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Laser-assisted exercise for adolescent with patellofemoral pain syndrome

Submission date
21/11/2025

Recruitment status
No longer recruiting

Registration date
25/11/2025

Overall study status
Completed

Last Edited
25/11/2025

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[X] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Patellofemoral Pain Syndrome (PFPS) is a common knee condition in adolescents, causing pain around the kneecap. This pain is often made worse by activities like running or squatting and can lead to a fear of movement, reduced physical function, and a lower quality of life. This study aimed at investigating the synergetic effects of low-energy laser therapy and a standard exercise program. This study aims to see if the combined approach is more effective at reducing pain, overcoming fear of movement, improving knee function, and enhancing quality of life in adolescents with PFPS compared to exercise alone.

Who can participate?
Adolescents aged 10 to 18 years, of either sex, who have been diagnosed with PFPS by an orthopedic physician. Eligible participants had knee pain for more than three months, with a pain level greater than 3 on a 10-point scale, which gets worse with activity and improves with rest.

What does the study involve?
In this study, participants were be randomly allocated into different groups. The groups received different combinations of the two main treatments:
• Low-energy laser therapy: A non-invasive, painless light therapy applied to the knee.
• Exercise program: A series of specific exercises tailored to the individual, focusing on strengthening and improving movement.
All treatments were supervised by a physical therapist. Before and after the intervention period, participants completed assessments, including:
• Pain intensity
• Kinesophobia
• Disability
• Quality of life

What are the possible benefits and risks of participating?
Benefits:
Participants may experience improvements in their knee pain, find it easier to perform daily activities and sports, and have a better overall quality of life. Their participation will also help researchers design better treatment plans for other young people with similar knee pain.

Risks:
The risks are minimal. The laser therapy is very safe, with the main precaution being the use of protective goggles. The exercises may cause temporary muscle soreness or a short-term increase in knee pain. All sessions are closely supervised by a qualified therapist to ensure safety and adjust the program as needed.

Where is the study run from?
The study was conducted at the Physical Therapy Clinic, College of Applied Medical Sciences, Prince Sattam bin Abdulaziz University, in Al-Kharj, Kingdom of Saudi Arabia.

When is the study starting and how long is it expected to run for?
August 2022 to July 2023.

Who is funding the study?
The Deanship of Scientific Research at PSAU, Kingdom of Saudi Arabia

Who is the main contact?
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Contact information

Type(s)
Principal investigator, Scientific, Public

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Study information

Scientific Title
Synergetic effects of low-energy laser and exercise on pain, kinesophobia, disability, and quality of life in adolescents with patellofemoral pain syndrome: A randomized clinical trial

Study objectives
This study aimed to determine if integrating low-energy laser therapy (LELT) with exercises is more effective than exercises alone for improving pain, kinesophobia, disability, and quality of life in adolescents with patellofemoral pain syndrome.

Ethics approval required

Ethics approval required

Ethics approval(s)
approved 21/08/2022, Physical Therapy Research Ethics Committee (College of Applied Medical Science, Prince Sattam Bin Abdulaziz University, Al-Kharj, 11942, Saudi Arabia; +96615886301; a.osailan@psau.edu.sa), ref: RHPT/0022/0029

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Patellofemoral Pain Syndrome

Interventions
This investigation recruited 64 children with a confirmed patellofemoral pain syndrome.

Randomization Method: The study employed stratified randomization method to balance the study groups. Four homogenous strata were created considering age and gender as relevant stratification factors. An independent researcher, not involved in recruitment or assessment, generated the randomization sequence using a web-based random number generator. This sequence was concealed from the investigators enrolling participants and administering the interventions to ensure blinding was maintained.

Participants were randomized into three cohorts:
A low energy laser group (received exercise + low energy laser therapy).
A control group; received exercise only

Participants in both groups performed a standardized 35-minute core exercise program focused on lower limb strengthening, flexibility, and balance/proprioceptive training. Each session was framed by a 5-minute warm-up and a 5-minute cool-down, incorporating dynamic and static stretching, respectively, resulting in a total session time of approximately 45 minutes.

Participants in the “low energy laser therapy group” underwent an additional active laser treatment applied to eight specific points around the kneecap for 30 seconds per point, totaling

8 minutes per session. The treatment used an infrared laser with a wavelength of 903 nm, delivering a dose of 1.5 J per point and a total of 24 J per session, accumulating to 864 J over the full 36-session intervention.

Intervention Type
Behavioural

Primary outcome(s)
1. Pain intensity measured using a 0-10 Numerical Pain Rating Scale (NPRS) at pre- and post-intervention

2. Kinesophobia measured using the Tampa Scale for Kinesophobia-17 (TSK-17) at pre- and post-intervention

3. Disability measured using the Patellofemoral Disability Index (PDI) at pre- and post-intervention

Key secondary outcome(s))
1. Quality of life measured using the Arabic MOS 36-Item Short Form Health Survey at pre- and post-intervention

Completion date
27/07/2023

Eligibility

Key inclusion criteria
1. Age of 10-18 years
2. Verified diagnosis of patellofemoral pain syndrome based on the ICD classification system (ICD-10 code for PFPS: M22.2X9)
3. Pain more than 3 on (0-10 pain scale).
4. Persistent pain more than 3 months
5. Pain get worse with activities and get better with rest.

Healthy volunteers allowed
No

Age group
Child

Lower age limit
10 years

Upper age limit
17 years

Sex
All

Total final enrolment

64

Key exclusion criteria
1. History of knee surgery
2. Recent trauma
3. Corticosteroids or anti-inflammatory medications in the past 6 months
4. Patellar subluxation or dislocation
5. Contraindications to low-energy laser therapy (e.g., local infection, malignancy, photosensitizing drug use)

Date of first enrolment
28/08/2022

Date of final enrolment
27/11/2022

Locations

Countries of recruitment
Saudi Arabia

Sponsor information

Organisation
Prince Sattam Bin Abdulaziz University

ROR
https://ror.org/04jt46d36

Funder(s)

Funder type

Funder Name
Deanship of Scientific Research, Prince Sattam bin Abdulaziz University

Alternative Name(s)
Deanship of Scientific Research, Deanship of Scientific Research at Prince Sattam bin Abdulaziz University, , DSR

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
Saudi Arabia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files			24/11/2025	No	No
Other files			24/11/2025	No	No
Participant information sheet			24/11/2025	No	Yes
Statistical Analysis Plan			24/11/2025	No	No