Telerehabilitation Versus Face-to-Face Supervised Rehabilitation for Patellofemoral Pain
A Randomized Non-Inferiority Trial

Version 1.0 (2024.12.5)

Study design	Randomized, parallel-group, assessor-blinded, non-inferiority trial
Population	Individuals with patellofemoral pain
Intervention duration	6 weeks
Assessment time points	Baseline, post-intervention at 6 weeks, and follow-up at 18 weeks
Primary purpose	Treatment

Study Title

Telerehabilitation Versus Face-to-Face Supervised Rehabilitation for Patellofemoral Pain: A Randomized Non-Inferiority Trial

Brief Title

Telerehabilitation for Patellofemoral Pain

Study Description

Brief Summary

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. Exercise therapy combined with patient education is considered first-line treatment, and supervised rehabilitation is commonly used to improve adherence and clinical outcomes.

Telerehabilitation may increase accessibility and reduce time and travel burden, but high-quality evidence remains limited regarding whether telerehabilitation provides outcomes that are not inferior to conventional face-to-face supervised rehabilitation in individuals with PFP.

This study is a randomized, assessor-blinded, non-inferiority trial designed to compare telerehabilitation with face-to-face supervised rehabilitation in individuals with patellofemoral pain. The trial will evaluate whether telerehabilitation is not inferior to face-to-face supervised rehabilitation in improving pain and knee-related function, while also examining psychological outcomes, self-satisfaction, and adherence.

Detailed Description

Patellofemoral pain is one of the most common causes of chronic anterior knee pain and is associated with persistent symptoms, functional limitations, reduced physical activity, and decreased quality of life. Current best practice supports exercise therapy and education as the core conservative management approach. However, barriers such as limited access to care, travel burden, time constraints, and uneven distribution of rehabilitation resources may restrict participation in supervised rehabilitation programs.

Telerehabilitation offers a potential alternative method for delivering structured rehabilitation while maintaining therapist supervision and progressive exercise prescription. If telerehabilitation can achieve outcomes that are not clinically worse than face-to-face supervised rehabilitation, it may serve as a feasible and scalable care model for individuals with PFP.

The purpose of this study is to determine whether telerehabilitation is non-inferior to face-to-face supervised rehabilitation in improving knee pain and function in individuals with patellofemoral pain. Secondary aims are to compare changes in pain intensity, symptoms, psychological factors, health-related quality of life, self-satisfaction, exercise self-efficacy, muscle strength, functional performance, adherence, and adverse events between groups.

Study Design

Study Type	Interventional
Allocation	Randomized
Intervention Model	Parallel Assignment
Masking	Single (Outcomes Assessor)
Primary Purpose	Treatment
Official Title	Telerehabilitation Versus Face-to-Face Supervised Rehabilitation for Patellofemoral Pain: A Randomized Assessor-Blinded Non-Inferiority Trial

Arms and Interventions

Experimental: Telerehabilitation Group

Participants allocated to the telerehabilitation group will receive a 6-week remotely delivered rehabilitation program for patellofemoral pain. The program will include patient education, progressive exercise therapy, and therapist supervision delivered through digital platforms such as smartphone applications, video conferencing, or online communication tools. The exercise program will include knee- and hip-targeted strengthening, functional closed-chain exercises, and progressive loading based on symptom response and movement quality. Participants will receive scheduled remote supervision and feedback throughout the intervention period.

Intervention: Telerehabilitation

A 6-week remotely supervised rehabilitation program including education, progressive exercise therapy, and regular therapist-guided follow-up delivered through digital communication platforms.

Active Comparator: Face-to-Face Supervised Rehabilitation Group

Participants allocated to the face-to-face supervised rehabilitation group will receive a 6-week in-person supervised rehabilitation program for patellofemoral pain. The intervention content will be matched as closely as possible to the telerehabilitation group, including patient education, progressive exercise therapy, and individualized progression principles. Supervision and feedback will be delivered during in-person rehabilitation sessions.

Intervention: Face-to-Face Supervised Rehabilitation

A 6-week in-person supervised rehabilitation program including education, progressive exercise therapy, and regular therapist-guided follow-up.

Outcome Measures

Primary Outcome Measure

Change in Anterior Knee Pain Scale (AKPS/Kujala score) from baseline to 6 weeks. The Anterior Knee Pain Scale (AKPS, also known as the Kujala score) will be used to assess knee-related symptoms and

function in participants with patellofemoral pain. The primary analysis will evaluate whether telerehabilitation is non-inferior to face-to-face supervised rehabilitation with respect to change in AKPS from baseline to 6 weeks.

Secondary Outcome Measures

- Change in Numerical Rating Pain Scale (NRPS) from baseline to 6 weeks and 18-week follow-up. Pain intensity will be assessed using the Numerical Rating Pain Scale. This may include average pain over the previous 7 days and/or pain during aggravating activities such as stair ambulation or squatting.
- Change in KOOS subscale scores from baseline to 6 weeks and 18-week follow-up. The Knee injury and Osteoarthritis Outcome Score (KOOS) will be used to assess pain, symptoms, activities of daily living, sport/recreation, and knee-related quality of life.
- Change in Tampa Scale for Kinesiophobia (TSK) from baseline to 6 weeks and 18-week follow-up. The TSK will be used to assess fear of movement or reinjury.
- Change in Pain Catastrophizing Scale (PCS) from baseline to 6 weeks and 18-week follow-up. The PCS will be used to assess pain-related catastrophic thinking.
- Change in EQ-5D-5L from baseline to 6 weeks and 18-week follow-up. The EQ-5D-5L will be used to assess health-related quality of life.
- Change in self-satisfaction score from baseline to 6 weeks and 18-week follow-up. Self-satisfaction with treatment outcomes will be assessed using a participant-reported satisfaction measure.
- Change in muscle strength from baseline to 6 weeks and 18-week follow-up. Muscle strength outcomes will include knee extensor strength, knee flexor strength, hip abductor strength, and hip adductor strength.
- Adherence during the 6-week intervention period. Adherence will be assessed based on rehabilitation completion rate, attendance/participation rate, or exercise completion records.
- Adverse events during the intervention and follow-up period. Any intervention-related or potentially intervention-related adverse events will be recorded throughout the study period.

Eligibility Criteria

Inclusion Criteria

- Aged 18 to 45 years
- Clinical diagnosis of patellofemoral pain
- History of anterior or retropatellar knee pain for at least 3 months
- Pain provoked by at least two of the following activities: stair ambulation, squatting, running, jumping, or prolonged sitting
- Baseline knee pain intensity of at least 3/10 on the Numerical Rating Pain Scale
- Willing and able to participate in the rehabilitation program and follow-up assessments
- Able to provide written informed consent

Exclusion Criteria

- Previous knee surgery
- History of patellar dislocation or instability
- Evidence of ligament injury, meniscal injury requiring separate management, moderate to severe knee osteoarthritis, or other major structural knee pathology
- Concurrent hip, ankle, lumbar spine, or other musculoskeletal disorders substantially affecting lower limb function
- Neurological disorders affecting movement or balance
- Severe cardiopulmonary or systemic disease contraindicating exercise
- Received structured lower limb rehabilitation within the previous 3 months
- Pregnancy

- Any other condition judged by the investigators to make participation unsuitable

Study Timeline

- Intervention duration: 6 weeks
- Assessment time points: baseline, post-intervention at 6 weeks, and follow-up at 18 weeks
- Participants will complete all study procedures according to the prespecified schedule of assessments

Study Hypothesis

Telerehabilitation will be non-inferior to face-to-face supervised rehabilitation in improving knee-related symptoms and function, as measured by the change in AKPS from baseline to 6 weeks, within a prespecified non-inferiority margin.

Study size calculation

Scale (AKPS, also known as the Kujala score) as the primary outcome. The non-inferiority margin was set at 8 points. This decision was based on prior literature showing that the minimal clinically important difference (MCID) for the AKPS in patellofemoral pain is approximately 10 points, while a recent randomized trial in anterior knee pain used a Kujala margin range of 8 to 10 points. Therefore, 8 points was selected as a clinically conservative non-inferiority margin. The standard deviation was assumed to be 13 points, consistent with the value used in recent anterior knee pain sample size planning. Using a one-sided alpha of 0.025, 80% power, equal allocation between groups, and assuming no true difference between groups, the sample size was calculated using the standard formula for a continuous outcome in a non-inferiority design: n per group equals 2 multiplied by the variance multiplied by the square of the sum of the standard normal values for alpha and beta, divided by the square of the non-inferiority margin. Substituting a standard deviation of 13, a non-inferiority margin of 8, a Z value of 1.96 for alpha, and a Z value of 0.84 for beta yielded 41.45 participants per group, which was rounded up to 42 participants per group. Allowing for a 20% dropout rate, the adjusted sample size was 52.5 participants per group. Therefore, 53 participants will be recruited per group, resulting in a total sample size of 106 participants. This approach was informed by published evidence on the clinical interpretability of the AKPS and by recent trial methodology in anterior knee pain

Statistical Analysis

The primary analysis will be conducted according to the intention-to-treat principle, with additional per-protocol analyses as appropriate for non-inferiority assessment. Between-group differences in change from baseline will be analyzed using appropriate repeated-measures models or analysis of covariance, adjusting for baseline values where applicable. Non-inferiority will be concluded if the confidence interval for the between-group difference does not cross the prespecified non-inferiority margin.

Safety Monitoring

Adverse events, including symptom aggravation, exercise-related injury, or other unexpected events during the intervention and follow-up period, will be monitored and recorded.

Ethics and Dissemination

The study protocol will be reviewed and approved by the relevant institutional ethics committee prior to 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 and academic conferences.