 16 weeks, 28 weeks and 52 weeks. The primary outcome will be the measurement of the fall risk stability index and overall stability index using the Biodex Balance System. Secondary outcomes include the Numerical Rating Scale, the Western Ontario and McMaster Universities Osteoarthritis Index, the 30 s Chair Stand Test, proprioception testing, the Timed Up and Go Test, the Short Form-36 scores, compliance and adverse events. Intention-to-treat principles will be applied in data analysis.

Ethics and dissemination This study has been approved by the Ethics Review Committee of the First Hospital of Quanzhou Affiliated Fujian Medical University (2024-K161). The results of the study will be disseminated through peer-reviewed publications.

Trial registration number ChiCTR2400087829.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is a randomised controlled trial that uses the Biodex Balance System to objectively quantify the changes in fall risk and balance function of patients with knee osteoarthritis before and after treatment.
⇒ The study design includes a 4-week intervention period and a follow-up period of up to 48 weeks, systematically evaluating the efficacy of low-load blood flow restriction training and low-load resistance training at different time points.
⇒ The training protocol of this study incorporates low-load resistance training that is more easily tolerated by patients with knee osteoarthritis.
⇒ A limitation of our study is the inability to implement blinding for both participants and therapists, as well as the potential that the 4-week intervention may not be sufficient to produce lasting effects.

INTRODUCTION

Balance impairment increases the risk of falls.[1] Fall-related costs are estimated to account for 0.85% to 1.5% of total healthcare expenditures.[2] Patients with knee osteoarthritis (KOA) are at an increased risk of falls and fractures compared with healthy individuals age-matched and sex-matched.[3 4] An 8-year longitudinal cohort study found that the severity of KOA symptoms is closely associated with the risk of falls.[5] The overall prevalence of KOA is 14.6%, and, given the ageing population, KOA is expected to impose a significant societal burden.[6 7] Therefore, the identification of effective training methods to improve balance function in patients with KOA is crucial for reducing fall risk, alleviating the societal burden and restoring patient independence.

Patients with KOA may experience impaired balance and an increased risk of falls due to

pain, reduced muscle strength and compromised proprioceptive function.[8–10] Interventions targeting balance training have been shown to be effective in reducing fall risk in older adults.[11] However, for patients with KOA, balance training alone may not completely alleviate clinical symptoms.[12] The American College of Rheumatology's osteoarthritis management guidelines recommend resistance training as an exercise modality for patients with KOA.[13] Given the association between muscle weakness and the symptoms of KOA, incorporating resistance training to enhance muscle strength is essential.[14 15] High-load resistance training is regarded as an effective method for enhancing muscle strength.[16] Patients with KOA are often affected by pain, and low-load resistance training offers an advantage over high-load resistance training in reducing pain. However, it is less effective than high-load resistance training in enhancing muscle strength.[17–19]

Blood flow restriction therapy (BFRT) is a novel rehabilitation method that offers several advantages, including non-invasiveness, ease of use, and reduced effort. During strength training, a pneumatic cuff is placed proximally on the limb and intermittently or continuously inflated to generate pressure, thereby partially or fully restricting arterial and venous blood flow.[20 21] Reduced oxygen availability and accumulation of metabolites induced by blood flow restriction may stimulate type III and IV afferent fibres, inhibit alpha motor neurons and enhance the recruitment of type II muscle fibres.[22 23] Combining BFRT with low-load resistance training (LL-BFRT) has been shown to improve pain, muscle strength, quadriceps size and functional performance in patients with KOA, compared with low-load or high-load resistance training alone, while also reducing joint stress.[24–26] Improving the symptoms of knee osteoarthritis can reduce the risk of falls.[27] Additionally, a study has demonstrated that blood flow restriction training, which includes both balance training and strength training, significantly improves muscle strength and balance function in patients following anterior cruciate ligament reconstruction surgery, compared with conventional strength training.[28] LL-BFRT may serve as a more effective and tolerable clinical rehabilitation measure.[29]

Although LL-BFRT has been shown to improve pain, muscle strength and functional performance in patients with knee joint disease,[30] the impact of this therapy on fall risk in patients with KOA remains unclear. Therefore, our aim is to investigate the effects of blood flow restriction therapy combined with low-load resistance training on fall risk, balance function, pain, lower limb muscle strength, proprioception and activities of daily living in patients with KOA.

METHODS

Study design

This study is a single-centre, two-arm, prospective, single-blind randomised controlled trial. Eligible participants will be randomly assigned to the intervention group, which will receive blood flow restriction therapy combined with low-load resistance training (LL-BFRT), or the control group, which will receive low-load resistance training (LL-RT). Trained therapists will administer strength training to each group of participants three times a week, with sessions lasting 30–45 min each, over a duration of 4 weeks. Follow-up assessments will be conducted at 12, 24 and 48 weeks after the completion of treatment (figure 1). This study adheres to the SPIRIT 2013 Statement, with the research plan expected to begin on 1 September 2024, and conclude on 31 July 31, 2026. (Please refer to online supplemental file 1 for details.)

The primary outcome will assess the fall risk stability index (FRSI) and overall stability index (OSI) using the Biodex Balance System (BBS). Secondary outcomes include the Numerical Rating Scale (NRS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), the 30 s Chair Stand, proprioception test, Time Up and Go Test (TUG), the Short Form-36 scores (SF-36), compliance and adverse events. Participants will be recruited from the inpatient and outpatient rehabilitation departments of the First Hospital of Quanzhou affiliated with Fujian Medical University. Each participant will provide written informed consent. This study protocol has been approved by the Ethics Committee of the First Hospital of Quanzhou affiliated with Fujian Medical University (2024-K161).

Sample size

The sample size analysis is based on changes in the overall stability index (OSI) score. For the primary outcome, which is the change in OSI from baseline to week 4, we assumed a two-sided α error probability of 0.05 and power of 0.8. The total sample size was estimated using G-Power software (V.3.1, Germany) through the t-test for means (difference between two independent mean measurements in two groups). Based on experimental data from similar studies, an OSI effect size of 0.65 was calculated using the software.[31] Considering an effect size of 0.65 and a dropout rate of 20%, we would need at least 98 participants or at least 49 participants per group in this study to detect significant clinical effects on balance function in knee osteoarthritis with LL-BFRT and LL-RT interventions over a period of 4 weeks.

Participants

Randomisation and blinding

We will use the block randomisation method, with block size randomly determined as 4, 6 and 8. After obtaining informed consent (please refer to online supplemental file 2 for details), 98 eligible participants who meet the inclusion criteria will be randomly assigned to the LL-BFRT group or LL-RT group in a 1:1 ratio. The randomisation sequence will be generated by an independent statistician using SPSS V.26.0 (SPSS Inc., USA). An opaque sealed envelope will be used to conceal the random allocation sequence. The researcher responsible for allocation will open the envelope and assign the participant

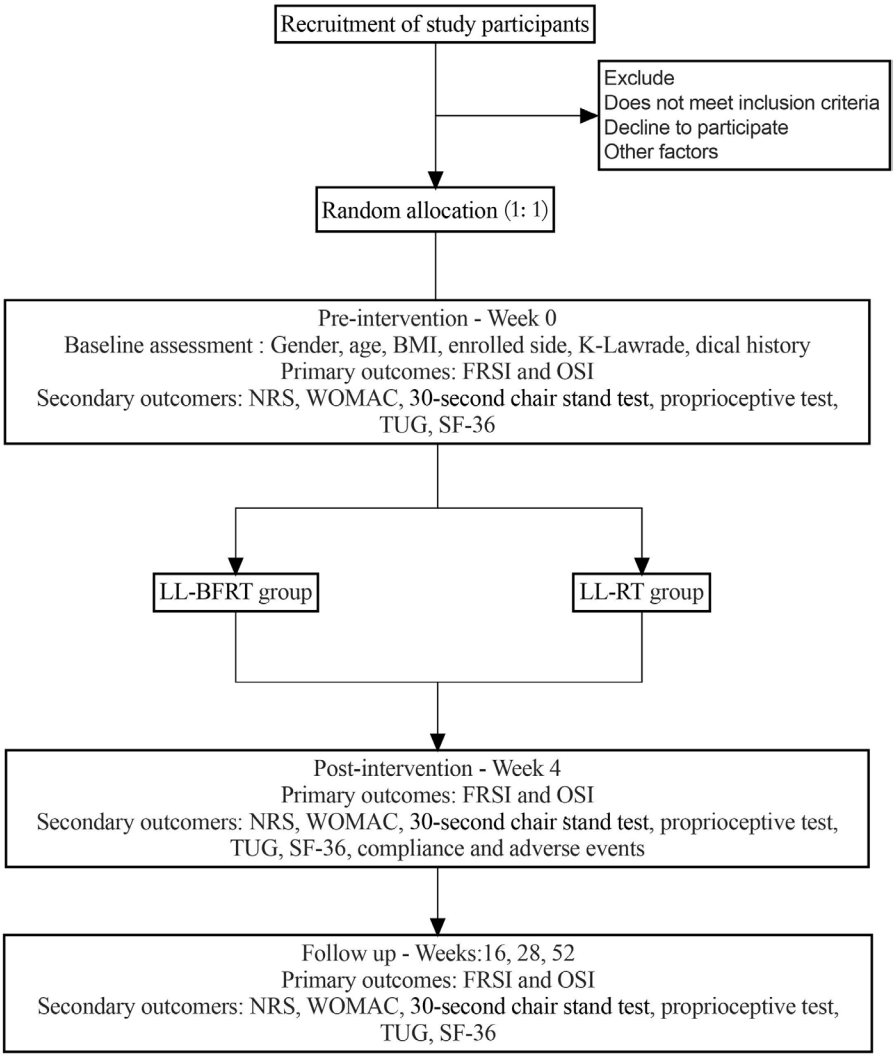

Figure 1 Study flowchart. FRSI, fall risk stability index; LL-BFRT, blood flow restriction training combined with low-load resistance training; LL-RT, low-load resistance training; NRS, Numerical Rating Scale; OSI, overall stability index; SF-36, the Short Form-36 scores; TUG, Time Up and Go Test; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

to the corresponding group only after confirming that the participant meets the inclusion criteria. This study will employ a blinded evaluation method, with all assessments conducted by the same researcher, who will remain unaware of the treatment allocation to minimise bias from subjective factors. Additionally, the statistician will conceal the group allocation and its corresponding meaning, and the code will remain undisclosed until the analysis is completed. If a serious adverse event occurs during the trial, unblinding may be necessary to administer appropriate treatment. Any decision to unblind must be approved by the chief investigator or trial physician and documented in the protocol, with the goal of minimising bias and ensuring the integrity of the data.

Inclusion and exclusion criteria

Inclusion criteria

1. Clinical diagnosis of knee osteoarthritis (clinical diagnosis: (1) knee joint pain occurred for most of the time last month; (2) age >38 years old; (3) joint crepitus; (4) morning stiffness; (5) osteophyte formation; the diagnosis of knee osteoarthritis can be made if (1) + (2) + (3) + (4) or (1) + (3) + (4) + (5) or (1) + (5) are present[32]).
2. Radiographically diagnosed as graded 1–3 according to the Kellgren-Lawrence classification (Kellgren-Lawrence grading system is used for evaluation; grade 0 represents no pathological findings, grade 1 is suspected osteophyte formation, grade 2 is definite osteophyte formation, grade 3 is definite joint space narrowing, grade 4 is late-stage joint space narrowing[33]).
3. The Knee Osteoarthritis Fall Risk Screening Tool (KOAF) will be used to screen patients with KOA for potential fall risk. A KOAF score of ≥1 indicates the presence of fall risk (refer to box 1).[34]
4. Clear consciousness and ability to communicate normally.
5. The patient agrees to participate and is willing to cooperate with the trial.

Box 1 Knee Osteoarthritis Fall Screening Tool (KOAF)

One-leg standing test
⇒ 1 point: <5.3 s.
⇒ 0 points: >5.3 s.
Five times sit-to-stand test
⇒ 1 point: >7.9 s.
⇒ 0 points: <7.9 s.

Exclusion criteria

1. Patients who have received physical therapy for knee arthritis within the past 6 months.
2. Patients with severe lower limb venous thrombosis.
3. Combined with other conditions such as infectious arthritis, rheumatoid arthritis, ligament tear, fracture, etc.
4. Individuals at high risk, such as those with severe hypertension, pregnant or lactating women, and other vulnerable populations.
5. Patients who have previously undergone surgical procedures on the lower limbs.
6. Individuals with significant warning signs of underlying systemic or visceral diseases, including inflammatory conditions, malignancies, unexplained weight loss, infections or recent trauma.

Intervention plan

Intervention location

The entire intervention will be conducted at Quanzhou First Hospital (Quanzhou City, Fujian Province, China). To prevent participants from becoming aware of the different intervention protocols, each group will be assigned to a separate room. Participants in the LL-BFRT group will receive intervention in the exercise therapy room at the Rehabilitation Center of Quanzhou First Hospital. Participants in the LL-RT group will receive intervention in the orthopaedic treatment room at the same center.

Intervention preparation

Determination of one-repetition maximum test (1RM)

1RM is defined as the maximum weight that can be lifted for one repetition. Prior to the intervention, all participants will undergo 1RM measurement. Since direct 1RM testing is not suitable for patients with KOA, an indirect method will be employed to estimate the 1RM, thereby reducing the risk of injury. The 10-repetition maximum (10RM) will be assessed for each participant, and the 1RM value will be calculated based on the 10RM value before the intervention begins.

Testing method

Each participant will begin with a 5 min warm-up, followed by 5 to 10 repetitions of each prescribed exercise (knee extension and leg press) at 40% to 60% of their estimated 1RM. After the warm-up, participants will stretch the relevant muscles or muscle groups before completing 10 repetitions at approximately 70% of their estimated 1RM. If the participant successfully completes 10 repetitions, the weight will be conservatively increased to the next available increment on the testing equipment. The participant will rest for 3 to 5 min and then attempt another 10 repetitions at the new weight. This process will continue until the participant is unable to complete 10 repetitions. The maximum number of repetitions completed will be recorded as the repetition maximum (RM), and the 1RM value will be calculated using the following formula: 1RM=RM/[1.0278−(maximum number of repetitions×0.0278)].[35]

Blood flow restriction therapy combined with low-load resistance training group (LL-BFRT group)

Intervention protocol

The portable blood flow restriction cuff (Theratools) with a cuff width of 13.5 cm will be used. The cuff is inflated and calibrated using a handheld pressure pump, with the cuff pressure set at 100 mm Hg.[36] Prior to each strength training session, the cuff will be applied to the proximal side of the affected thigh, near the groin. The cuff will be inflated before each exercise and deflated after each exercise, followed by a 30 s rest. Each participant will undergo blood flow-restricted low-load resistance training at 35% 1RM once a day, three times a week, for four consecutive weeks.

Resistance training plan

Open chain training

Open chain training (restrict blood flow before training, start the first exercise after inflation is completed):

1. Straight Leg Raise: The patient lies supine on the bed, raises and straightens the legs, then slowly lowers them. Four sets will be performed, with each set consisting of 30, 15, 15 and 15 repetitions. After completing the four sets, the blood flow restriction will be released for 30 s, followed by reinflation to proceed with the next exercise.
2. Prone Knee Extension Raise: The participant lies prone on the bed with the knee joints slightly flexed, extends the entire leg backwards, then slowly lowers it. Four sets will be performed, with each set consisting of 30, 15, 15, and 15 repetitions. After completing the four sets, the blood flow restriction will be released for 30 s, followed by reinflation to proceed with the next exercise.
3. Knee Extension Resistance Training: A knee extension resistance apparatus will be used, with the resistance set at 35% 1RM. Participants will perform knee joint extension exercises. Four sets will be performed, with each set consisting of 30, 15, 15 and 15 repetitions. After completing the four sets, the blood flow restriction will be released for 30 s, followed by reinflation to proceed with the next exercise.

Closed chain training

1. Half Squat (Wall Squat): the participant stands next to a wall with feet hip-width apart, then slowly bends the

knees until they are approximately 90 degrees flexed, before slowly standing up. Four sets will be performed, with each set consisting of 8 to 12 repetitions. After completing the four sets, the blood flow restriction will be released for 30 s, followed by reinflation to proceed to the next exercise.

2. Leg Press: the participant sits on the leg press machine, ensuring that the back is in close contact with the backrest. Both feet will be placed flat on the support board provided by the machine. The participant will push the support board forward with both feet and extend the legs until fully straightened. The resistance will be set to 35% 1RM for the leg press, and four sets will be performed, with each set consisting of 30, 15, 15 and 15 repetitions. After completing the four sets, the blood flow restriction will be released for 30 s, followed by reinflation to proceed to the next exercise.
3. Jumping Exercises: the participant will perform both two-leg jumps or single-leg jumps to enhance muscle strength and explosive power. Four sets will be performed, with each set consisting of 8 to 12 repetitions. The blood flow restriction will be released after completing the four sets of training.

Low-load resistance training group (LL-RT group)

The control group participants performed resistance training without blood flow restriction at 35% of their one-repetition maximum (1RM). The resistance training programme was identical to that of the experimental group, consisting of a total of six exercises. Each participant completed one session per day, 3 days a week, for a duration of four consecutive weeks.

Intervention description

To reduce the bias introduced by variations in participants' lifestyles on the outcomes during the follow-up period, we will conduct a health education programme for the participants 4 weeks after treatment. The content of the session will focus on the benefits of weight loss, regular low-intensity physical activity, and strength and flexibility exercises for managing knee osteoarthritis. Outcome measures will be assessed at five time points: baseline, 4 weeks, 16 weeks, 28 weeks and 52 weeks. We designed figure 2 based on the SPIRIT guidelines (figure 2,).

Outcome measurements

Baseline measurements will be taken prior to the intervention, which will include the completion of a demographic questionnaire assessing participant characteristics, such as gender, age, body mass index, side of involvement, Kellgren-Lawrence grade and disease duration.

Primary outcomes

To assess the balance function of patients with KOA, this study used the BBS (Biodex Medical Systems, Shirley, New York, USA), which features a movable balance platform capable of providing up to 20° of surface tilt within a 360° range of motion. The platform offers 12 stability levels that can be adjusted in both anterior-posterior and medial-lateral directions. A level of 1 indicates the least stable position, while 12 represents the most stable.[37] The system interfaces with computer software (Biodex, V. 3.1, Biodex Medical Systems) enable objective assessment of balance.[38] It can be used to evaluate postural stability limits, static postural stability and dynamic fall risk. The BBS demonstrates excellent test-retest reliability for postural stability, with an intraclass correlation coefficient (ICC) of 0.93.[39]

1. The fall risk assessment measures the patient's overall postural sway on uneven surfaces to predict the risk of falls. During testing, the platform provides feedback on the participant's centre of gravity, displayed as a black dot marker on a visual screen. As the test progresses, the stability of the platform gradually decreases. Participants must adjust their balance to maintain their centre of gravity and ensure the black dot remains at the target position as the platform's stability changes. The overall sway of the participant's balance is calculated and represented by the FRSI, with higher scores indicating a greater fall risk.[40] The test is performed three times, and the average score is recorded.
2. The purpose of the postural stability test is to assess the participants' ability to control their centre of gravity while maintaining body posture stability. The balance test using the BBS is conducted as follows: the participant is instructed to stand barefoot with slightly bent knees, place their hands on the iliac crest and position their unsupported leg behind the weight-bearing leg. They are then instructed to align their centre of pressure within the smallest concentric circle (balance zone) displayed on the BBS monitor. Each balance trial lasts for 30 s, and reliability is measured by conducting multiple trials. A 10 s rest period between trials is implemented to reduce fatigue in the testing leg. In this test, participants are instructed to maintain their position on the unstable platform of the BBS, with a resistance level set at 8. The OSI is used as one of the outcome measures; a higher OSI indicates greater difficulty or instability in balancing on the platform.[37] The test is performed three times, and the average score is recorded.

Secondary outcomes

1. The NRS is a unidimensional pain scale consisting of 11 numbers, ranging from 0 to 10, that describe the intensity of pain in an incrementally increasing manner. The NRS demonstrates good test-retest reliability, with an ICC of 0.92.[41] It assesses the most severe pain experienced by the participant in the past week. A higher score indicates more intense pain.[42]
2. The WOMAC is a comprehensive assessment tool for evaluating lower limb joints in participants with KOA, encompassing three domains: pain, joint stiffness and daily life function. The pain domain includes 5 items, joint stiffness includes 2 items and daily activity capacity includes 17 items. This tool quantifies the partic-

	STUDY PERIOD						
	screening	Baseline	intervention		Follow-up		
TIMEPOINT**	*Week-1*	*Week-0*	*Week-1*	*Week-4*	*Week-16*	*Week-28*	*Week-52*
ENROLMENT:							
Eligibility screen	X						
Informed consent	X						
Allocation		X					
INTERVENTIONS:							
[LL-BFRT]			←	→			
[LL-RT]			←	→			
ASSESSMENTS:							
FRSI		X		X	X	X	X
OSI		X		X	X	X	X
NRS		X		X	X	X	X
WOMAC		X		X	X	X	X
30-Second Chair Stand test		X		X	X	X	X
proprioceptive test		X		X	X	X	X
TUG		X		X	X	X	X
SF-36		X		X	X	X	X
compliance and adverse events				X	X	X	X

Figure 2 Study design timeline. FRSI, fall risk stability index; LL-BFRT, blood flow restriction training combined with low-load resistance training; LL-RT, low-load resistance training; NRS, Numerical Rating Scale; OSI, overall stability index; SF-36, The Short Form-36 Health Survey; TUG, Time Up and Go Test; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

ipants' subjective experience through self-reported scores, with participants rating their condition after each item. A lower score indicates better function and less severity.[43] All WOMAC subscales (pain, stiffness and physical function) exhibit satisfactory test-retest reliability, with ICC of 0.86, 0.68 and 0.89, respectively.[44]

3. Leg strength and endurance will be assessed using a 30 s Chair Stand Test. Participants will sit on a chair (43 cm in height) and, without using their upper limbs for support, will stand up and sit back down as many times as possible within 30 s. The total number of repetitions completed will be recorded.[45] A higher number of repetitions indicates better functional performance and endurance.[46] The 30 s Chair Stand Test demonstrates adequate test-retest reliability, with an ICC of 0.84.[47]
4. Proprioception testing: instruct the participants to stand with their knee fully extended and position the electronic inclinometer on the lateral lower third of the thigh. The participants are then asked to squat until they reach a target angle of 30°. They are allowed to use one hand to hold onto a wall or support for balance during the single-leg squat. Once the target angle is reached, they are instructed to hold the position for 5 s before returning to the starting position (knee fully extended). This task is repeated three times. This test demonstrates excellent test-retest reliability, with an ICC of 0.88.[48] The difference between the perceived and reproduced angles is recorded. A smaller difference indicates better proprioception.
5. TUG test: the TUG test measures the time, in seconds, required for the participant to stand up from a chair, walk a distance of 3 metres, turn around, return to the chair and sit down. This test is widely used in geriatric medicine to assess balance, gait and functional ability in performing basic activities of daily living in older adults.[49] The TUG is a reliable and effective measure

for quantifying functional capacity and serves as a strong predictive indicator of patients' ability to perform daily activities safely. It is also recommended as a functional outcome for KOA. The test is simple to administer and typically takes 2–3 min to complete.[50] The TUG test demonstrates excellent test-retest reliability, with an ICC of 0.97.[51]

6. SF-36 Health Survey: the SF-36 Health Survey is one of the most widely used tools for assessing various aspects of health. It evaluates eight dimensions: physiological function, physical role, bodily pain, general health, vitality, social function, emotional role and mental health.[52] The survey is known for its high reliability and validity, with higher scores reflecting better quality of life. The SF-36 exhibits good test-retest reliability, with ICC ranging from 0.66 to 0.94.[53]
7. Compliance and adverse events: compliance will be assessed by the percentage of participants who complete the intervention, the total percentage of participants adhering to the exercise regimen, the number of withdrawals due to reasons related to the exercise programme or overall study, the number of exercises discontinued due to pain, and any adverse events or incidents that prevent participants from completing the prescribed exercises.

Data management and analysis

Data management

Upon successful recruitment, participants will be assigned numerical codes to replace their personal identifiers, ensuring their privacy. Data will be collected at baseline and at weeks 4, 16, 28 and 52. Two researchers will be responsible for entering the paper-based data into a centralised database. To ensure data quality and accuracy, a third researcher will review the entered data, comparing it with the original source. All paper-based documents and electronic files will be securely stored and backed up by the principal investigator. These files will be retained for 5 years after the completion of the study.

Data analysis

Data analysis will be performed according to the intention-to-treat principle. All data will be entered and analysed using Microsoft Excel 2016 and IBM SPSS Statistics V.26.0 (SPSS Inc., Illinois, USA). For continuous variables such as age, BMI, disease duration, OSI, FRSI, NRS, WOMAC, 30 s chair stand test, angle reproduction difference, TUG and SF-36, normality will be assessed using the Shapiro-Wilk test. If the data are normally distributed, they will be presented as mean±SD ($\bar{X}$±s) and analysed using t-tests or ANOVA. If the data are not normally distributed, they will be presented as median and IQR (M (P25, P75)) and analysed using the Wilcoxon rank-sum test. Categorical variables, including gender, K-L grade, affected side, percentage of participants who completed the intervention, and incidence of adverse events, will be presented as percentages (n%) and analysed using the χ^2 test or Fisher's exact test. Considering the potential for missing data during follow-up, this study will use a linear mixed-effects model (LME) to analyse both the primary outcomes (OSI and FRSI) and secondary outcomes (NRS, WOMAC, STS, angle reproduction difference, TUG, SF-36, completion rate and incidence of adverse events), as the LME is robust to missing values. Fixed effects will include group effects (LL-BFRT, LL-RT), time effects (baseline, 4 weeks, 16 weeks, 28 weeks, 52 weeks), and group-time interaction effects. Random effects will include both intercept and slope, which may vary over time. Effect sizes will be reported by estimating the marginal means along with their 95% CIs. The significance level will be set at $p<0.05$.

Patient and public involvement

None

DISCUSSION

With the ageing population and the increasing prevalence of KOA, reducing the risk of falls in this cohort has become increasingly important. LL-BFRT offers a convenient and effective approach for managing KOA. While previous systematic reviews have demonstrated its therapeutic benefits in improving muscle strength, function and pain in KOA, there is limited research regarding its impact on fall risk and balance function.[26 54] Therefore, we plan to conduct a single-centre, cluster-randomised, single-blind study to compare the effectiveness of blood flow restriction training combined with low-load resistance training in reducing fall risk and enhancing balance function in patients with KOA.

This study offers several notable advantages. First, it is the first to specifically investigate the impact of LL-BFRT on fall risk and balance function in patients with KOA, addressing a significant gap in the current literature. Second, the study design incorporates a 4-week intervention period followed by a follow-up of up to 48 weeks, enabling a comprehensive evaluation of the efficacy of both LL-BFRT and LL-RT at various time points. Third, LL-RT is expected to significantly reduce pain and discomfort during training, enhancing patient comfort and acceptability, which, in turn, is anticipated to improve compliance and ensure the continuity and effectiveness of the intervention. Fourth, this study uses multiple outcome measures, including OSI, FRSI, NRS, WOMAC, 30 s Chair Stand Test, proprioceptive measurements, TUG and SF-36, as well as compliance and adverse events. Finally, this study employs rigorous randomisation and blinding procedures, alongside linear mixed-effects models for data analysis, ensuring the scientific validity and reliability of the findings. However, despite these strengths, our study still has the following limitations. First, we were unable to blind the participants and therapists. Second, during the measurement period, participants needed to learn to use the BBS, and their learning ability may affect the measurement of fall risk stability index and overall stability index. Additionally, the 4-week

intervention duration may be insufficient to observe long-term sustained effects.

Our study aims to compare the effects of blood flow restriction therapy combined with low-load resistance training on fall risk, balance function, pain, lower limb strength, proprioception and activities of daily living in patients KOA. The findings from this research will provide valuable guidance for the clinical application of LL-BFRT in managing knee osteoarthritis.

Trial status

This study is currently recruiting participants. The first patient was enrolled in September 2024, and the study is expected to conclude in July 2026.

ETHICS AND DISSEMINATION

The results of the study will be disseminated through peer-reviewed publications. This study has been approved by the Ethics Review Committee of the First Hospital of Quanzhou Affiliated Fujian Medical University (2024-K161).

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Contributors QL is the principal investigator of this study and drafted the initial manuscript. QL, TL and YZ contributed to the conception design of the study. QL, TL, YZ, YD and XC contributed to the development and optimisation of the intervention. YD and JQ contributed to statistical description and analysis. FW critically reviewed and revised the manuscript. All authors have read and approved the final manuscript. FW acted as the guarantor.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

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