



**Therapeutic Effect of Two Muscle Strengthening  
Programs in Patients with Patellofemoral Pain  
Syndrome from Bogota, Colombia.  
Experimental Study, Clinical Controlled Trial.**

**NCT: not available.**

**Date of creation: July 1, 2018.**

## INFORMED CONSENT

**Research Title:** Therapeutic Effect of Two Muscle Strengthening Programs in Patients with Patellofemoral Pain Syndrome from Bogota, Colombia. Experimental Study, Clinical Controlled Trial.

### Researchers:

**LUISA FERNANDA PRIETO GARCÍA, Ft.**

Master's candidate in Physiotherapy of Sport and Physical Activity, Universidad Nacional de Colombia

[lfprietog@unal.edu.co](mailto:lfprietog@unal.edu.co)

Phone: +57 320 208 2723

**EDGAR CORTÉS REYES, Ft, MSc in Epidemiology.**

Professor and Secretary, School of Medicine, Universidad Nacional de Colombia.

[ecortesr@unal.edu.co](mailto:ecortesr@unal.edu.co)

Phone: +57 310 241 6865

**GILBERTO LARA, MD, Esp.**

Orthopedist Hospital Universitario Nacional de Colombia.

[glara1co@hotmail.com](mailto:glara1co@hotmail.com)

Phone: +57 310 305 1794

In accordance to the principles established in Resolution 008430 of October 4, 1993, which establishes the norms for health research, specifically in Article 15, regarding the Informed Consent, you must know about this investigation and accept to participate in it, if it considers it convenient.

Please read carefully and ask the questions you want until you fully understand them.

**Justification:** Patellofemoral pain syndrome (anterior knee pain) is one of the most common musculoskeletal problems seen during medical consultations, which generally affects the physically active young adult population or athlete, being more common in women than in men. Over the years, it has been observed that conservative treatment through physiotherapy exercises to treat this disease can result in a significant reduction in pain and in the improvement of the ability to perform several activities of daily life; However, the best form of physical therapy to treat people suffering from this syndrome is not yet known, for this reason, the present study seeks to determine which are the most effective muscle strengthening exercises to reduce pain in this group of patients.

**Description:** Men and women who are not athletes between 15 and 40 years of age who perform physical activity 3 to 5 days a week in a mild-moderate manner, with a medical diagnosis of patellofemoral syndrome. Compliance with the inclusion criteria will be verified through a screening

format that you will complete once you decide to participate in this study and after signing this document.

**Procedure:** A random (random) assignment of the participants to two intervention groups (group A: Strengthening of the core, hip and knee muscles) and (group B: strengthening of the hip musculature and the knee), additionally, each group will perform stretching and neuromuscular control exercises to improve flexibility and balance. All exercises will be directed by a Physiotherapist. Each group will be given a survey to know the level of physical activity in which the participant is, additionally an initial and final pain measurement will be made (through a questionnaire), a measurement of the angle Q (measured with a goniometer) or 360 ° rule on both legs), measurement of muscle strength (of the abdomen, hip and thigh), flexibility measurement (Trunk, and legs), as well as foot balance (using the Single Leg Stance test with open and closed eyes).

**Possible risks derived from their participation and their minimization:** All the procedures performed in this study will be applied and supervised by physiotherapists with extensive professional experience and advanced training. This research project recruits individuals with an accurate diagnosis of patellofemoral syndrome performed by an orthopedist. All participants must be linked to the social security system.

**Benefits:** The results of this research will contribute to the scientific basis of the professional practice of physiotherapy, by determining the therapeutic effect on pain, a muscle strengthening program that will identify and prescribe the best form of physical exercises that treat the Pain in patients with patellofemoral syndrome (anterior knee pain) more effectively. As well as improving their physical condition and quality of life, by including physical exercises. Additionally, during their participation in the research project, the best physiotherapeutic interventions currently carried out to treat their disease will be used, guaranteeing an adequate time for each session of Physiotherapy.

**Confidentiality:** The registration forms that will be used during this investigation contain only the information relevant to this research project. Additionally, the information will be encoded, your name and personal data will not be related to the results of the evaluations. Likewise, the confidential information will be maintained by the principal investigator, Ft Luisa Fernanda Prieto García in a secure site with restricted access in the facilities of the research laboratory in Physiotherapy. You are at liberty to authorize or not that the data obtained in this study can be used in other studies and laboratories, prior approval of the Ethics Committee for Scientific Research of the School of Medicine at the Universidad Nacional de Colombia.

Your participation is voluntary, and you are free to withdraw from the study at the time you consider, your decision will not be questioned. The expenses of all experimental procedures will be covered by **IPS-CAFAM** and the principal investigators.

Any additional concerns that arise in relation to the procedures, risks, benefits and other matters related to the investigation will be answered by the investigators. If you have any questions regarding your rights as a research participant, you can contact the Ethics Committee in Scientific Research.

#### **ETHICS COMMITTEE**

eticasalud\_fm bog@unal.edu.co

School of Medicine- Building 471- Office 136 National University of Colombia.  
Tel. 316 50 00 extension 15167

If you decide to participate please sign this document. Remember that this signature does not obligate you to complete the study, it only confirms that you have been informed about the nature, risks and procedures of your participation in this research project.

On \_\_\_\_\_, having understood the above and once all the doubts that arose regarding his participation in the investigation were clarified, I \_\_\_\_\_ identified with identity card No. \_\_\_\_\_ I agree to participate in the research titled: **"THERAPEUTIC EFFECT OF TWO MUSCLE STRENGTHENING PROGRAMS IN PATIENTS WITH PATELLOFEMORAL PAIN SYNDROME IN BOGOTÁ, COLOMBIA. EXPERIMENTAL STUDY, CLINICAL CONTROLLED TRIAL"**.

**IN CASE OF BEING A MINOR:**

I \_\_\_\_\_ of legal age, with CC: \_\_\_\_\_, mother / father of the minor with IT: \_\_\_\_\_

MANIFESTO that I agree with the participation in the research entitled **"THERAPEUTIC EFFECT OF TWO MUSCLE STRENGTHENING PROGRAMS IN PATIENTS WITH PATELLOFEMORAL PAIN SYNDROME IN BOGOTÁ, COLOMBIA. EXPERIMENTAL STUDY, CLINICAL CONTROLLED TRIAL"** of my son / daughter's \_\_\_\_\_ years of age, we have been informed that the information provided to the Physiotherapist during the therapeutic process is approved to be treated only for research purposes.

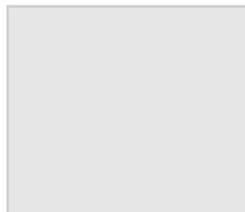
We accept that as parents we will be informed of the aspects related to the therapeutic process and its evolution, keeping as confidential the data that we have previously agreed between us, our child and the therapist.

Finally, we have been informed and we consent to our son / daughter attending 24 sessions (two months) total, 3 weekly sessions of 60 minutes each.

**Name of the participant:**

**Firm:**

The signature can be replaced by the fingerprint in the cases that are so deserved.



**Witness name 1**

**Firm**

Address \_\_\_\_\_

Phone: \_\_\_\_\_

Relationship with the competitor

Signature \_\_\_\_\_

Date \_\_\_\_\_

**Witness name 2**

**Firm**

Address \_\_\_\_\_

Phone: \_\_\_\_\_

Relationship with the competitor

Signature \_\_\_\_\_

Date \_\_\_\_\_