

Participant Information Sheet

Study 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.

1. What is this study about?

This research study aims to understand how different combinations of low-energy laser therapy and personalized exercise programs affect the health of adolescents with patellofemoral pain syndrome.

We are especially interested in how these treatments influence:

- Pain levels and physical function
- Fear of movement (kinesophobia) and self-reported disability
- Overall quality of life and participation in daily activities

Your participation will help researchers design safer and more effective treatment plans for adolescents with similar knee pain conditions.

2. Who is conducting the study?

This study is being carried out by a team of qualified healthcare professionals and researchers specializing in physical therapy, orthopedic rehabilitation, pediatric musculoskeletal health, and pediatric exercise science.

This study has received ethical approval from the Physical Therapy Research Ethics Committee at PSAU [Protocol No: RHPT/0022/0029]. Your rights and well-being as a participant are our top priority.

3. Who can take part?

To ensure the study is safe and a good fit for you, participants need to meet the following criteria:

You may be eligible to take part if you:

- Are between 10 and 18 years old.
- Have been diagnosed with patellofemoral pain syndrome by an orthopedic doctor.
- Have experienced pain in the front of your knee for more than 3 months.
- Have a usual pain level of more than 3 on a 0-to-10 scale (where 0 is no pain and 10 is the worst pain imaginable).
- Find that your knee pain gets worse with activities like running, jumping, squatting, or going up and down stairs.
- Find that your knee pain gets better when you rest

4. What will happen if my child takes part?

If you agree to participate, your child will:

- Attend a screening visit to confirm you are eligible for the study.
- Be randomly assigned to one of the study groups, which will receive different combinations of low-energy laser therapy and a supervised, individualized exercise program.
- Attend scheduled assessment sessions before, during, and after the treatment period

During these sessions, we will collect the following information:

A. Background and Clinical Information

We will record:

- Age, sex, height, weight, and BMI.
- Your medical history related to your knee pain.
- The specific activities that make your knee pain worse.
- Your current level of physical activity and participation in sports

B. Health and Functional Assessments

You will undergo the following measurements, which are focused on your knee pain, movement, and overall well-being:

1. **Pain and Functional Questionnaires:** You will fill out standardized questionnaires to measure:
 - **Pain Intensity:** Using a Numerical Pain Rating Scale (NPRS).
 - **Kinesophobia:** Your fear of movement due to pain, using the Tampa Scale of Kinesophobia (TSK).

- **Disability:** How the pain affects your daily life, using the Patellofemoral Disability Index (PFDI).
 - **Quality of Life:** How your knee pain impacts your overall well-being will be measured using the Arabic MOS 36-Item Short Form Health Survey (SF-36).
2. **Physical Performance Tests:** A therapist will guide you through simple, safe tests to assess:
- **Muscle Strength:** Strength of your thigh and hip muscles.
 - **Functional Movement:** Your ability to perform tasks like single-leg squats, step-downs, or jumping.
 - **Joint Range of Motion:** The flexibility of your knee and hip.
3. **Clinical Examination:** A physical therapist will perform a non-invasive examination of your knee, hip, and foot alignment to understand the factors contributing to your pain

All procedures will be explained to you in detail before they are performed, and you may stop any part of the assessment or the study itself at any time without giving a reason.

5. Are there any risks or discomforts?

While the treatments in this study are generally considered safe and are performed by qualified professionals, it is important for you to be aware of potential risks and discomforts.

A. Risks Related to the Low-Energy Laser Therapy:

The laser therapy used in this study is classified as "low-energy" and is non-invasive. It is not a surgical laser and does not cut or burn the skin. Potential, but unlikely, risks include:

- **Eye Safety:** Although the risk is extremely low with proper safety measures, laser light could be harmful to the eyes. You and the therapist will be required to wear protective goggles during all laser application sessions.
- **Skin Sensation:** You may feel a slight warmth or tingling at the application site, which should resolve immediately after treatment.
- **Theoretical Risk:** There is a very remote theoretical risk of stimulating an unknown underlying condition, though no such occurrences have been reported with this type of therapeutic laser.

B. Risks Related to the Exercise Program:

The exercise program is personalized and supervised to minimize risk. However, as with any physical activity, there is a possibility of:

- **Muscle Soreness:** It is common to experience some muscle soreness or stiffness 24-48 hours after starting a new or intensified exercise routine. This is normal and usually temporary.
- **Increased Pain:** Since the study involves participants with knee pain, the exercises may temporarily provoke or increase your usual knee pain during or after the session.
- **Muscle Strain or Injury:** There is a very small risk of minor muscle strains or overuse injuries, despite careful supervision and proper technique. The therapist will monitor you closely to adjust the exercises and prevent injury.

C. What measures are in place to protect you?

- **Qualified Staff:** All procedures will be conducted by trained physical therapists or researchers.
- **Supervision:** All exercise and testing sessions will be closely supervised.
- **Individualization:** The exercise program and testing will be tailored to your capabilities and will be progressed gradually.
- **Open Communication:** You will be encouraged to report any pain or discomfort immediately. The therapist will adjust or stop any activity at your request.
- **Safety Protocols:** All equipment is regularly maintained, and safety procedures (like laser goggles) are strictly followed.

Your well-being is our highest priority. You have the right to stop any procedure or withdraw from the study at any time without penalty.

6. Are there any benefits?

Your participation in this study may offer several potential benefits, both direct and indirect.

Potential Direct Benefits to You:

- **Potential Improvement in Symptoms:** You may experience a direct improvement in your knee pain, strength, and overall function as a result of receiving a structured, supervised treatment program combining laser therapy and exercise.

- **Comprehensive Health Insight:** You will receive a detailed physical therapy assessment, which can provide you with a deeper understanding of your condition, including specific strengths and weaknesses in your muscles and movement patterns.
- **Close Monitoring and Support:** Throughout the study, you will be closely monitored by a team of specialists in musculoskeletal health. This provides a unique level of attention and support for managing your knee pain.

Broader Benefits to Society:

- **Contribution to Medical Knowledge:** The most certain benefit of this study is the contribution you will make to scientific knowledge. Your participation will help researchers and clinicians better understand how to best combine laser therapy and exercise for adolescents with patellofemoral pain.
- **Helping Others in the Future:** The information gathered from this study will be used to design safer and more effective treatment plans for other young people who suffer from similar knee pain conditions in the future.

Important Note on Benefits:

It is important to understand that participation in a research study does not guarantee a personal health benefit. The treatments being tested may not be more effective than standard care. However, the knowledge we gain from your participation will be invaluable

7. Will my child's information be kept confidential?

Yes. All personal and medical information will be stored securely using a unique study ID (not your child's name). Only the research team will have access. Data may be used in scientific publications, but your child will never be identified.

8. Participation is voluntary

You and your child can withdraw from the study at any time without affecting your regular medical care.

9. Who should I contact with questions?

For questions about the study or your child's rights as a participant, please contact:

Principal Investigator: Prof. Ragab K. Elnaggar

Email: r.elnaggar@psau.edu.sa , rke_pt2001@yahoo.com

Phone: 0115886321

For concerns about your child's well-being during the study, immediate medical support will be available on-site.

Thank you for considering participation in this important research.