Clinical Trial Protocol

Title

Effectiveness of Gait Retraining in Female Runners with Patellofemoral Pain: A Randomized Controlled Trial

1. Administrative Information

Sponsor / Responsible Party: Beijing Sport University

Collaborators: Sports Medicine Center, West China Hospital, Sichuan 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 2022 – December 2023

2. Background and Rationale

Patellofemoral pain (PFP) is the most common running-related overuse injury, with prevalence up to 17% among runners. Increased patellofemoral joint stress (PFJS) is a major biomechanical contributor to PFP. Traditional strengthening exercises improve function but do not alter running biomechanics. Gait retraining, particularly cadence modification, has been proposed as a promising approach to reduce PFJS and alleviate symptoms. However, evidence from randomized controlled trials remains limited. This study investigates whether wearable device-assisted gait retraining reduces pain, improves function, and modifies running biomechanics in female runners with PFP compared to education alone.

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 + Wearable device-assisted 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 & 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)

- Function: Anterior Knee Pain Scale (AKPS)

- Running-related measures: weekly mileage, cadence (smartwatch logs)

- Running mechanics: 3D kinematics, GRF, PFJS and contact force calculations

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 (η^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.