Clinical Trial Protocol

Gait Retraining for Runners With Patellofemoral Pain

Version 1.0 | Date: 2026.04.01

1. Administrative Information

Sponsor / Responsible Party

Beijing Sport University

Principal Investigator

Haonan Wang, PhD

Trial Registration

ClinicalTrials.gov (to be assigned)

Ethics Approval

Approved by Ethics Committee of Beijing Sport University

Study Period

December 2026 - December 2026

2. Background and Rationale

Patellofemoral pain (PFP) is a common overuse injury in runners. Increased patellofemoral joint stress (PFJS) is considered an important biomechanical factor related to PFP. Although traditional strengthening exercises can improve symptoms and function, they may not change running biomechanics. Gait retraining, especially increasing cadence, may help reduce PFJS and relieve symptoms, but evidence from randomized controlled trials is still limited. Therefore, this study investigated whether wearable device-assisted gait retraining was more effective than education alone in reducing pain, improving function, and changing running biomechanics in female runners with PFP.

3. Objectives

Primary Objective

To determine the effectiveness of wearable device-assisted gait retraining on pain reduction during running in female runners with PFP.

Secondary Objectives

- To assess improvements in function (Anterior Knee Pain Scale, AKPS).
- To examine changes in running mechanics (knee kinematics, kinetics, PFJS).
- To evaluate adherence, feasibility, and safety of wearable device-assisted gait retraining.

4. Study Design

Type

Randomized, controlled, single-blind, parallel-group trial

Allocation

1:1 randomization

Masking

Outcome assessors blinded; participants not blinded due to intervention nature

Arms

- Intervention Arm: Education + Gait retraining
- Control Arm: Education only

Study Duration

18 weeks per participant (6-week intervention + 12-week follow-up)

5. Participants

Inclusion Criteria

- Female, age 18-45 years
- Unilateral/bilateral anterior knee pain > 4 weeks
- VAS pain >= 3/10 during running and >= 2 of the following: jumping, squatting, kneeling, stairs, prolonged sitting, or resisted knee extension
- Running >= 15 km per week
- Natural rearfoot striker (verified by high-speed video)

Exclusion Criteria

- Acute trauma, history of patellar dislocation, meniscal/chondral lesions
- Prior knee surgery or injection in past 12 months
- Rheumatologic, neurologic, or degenerative disease
- Pregnancy

6. Interventions

6.1 Control Group (Education)

Delivered via WeChat platform. Content: PFP education, load management strategies, symptom-based training modifications, and strengthening exercises (quadriceps and hip). Self-monitored running program guided by pain thresholds.

6.2 Intervention Group (Gait Retraining + Education)

Same education program as control. Gait retraining protocol: 6-week program, twice per week. Step rate increased by 10%, monitored via smartwatch (Huawei GT4). Real-time cadence feedback via auditory metronome cues. Feedback frequency: every session (weeks 1-4), once (week 5), faded (week 6). Duration progressed from 15 min to 30 min per session. Pain monitoring: <= 3/10 during running, return to baseline within 60 min.

7. Outcomes

7.1 Primary Outcome

Pain during running (VAS-R, 0-100 mm) at baseline, 6 weeks, and 18 weeks.

7.2 Secondary Outcomes

- VAS-U (usual pain), VAS-W (worst pain) at baseline, 6 weeks, and 18 weeks.
- Function: Anterior Knee Pain Scale (AKPS) at baseline, 6 weeks, and 18 weeks.
- Running-related measures: weekly mileage, cadence (smartwatch logs) at baseline and 6 weeks.
- Running mechanics: 3D kinematics, GRF at baseline and 6 weeks.

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7.3 Safety Outcomes

Adverse events (pain exacerbation, injuries, withdrawal).

8. Sample Size

Sample size estimated with G*Power. Detectable difference: 20 mm VAS (MCID for PFP). Power: 80%, alpha = 0.05. Estimated: 22 participants per group (total n = 44), accounting for 15% dropout.

9. Randomization and Blinding

Random sequence generated by independent statistician. Allocation concealed in sequential opaque envelopes. Assessors blinded to group assignment. Participants instructed not to disclose intervention to evaluators.

10. Data Analysis

Approach: Intention-to-treat and per-protocol. Statistical tests: Repeated measures ANOVA and linear regression models (adjusted for baseline, age, BMI, running duration, symptom duration). Multiple imputation for missing data. Effect size: Partial eta squared (eta^2). Significance: $p < 0.05$.

11. Ethics and Dissemination

Ethical approval granted by Beijing Sport University Ethics Committee. Informed consent obtained from all participants. Results will be disseminated via peer-reviewed journals, academic conferences, and ClinicalTrials.gov.