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Effects of proprioceptive training on gait and plantar pressure after anterior cruciate ligament reconstruction: study protocol for a randomized controlled trial

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Research Article

Keywords: proprioceptive training anterior cruciate ligament reconstruction gait plantar pressure

Posted Date: May 19th, 2023

DOI: https://doi.org/10.21203/rs.3.rs-2694751/v1

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Version of Record: A version of this preprint was published at Trials on November 9th, 2023. See the published version at https://doi.org/10.1186/s13063-023-07759-2.

Abstract

Background People who have undergone anterior cruciate ligament reconstruction have an increased risk of osteoarthritis. Abnormality of lower limb kinematics will occur after operation. This may be related to lower limb muscle strength, the co-excitation of hamstrings and quadriceps femoris and the weakness of proprioception. Proprioceptive training can improve the proprioception of lower limbs and promote the recovery of lower limb kinematics. Our research objective is to observe whether proprioceptive training can improve the proprioception and whether the recovery of proprioception of lower limbs within 1 year after surgery and whether the recovery of proprioception can correct the abnormal lower limb kinematics. The secondary objective is to explore the underlying mechanism of postoperative lower limb gait abnormalities.

Methods/design This study is a prospective single-center randomized clinical trial to be conducted in the Sports Medicine and Orthopedics of Zhongda Hospital Southeast University. Forty participants aged 18-50, undergoing anterior cruciate ligament reconstruction between 3 months and 1 year, stopping using crutches and braces after 6 weeks, initial anterior cruciate ligament reconstruction using hamstring tendons as grafts will be randomly assigned to the intervention or control group. All participants will receive routine rehabilitation training after surgery. People in the intervention group will add proprioceptive training three times a week, 20 minutes each time. The researcher mainly collects the data of joint of sense, gait and plantar pressure. Data collection will be conducted before the intervention,6 weeks after the intervention and 12 weeks after the intervention.

Discussion The main purpose of our study is to explore whether the proprioception of patients after anterior cruciate ligament reconstruction is weakened, whether the lower limb kinematics is abnormal, and whether the lower limb kinematics can be corrected through proprioceptive training.

Trial registration

Chinese Clinical Trial Registry ChiCTR2200065808 Registered on 15 November 2022 Version 1.

Introduction

Background and rationale {6a}

After anterior cruciate ligament reconstruction (ACLR), the incidence of osteoarthritis is higher than that of healthy people^[1-4]. According to the known research, it may be related to postoperative gait abnormalities^[5]. Within one year after the operation, the biomechanics of knee joint gait can't return to the normal mode, characterized by the reduction of the peak knee joint flexion angle, the reduction of knee joint flexion and extension moment, and the reduction of the peak vertical ground reaction force^[6]. This may be caused by the weakness of quadriceps femoris muscle strength, the co-excitation of hamstrings and quadriceps femoris, and the weakness of proprioception. Some studies have found that the symmetry of quadriceps strength among people who have completed recovery training after ACLR has nothing to do with the ongoing asymmetry of gait biomechanics. After reaching the previous strength

threshold of the quadriceps femoris, simply strength exercises may not improve gait asymmetry^[7]. Proprioception is an important part of neuromotor control, which can accurately detect the movement and position of joints. The central nervous system receives signals from proprioceptors at joints, muscles and tendons which send feedback to joints and muscles for muscle control. A study has found that the proprioception of patients with ACLR is weakening after surgery^[8], which affects the kinematics of the knee joint of the lower limb^[9, 10]. But some studies have found that no significant differences in the proprioception were found between unaffected and affected leg of patients with ACLR^[11]. It is possible that the proprioception disorder after surgery occurs in both lower limbs, not just the surgical side as previously thought^[12]. Therefore, despite the study found that the gait of patients after ACLR surgery is abnormal and related to proprioception^[13], it is not clear whether the proprioceptive training is effective after surgery and whether it will affect the gait of lower limbs.

Objectives {7}

This study aims to demonstrate: (1) the effective of proprioceptive training on the restoration of knee joint proprioception; (2) if proprioceptive training can promote the restoration of lower limb kinematics; and (3) the mechanism underlying aberrant lower limb gait following surgery.

Trial design{8}

This trial is a single center, single-layer (the experimental group and the control group were randomly assigned in a 1:1 balanced manner), and the evaluator was blind.

Methods: Participants, interventions and outcomes

study setting {9}

The study was conducted in the Sports Medicine and Orthopedics of Zhongda Hospital Southeast University in Nanjing from January 2023 to June 2024. Data management will be conducted before the intervention 6 weeks after the intervention and 12 weeks after the intervention (Fig.1).

Eligibility criteria {10}

Inclusion criteria

Aged 18-50;

From March 2022 to March 2024, 3 months to 1 year after anterior cruciate ligament reconstruction in the Sports Medicine and Orthopedics of Zhongda Hospital Southeast University;

Stopping using crutches and braces after 6 weeks;

Initial anterior cruciate ligament reconstruction using hamstring tendons as grafts.

Exclusion criteria

Insufficient range of motion;

Postoperative complications such as knee stiffness and infection;

Anterior cruciate ligament rupture for more than 1 month;

Other diseases affecting gait: chronic ankle instability, scoliosis, etc;

Accompanied by injury of articular cartilage and other ligaments.

Who will take informed consent? {26a}

When the patient passes the qualification screening, the informed consent form will be signed within two weeks of being included in the study. Before signing the consent form, the main responsible person will be contacted and questions will be answered.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

There is no ancillary studies, since don't need additional consent provisions for collection and use of participant data and biological specimens.

Interventions

Explanation for the choice of comparators{6b}

This program is designed by enhanced recovery after surgery and the latest evidence-based researches.Patients'functional activities can recover faster and improve the quality of life.

Intervention description {11a}

The control group receives routine rehabilitation training after surgery, which is the first option for ACLR (Table 1). Intervention group program adds proprioceptive training on the basis of routine rehabilitation training, three times a week, 20 minutes each time.

Proprioceptive program: The therapist ties the mobile phone with the software to measure the flexion angle of the joint above the patient's lower leg. Participants take supine position with eyes closed and the therapist passively flexes the knee joint on the operative side of the participants to any angle. Participants will be asked to repeatedly bend to this angle three series of 10 repetitions, per angle. Three angles are randomly set 5 degrees of error ; The therapist ties the mobile phone with the software to measure the flexion angle of the joint above the patient's lower leg. Participants take sitting position with eyes closed. Patients actively extend the knee joint to any angle. Participants will be asked to repeatedly bend to this angle three angles are randomly set 5 degrees of 10 repetitions, per angle. Participants take sitting position with eyes closed.

Focus on functional training
1.Jogging training 10min
2.Single-leg squat exercise three series of 10 repetitions
3.Jump training three series of 10 repetitions
4.Strength exercise of quadriceps femoris 70-80% 1RM 1 Repetition Maximum two series of 8-12 repetitions

Surgical methods

After the anesthesia taking effect, the patient took a flat lying position. Placed the tourniquet on the left femur to be inflated for standby, and carried out a physical examination under anesthesia. The lachman test the axial shift test and of the knee joint were positive. The valgus stress test was negative. The lower limb on the surgical side was routinely disinfected and covered with a towel. Then connected to the arthroscopic system. Surgeons performed lower limb Blood evacuation, and put on an electric tourniquet. Then set the pressure at 260 mmHg. Making a small incision on the medial side of the tibial tubercle, separated the gracilis and semitendinosus tendon. Surgeons took off the tendon with a tendon extractor, and weaved it into 4 strands of the transplanted tendon for standby. The arthroscopic exploration and operation channel on the operative side of the knee was established routinely to detect the rupture of the anterior cruciate ligament, removing part of the residual end of the anterior cruciate ligament, and retained part of the residual end. The femoral tunnel was established through the anterior internal auxiliary approach, and the tibial bone tunnel was established under the guidance of the locator. According to the diameter of the transplanted tendon, the tibial and femoral bone tunnels were established, and the tendon was introduced. The femoral side was fixed with the overturned steel plate and the interface compression screw, and the knee joint was moved. The tibial side was fixed by squeezing screws, and the tibial side was drilled and suspended at the distal end of the tunnel. Under the microscope, it was confirmed that the tendon was fixed reliably. The articular cavity was washed, cleaning debris, and a drainage tube was placed.

Criteria for discontinuing or modifying allocated interventions {11b}

Intervention will be discontinued when there is unbearable knee pain, ligament rupture again and the patient's exercise frequency is less than 80%.

Strategies to improve adherence to interventions {11c}

All participant will be pulled into WeChat group and they can ask questions directionally.Participant need to clock in one time every week and will be reminded monthly about their rehabilitation plan through phone.

Relevant concomitant care permitted or prohibited during the trial {11d}

In order to make the patients receive the same rehabilitation as possible within three months after surgery. The early rehabilitation training is printed and taken home after discharge(Table 2).Participants will be informed that rehabilitation interventions, other than those that will be received during the period of the study, will not be allowed.

Table 2, the early rehabilitation training

Stage	the early rehabilitation training				
0-3w	1.Using fascial knife to reduce swelling 5 min				
	2.Moving patella 2 series of 10 repetitions				
	3.Flexing knee joint 0-90° three series of 10 repetitions				
	4.Straightening the knee joint to the level of the healthy side				
	5.Straight Leg Raising(SLR), three sets of 10 reps				
	6.Glute Bridge, three sets of 10 reps				
	7.Walking with crutches				
3-6w	Besides the above scheme				
	1.Increasing the flexion angle of the knee joint to achieve full range of activities in 6 weeks				
	2.Gradually reducing the use of crutches, and do not use braces and crutches when walking for 6 weeks;				
	3. The resistance can be increased when the straight leg is raised;				
	4.Step up exercise;				
	5.Intensive exercise of vastus medialis;				
6-12w	If the above actions have been completed easily, go to the next step (pay attention to the training intensity in 8-10 weeks, and the ligament strength in the remodeling period is insufficient), and focus on flexibility training:				
	1.Squat training against the wall;				
	2.Abduction training of muscles around the hip;				
	3.Power bicycle training;				
	4.Stair down training (after 10 weeks)				
	5.Seat squatting training				

Provisions for post-trial care (30)

If the patient's function is limited due to participating in the test or due to the researcher's manipulation problems, the center will provide follow-up rehabilitation treatment free of charge.

Study outcomes {12}

Primary outcomes

(1) Joint position sense: uses the isokinetic training instrument to evaluate the patient's active position perception^[15, 16]. The patient sits on the isokinetic training instrument, flexes the knee joint to 90 degrees, and extends the knee 15, 45, and 75 degrees actively respectively. When reaching the target position, the patient stays for 10s, puts it down, and rests for 10s. The therapist sends a command to let the patient move to the target angle and maintain it for 10s with the eyes closed. Record the difference between the angle and the angle when opening the eyes, and repeat it three times

(2) Gait: The patient used the FastMove Easy Lab biomechanical multi-function evaluation system to conduct the AI three-dimensional motion capture module in the runway, and walked in a normal gait. The symmetry of gait was evaluated by measuring the bilateral step length, duration of support period and swing period, foot axis angle, average heel landing angle and average toe off ground angle, peak hip, knee, ankle joint motion angle and hip, knee joint adduction and abduction peak angle.

(3) Plantar pressure

Dynamic test: all subjects took off their shoes, walked at normal walking speed on the pressure board, and conducted three rounds of foot pressure analysis using the freestep system back and forth. The dynamic foot analysis measured the time of the support period: the early support period (heel landing period); Initial stage of support (from heel landing to forefoot landing); Mid support (full foot landing time); End of support (the period when the heel is lifted to the toe off the ground).

Static test: the subject stands on the pressure plate normally, with his feet naturally separated, and his upper limbs on both sides of his trunk. After the data is stable, the load ratio of the left and right front and rear feet is measured.

Secondary outcomes

(1) Surface electromyography: The surface electromyography signal is collected synchronously with the three-dimensional gait analysis system. The specific operation is as follows: On the wireless surface electromyography control terminal, select 8 muscles on both sides, including rectus femoris, biceps femoris, anterior tibial muscle and gastrocnemius muscle, activate the wireless surface electromyography electrode, pair it with the control terminal through wireless wifi and set the wireless channel of the relevant muscles in sequence; Place the common monitoring electrode at the thickest position of the abdomen of the relevant muscles of the lower limbs, parallel to the direction of the muscle fibers, Finally,

install the surface electromyography electrode on the electrode piece Set the signal acquisition mode to "remote" mode. At the same time of three-dimensional gait analysis, the system will automatically record the original myoelectric signals of the relevant muscles synchronously, and automatically transmit the myoelectric data from the control end to the computer after the acquisition and save it to the database of three-dimensional gait analysis. The original surface EMG signal is processed by the righting and debluring provided by the software. The derived data include: original data, root mean square amplitude (RMS), activation period (ACTI); Integral EMG and median frequency.

(2) isokinetic muscle strength test

Isokinetic muscle strength is measured on the peak moment of knee flexion and knee extension at the angular velocity of 30 degrees/s and 90 degrees/s.

(3) Lysholm score is a rating Systems in the Evaluation of Knee Ligament Injuries and is comprised of 8 tissues, of which patient can achieve a maximum score of 100 ^[17]. The content includes limp (5 scores), support (5 scores), locking (15 scores), instability (25 scores), pain (25 scores), swelling (10 scores), stairclimbing (10 scores), squatting(5 scores). Above 91 points is excellent; 84-90 points is good; 65-84 points is fair, and less than 65 points is poor.

(4) Thigh circumference is using a tape measure to measure the circumference of the thigh at 10cm above the patella.

Participant timeline {13}

This paper is written according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) 2013 Statement for the reporting of clinical trial protocols (Table 3)^[14].

Table 3, Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) figure showing the schedule of enrollment, interventions, and assessments

	Study period				
Timepoint	Enrollment	Baseline visit	Allocation	Post- allocation	Close-out
	-t	t1		t2 16 weeks1	t3 012 weeks0
Enrollment:					
Eligibility screen	Х				
Informed consent	Х				
Demographics, clinical data	Х				
Allocation			Х		
Interventions:					
Proprioceptive Training			•		 •
Routine rehabilitation training			•		 •
Assessments:					
JPS		Х		Х	Х
Gait		Х		Х	Х
Plantar pressure		Х		Х	Х
Surface electromyography		Х		Х	Х
isokinetic muscle strength test		Х		Х	Х
Lysholm score		Х		Х	Х

Sample size {14}

Using the G Power 3.1.9.7 software, previous studies showed that between the proprioceptive training group and the control group, the effective amount of JPS joint position perception difference d=0.97 ^[15]; According to power=80%, alpha=0.05 and d=0.97, the required sample size n=36 is calculated. Considering the loss of 10% sample size, 40 subjects are required.

Recruitment {15}

Patients will be recruited at the Sports Medicine and Orthopedics of Zhongda Hospital Southeast University in Nanjing.

Assignment of interventions: allocation

Sequence generation {16a}

Use Excel to create sample size values, generate random numbers, copy and paste new units (only copy values), divide them into experimental group and control group.

Concealment mechanism {16b}

Write number into envelopes according to the sequence and put them into kraft paper by researchers unrelated to this clinical trial. All personnel did not know the sequence details in the envelope.

Implementation {16c}

When the subject was confirmed to be included in the group, the implementer opened the envelope in the office to determine whether to enter the test group or the control group.

Assignment of interventions: Blinding

Who will be blinded {17a}

Because the implementers and patients of proprioceptive training group and conventional group can clearly observe; Therefore, the blind method of this study is only blind for the evaluators of outcome indicators and data analysts. Data collection and analysis shall be conducted independently by researchers who do not participate in the trial.

Procedure for unblinding if needed {17b}

Because the blind method of this study is only blind for the evaluators of outcome indicators and data analysts there is no need to unblind.

Data collection and management {18a 18b 19}

Plans for assessment and collection of outcomes {18a}

Non-intervention researcher will record the included patient information in the form of spreadsheet, including baseline data and research data. Before the clinical research data collection, the data collection researcher shall be trained, and more than three times of data simulation records shall be completed to understand the definition of the outcomes.

Plans to promote participant retention and complete follow-up {18b}

We will use an intention-to-treat (ITT) analysis. A study participant is analyzed as belonging to whatever treatment group he/she was allocated, whether or not the treatment course was completed as intended.

Data management {19}

The information during the telephone follow-up will be recorded on paper, locked in the cabinet, and registered in the electronic form by non-intervention researcher.

Confidentiality {27}

Research data will be only available to the responsible researcher and co-authors. All data will be used for academic study and participant's information details will not be reported in publications.

Biological specimens {33}

N/A this study does not have biological specimens

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

The data are presented as the mean \pm standard deviation for normally distributed continuous variables and as proportions for categorical variables. The continuous variables were compared using Student's ttest, and categorical variables using X² test. To analyse the effectiveness of the trial with change over time from baseline to week 6 and week 12 repeated measures analysis of covariance ANCOVA will be applied and treatment, time, and the treatment × time interaction as independent variables. The results are reported as mean \pm SD and their 95% Cls and P values < 0.05 were considered statistically significant.

Interim analyses {21b}

There are no interim analyses planned.

Methods for additional analyses (e.g. subgroup analyses) {20b}

Pearson correlation analysis method was used to analyze the correlation between joint position perception errors and gait plantar pressure parameters after adjusting for known or selected confounders.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

The intention-to-treat (ITT) paradigm was used to solve compliance problems, and patients who wanted to withdraw from the control group were included in the intervention group.

Plans to give access to the full protocol, participant level-data and statistical code {31c}

Reasonable data and full protocol application in the study can be requested from the corresponding author.

Oversight and monitoring

Data monitoring {21a}

Because the intervention protocol is of low risk a data monitoring committee is not necessary in this trial. The research team is in charge of reporting immediately to the leading researcher about any accident.

Adverse event reporting and harms {22}

Adverse reactions include ligament rupture again, patients receiving other rehabilitation intervention program midway, or patients unwilling to continue training because of slow functional recovery, patients will be rejected and the project will be terminated.

Frequency and plans for auditing trial conduct {23}

There will be no audit program, since the intervention protocol is invasive and the intervention therapist is experienced. The Institutional Ethics Committee will review the trial conduct and final findings.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

When there is a major amendment to the protocol, it will be reported to the Ethics Research Committee and revised in the Chinese Clinical Trial Registry online. All decisions should be determined by the corresponding author.

Dissemination plans {31a}

Full ethical approval for this study has been obtained by the Independent Ethics Committee for Clinical Research of Zhongda Hospital Southeast University (Approved No. of ethic committee 2021ZDSYLL341-P01). The trial was registered in the Chinese Clinical Trial Registry (Registration number: ChiCTR2200065808). The study will be conducted in agreement with the Helsinki declaration. Written and informed subjects consent will be obtained prior to study enrolment by the study investigator. The research results will be published in journals in the form of papers.

Discussion

This protocol describes a single-center randomized controlled trial designed to observe whether proprioceptive training can promote the recovery of lower limb kinematics (gait and plantar pressure) after anterior cruciate ligament reconstruction within one year after surgery compared with the conventional training group. Although some studies have proved that proprioceptive training is effective for the recovery of specific movements, there is a lack of relevant research on gait and plantar pressure.

Because unlike athletes, most patients with anterior cruciate ligament reconstruction do not need strong athletic ability. Walking and standing are the most common actions that all people perform every day. When walking mode is abnormal or standing is unbalanced, lower limb biomechanics abnormalities will occur, which is more likely to lead to osteoarthritis. Through three-dimensional gait and plantar pressure analysis, the lower limb kinematics after anterior cruciate reconstruction can be quantitatively analyzed and the results of reconstruction can be evaluated. Another advantage of this study is the evaluation of muscle related parameters, such as muscle circumference, muscle strength and muscle activation. Some studies have shown that the increase of muscle function level has a certain effect on the recovery of lower limb kinematics. We hope to observe the effect of proprioceptive training on lower limb gait and plantar pressure within one year after the operation by excluding the influence of quadriceps femoris.

Trial status

Chinese Clinical Trial Registry Identifier: ChiCTR2200065808.

Recruitment status: Not yet recruiting.

Trial Registration Date: November 15th, 2022.

Date Recruitment Began: March 10th, 2023.

Estimated Primary Completion Date: January 2024.

Estimated Study Completion Date: January 2024.

Abbreviations

ACLR: Anterior Cruciate Ligament Reconstruction; SLR: Straight Leg Raising; PNF: Proprioceptive Neuromuscular Facilitation; JPS: Joint Position Sense; EMG: Electromyogram; ITT : intention-to-treat.

Declarations

Acknowledgements

None

Authors' contributions (31b)

All seven authors contributed to the study protocol formation.ZXJ and MM finished the training protocol for the intervention group and provided study outcome measures.GJY, SWD and CJ planned the timeline and proposed advices for trial design.FPP and QYcollected the data.HLQ analyzed all the data. All authors read and approved the final manuscript.

Fund {4}

Major sports scientific research project of Jiangsu Provincial Sports Bureau ST221106 ; Horizontal project of Zhongda Hospital Southeast University (2021HX30)

Availability of data and materials {29}

After the publication of this trial, the study data are available from the corresponding author upon reasonable request.

Ethics approval and consent to participate {24}

Full ethical approval for this study has been obtained by the Independent Ethics Committee for Clinical Research of Zhongda Hospital Southeast University (Approved No. of ethic committee 2021ZDSYLL341-P01). All participants will sign approved informed consent forms.

Consent for publication {32}

The authors will obtain consent from the participants to publish individual patient data without personal details.

Competing interests {28}

N/A the authors declare that they have no competing interests.

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Figures

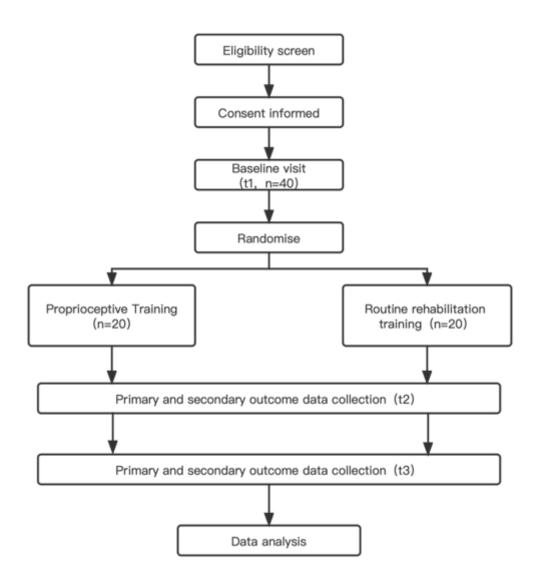


Figure 1

Study design diagram

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

• SPIRITchecklist.docx