Study Protocol Draft

Digital Health–Based Rehabilitation for Participants with Patellofemoral Pain

Randomized Controlled Trial
Version: 1.0 (2025.10.9)

Design	Two-arm, parallel-group, assessor-blinded randomized controlled superiority trial
Population	Adults with patellofemoral pain (PFP)
Intervention	6-week digital health program
Comparator	6-week self-guided exercise using written home exercise instructions without ongoing digital supervision
Assessments	Baseline, post-intervention at 6 weeks, and follow-up at 18 weeks
Primary outcome	Change in Anterior Knee Pain Scale (AKPS) from baseline to 6 weeks

1. Background and Rationale

Patellofemoral pain (PFP) is a common musculoskeletal condition characterized by pain around or behind the patella during activities such as stair ambulation, squatting, running, jumping, and prolonged sitting. PFP is associated with reduced function, activity limitation, and lower quality of life. Exercise therapy and patient education are considered core conservative treatments; however, adherence is often suboptimal, progression may be inconsistent, and access to supervised care may be limited.

Digital health interventions may help address these barriers by combining exercise prescription, educational content, symptom monitoring, adherence support, and remote feedback within a single platform. Compared with self-guided exercise alone, digital health delivery may improve both clinical outcomes and treatment engagement in individuals with PFP.

2. Objectives

Primary objective: To compare the effectiveness of a digital health rehabilitation program versus self-guided exercise in improving knee-related function in individuals with PFP.

Secondary objectives: To compare the effects of the two interventions on pain intensity, knee symptoms, self-satisfaction, exercise self-efficacy, kinesiophobia, pain catastrophizing, health-related quality of life, muscle strength, adherence, and adverse events.

3. Hypothesis

Participants receiving the digital health intervention will demonstrate greater improvement in knee-related symptoms and function than participants receiving self-guided exercise.

4. Study Design

This study is a single-center or multicenter, two-arm, parallel-group, assessor-blinded randomized controlled superiority trial. Eligible participants will be randomly allocated in a 1:1 ratio to either a digital health rehabilitation group or a self-guided exercise group.

Intervention period: 6 weeks
Assessment time points: baseline, 6 weeks (post-intervention), and 18 weeks (follow-up)

5. Participants

Inclusion criteria:
• Age 18–45 years
• Clinical diagnosis of patellofemoral pain
• Symptoms for at least 3 months
• Anterior or retropatellar knee pain provoked by at least two aggravating activities such as stair ambulation, squatting, running, jumping, or prolonged sitting
• Baseline pain intensity of at least 3/10 on the Numeric Rating Pain Scale
• Ability to provide written informed consent and comply with study procedures

Exclusion criteria:
• Previous knee surgery
• Patellar dislocation or obvious instability
• Ligament injury, clinically important meniscal injury, moderate to severe knee osteoarthritis, or other major structural knee pathology
• Major hip, ankle, or lumbar disorders substantially affecting lower-limb function
• Neurological disorders affecting movement or balance
• Pregnancy
• Structured PFP rehabilitation within the previous 3 months
• Any other condition deemed unsuitable by the investigators

6. Randomization and Blinding

Participants will be randomly assigned in a 1:1 ratio using a computer-generated randomization sequence. Allocation will be concealed using opaque sealed envelopes or a centralized allocation system. Because of the nature of the interventions, participants and treating personnel cannot be blinded. Outcome assessors and data analysts will remain blinded to group allocation whenever feasible.

7. Interventions

Digital health group:
Participants will receive a 6-week digital health program delivered through a smartphone application mini-program. The intervention will include:
• PFP education (condition information, pain management, load management, and activity advice)
• Progressive exercise advancement according to pain response and performance
• Video demonstration and structured session guidance
• Symptom tracking and exercise logging
• Automated reminders and adherence support
• Remote therapist feedback when required

Self-guided exercise group:
Participants will receive a 6-week self-guided home exercise program with initial instruction delivered in printed format. Participants will be advised to perform the exercises independently at home. No ongoing digital supervision, tailored feedback, or structured adherence prompts will be provided.

8. Outcome Measures

Primary outcome:
• Change in Anterior Knee Pain Scale (AKPS) from baseline to 6 weeks

Secondary outcomes:
• Numeric Rating Pain Scale (NRPS)
• Knee injury and Osteoarthritis Outcome Score(KOOS)
• Tampa Scale for Kinesiophobia (TSK)
• Pain Catastrophizing Scale (PCS)
• Muscle strength
• Adherence
• Adverse events

9. Assessment Schedule

All primary and secondary outcomes will be assessed at:
• Baseline
• 6 weeks (post-intervention)
• 18 weeks (follow-up)

Adherence will be recorded throughout the 6-week intervention period. Adverse events will be monitored throughout the intervention and follow-up period.

10. Sample Size Calculation

Sample size was calculated for a two-group superiority trial using change scores (pre–post differences). The calculation was based on previous data reporting a mean change of 10.8 (SD 8.2) in the digital health group and 1.8 (SD 6.7) in the self-guided exercise group.

Expected mean difference in change scores	9.0 points
Pooled SD	7.49
Standardized effect size (Cohen's d)	1.20
Required sample size per group (80% power, two-sided alpha 0.05)	11 participants
Required sample size per group (90% power, two-sided alpha 0.05)	16 participants
Recommended recruitment target	At least 20 participants per group (20 total) allowing for approximately 20% dropout

Formula used for superiority testing with two independent groups: $n = 2 \times (Z_1-\alpha/2 + Z_1-\beta)^2 \times SD_p^2 / \delta^2$, where δ is the expected between-group difference in change scores and SD_p is the pooled standard deviation.

11. Statistical Analysis

The primary analysis will follow the intention-to-treat principle. Continuous outcomes will be summarized using means and standard deviations or medians and interquartile ranges as appropriate. Baseline characteristics will be described for both groups.

Between-group comparisons of the primary and secondary continuous outcomes will be performed using analysis of covariance (ANCOVA) with baseline values as covariates, or linear mixed-effects models to account for repeated measurements over time. The main treatment effect will be examined at 6 weeks and maintained-effect analyses will be performed at 18 weeks.

A two-sided significance level of 0.05 will be used. Adverse events will be summarized descriptively.

12. Ethics and Dissemination

The study protocol should be approved by the relevant institutional ethics committee before participant enrollment. Written informed consent will be obtained from all participants before any study procedures are performed.

Study findings will be disseminated through peer-reviewed publications, academic conferences, and other scholarly communication channels.

13. Registration-Ready Summary Paragraph

This randomized controlled superiority trial will compare a 6-week digital health rehabilitation program with a 6-week self-guided exercise program in adults with patellofemoral pain. Assessments will be performed at baseline, 6 weeks, and 18 weeks. The primary outcome will be change in AKPS from baseline to 6 weeks. Secondary outcomes will include pain intensity, self-reported function, psychological outcomes, quality of life, muscle strength, adherence, and adverse events.