# Informed Consent Form

**The Official Title:** Effects of Preoperative Rehabilitation on Tendon Healing, Bone Mineral Density, and Cartilage After ACLR and Patellar Dislocation

**NCT Number:** 059**2**4178

**Date of the Document:** 06/10/2025

You are invited to participate in this study because you meet the eligibility criteria for this study. Your study doctor or researcher will fully explain the informed consent for you. Please read this informed consent carefully before making a decision on whether to participate in the study. If you are participating in another study, please inform your study doctor or researcher. The content/nature, risks and other important information of this study are as follows:

*(Ren Shuang) will carry out the study。*

**1. Why did this study take place?**

ACL injury is a common knee injury. The incidence of ACL injury in the general population is about 1/3000, and the annual incidence of ACL rupture is 68.6 per 100,000 people, and the trend continues to rise. ACL rupture can not heal itself, arthroscopic ACL reconstruction is the first choice of treatment. Bone and bone canal are important factors affecting tendon healing. Preoperative exercise rehabilitation can not only make full preoperative preparation for surgery, improve knee bone, but also significantly shorten the postoperative rehabilitation process, promote patients to resume daily activities as soon as possible, and promote the healing of tendon bone after surgery. Therefore, this study intends to carry out 6 weeks of preoperative rehabilitation to evaluate the motor function and tendon bone healing of patients at different stages. The study is expected to guide the preoperative rehabilitation of patients, promote the postoperative tendon healing and improve the prognosis of patients.

**2. How many people will participate in the study?**

Sixty.

**3. What does this study include?**

1. Research design Clinical randomized controlled trial study.

2. Inclusion criteria

1) Patients aged 18 to 40 years with ACL rupture diagnosed by MRI.

2) Unilateral ACL rupture for the first time requires reconstruction in our hospital.

3) More than 6 weeks from the trauma and within 6 months.

4) The affected knee joint has passed the acute stage, no obvious redness, pain, inflammation, and limited joint motion

5) No or minor damage to the posterior cruciate ligament, medial collateral ligament orlateral collateral ligament.

3. Exclusion criteria

1) BMI less than 18.5 or greater than 35 kg/m2 .

2) Over 40 years old, or under 18 years old.

3) Within 6 weeks of the time of trauma, or more than 1 year.

4) Serious injury to the posterior cruciate ligament, medial collateral ligament, or lateral collateral ligament.

5) Combined with severe meniscus tear.

6) History of knee joint trauma.

7) Other knee diseases, such as knee osteoarthritis, knee tumor, rheumatoid, tuberculosis, etc.

8) Those who do not want to accept this treatment.

3. Research process

Bone mineral density, MRI and motor function were measured after rehabilitation training. If you agree to participate in the study and sign the informed consent form, you will undergo tests and procedures according to the protocol to confirm whether you are suitable to participate in the study.

**What do I need to do to participate in the study?**

**You will receive professional rehabilitation training and cooperate with the completion of rehabilitation training and related examinations.**

**4. How long will the study last?**

1 year follow-up.

**5. What are the risks of participating in this study?**

This study is a non-invasive functional assessment. Professional physicians and rehabilitation therapists will perform functional assessment tests for you. The study risk is very low. During the preoperative exercise rehabilitation process, there may be discomfort such as pain, redness and swelling of the knee joint. We will communicate with you at any time to adjust the exercise intensity and carry out corresponding diagnosis and treatment measures. If you have pain or other related conditions during the test, we will stop the test in time and arrange professional treatment for you if necessary.

**6. What are the benefits of participating in the study?**

If you agree to participate in this study, you can receive:

1. One-year free professional rehabilitation guidance;

2.1 Free bone mineral density tests and their reports.

**7. What other medical options are available?**

You could choose not to participate in the study, which will have no adverse effect on youraccess to conventional treatment.

**8. Will my information be kept confidential?**

We will keep your research records confidential as required by law. The relevant laws in our country provide guarantees for privacy, data and the security of authorized access. Regarding your research information, we will use a unique number to represent you, and the coded information will be stored in the Peking University Third Hospital. Your identity will not be disclosed if you publish research information and data obtained from this study at scientific conferences or in scientific journals. However, your records may be reviewed to ensure that the study complies with relevant laws and regulations. The reviewers included relevant national administrative departments and the Ethics Committee of Peking University Third Hospital.

**9. About the cost of the research?**

You will receive free professional rehabilitation guidance, free bone density testing, and routine nuclear magnetic medical testing at your own expense.

**10. If a study-related injury occurs**

If you are injured as a result of your participation in the study, (the principal investigator's department) will immediately provide the necessary medical care and bear the costs of treatment and the corresponding financial compensation in accordance with the applicable laws and regulations. Please contact Wu Yue at 86+18210066530.

**12. Refusing to participate or withdrawing from the study**

Your participation in the trial is voluntary and you may refuse to participate or withdraw from the trial in any way at any stage of the trial without discrimination or retaliation, and your medical treatment and rights will not be affected.

If you experience a serious adverse reaction, or if your study doctor feels that continuing to participate in the study is not in your best interest, he/she will decide to withdraw you from the study. If this happens, we will notify you in a timely manner, and your study doctor will also discuss with you the other options you have. If your doctor believes that stopping the trial abruptly will affect your health, you may be asked to come to the hospital for a check-up before stopping the trial.

**13. Related consultation**

If you have any questions related to this study, please contact Yue Wu at 86+18210066530. If you have any questions related to your own rights, or if you would like to express your dissatisfaction and concerns about participating in this study, please contact the Research Ethics Office of Peking University Third Hospital at 010-82265571.

**Notification statement**

"I have informed the subject of the research background, purpose, procedure, risks and benefits (study on the effect of exercise rehabilitation on knee bone mineral density change after ACL rupture and the healing of reconstructed ligament-tendon bone), given him/her sufficient

time to read the informed consent, discuss with others, and answer his/her questions about the study; I have told the subject to contact (Dr. Wu Yue) at any time when he has problems related to the research, and to contact the Comprehensive Office of Research Ethics of Peking University Third Hospital at any time when he has problems related to his own rights/interests, and provided accurate contact information; I have informed the subject that he may withdraw from the study at any time without any reason; I have advised that the subject will be provided with a copy of this informed consent with my and his/her signatures."

Signed by the Researcher:

Contact Number:

Date:

**Informed consent statement**

"I have been informed of the background, purpose, procedure, risks and benefits of the study" Effect of exercise Rehabilitation on Knee bone mineral density Change and Reconstruction ligament tendon bone Healing after ACL rupture ". I had plenty of time and opportunity to ask questions, and I was satisfied with the answers. I was also told who to contact when I had questions, complaints, concerns, or wanted further information. I have read this informed consent and agree to participate in this study, and I promise that the data and test results provided to the researchers are true and effective. I know that I can withdraw from the study at any time without any reason. I was told that I would get a copy of this informed consent form with my signature and that of the researcher."

Subject Signature:

Contact Number:

Date: