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Protocol for double-blinded randomized trial to enhance postural control after anterior cruciate ligament reconstruction by balance training and concurrent cognitive demands or external focus of attention

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Abstract

Anterior cruciate ligament (ACL) injury is one of the most common injuries among athletes that lead to postural control disorders. The aim of this study is to compare the effects of balance training with and without cognitive task and external focus of attention on postural control in individuals with ACL reconstruction. Sixty participants with ACL reconstruction, between the ages of 18 and 47 will be randomly allocated to three group's including routine balance training, balance training with external focus of attention. Patients will be assessed at the baseline, after receiving eight weeks of intervention, and four weeks later. A double-blinded design will be used. Center of pressure data acquired from a forceplate will be used to assess amount and velocity of sway, local dynamical stability, and global stability of upright balance. Also, dynamic balance will be assessed using Star Excursion balance test. The results of this research will be used to establish effectiveness of treatment strategies for postural control in individuals with anterior cruciate ligament reconstruction. The suggested interventions would be clinically applicable in the athlete with ACL injury.

Key Words: ACL reconstruction; postural control; balance training; attentional focus; cognitive task.

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Anterior cruciate ligament injury is one of the most common injuries among athletes.[1,2] Athletes who wish to resume high-level activities after an injury to the anterior cruciate ligament (ACL) are often advised to undergo surgical reconstruction.[2] However, the effectiveness of anterior cruciate ligament reconstruction on postural is not acceptable in many cases.[3] Studies show that postural control disorder in individuals with anterior cruciate reconstruction is a risk factor for recurrent anterior cruciate ligament injury.[4] People after reconstrution of anterior cruciate ligament increased focus of attention or the cognitive load is used to return to the normal state of motor control and skills that can interfere with learning processes, so need to reduce the dependence of motor skills and postural control, or increase outomaticity of motor skills and postural control.[5,6] The amount of attention required to postural control indicates automaticity. A common method is used to automate the motion and modify performance of central nervous system is training using feedback.[5,7] The external focus of attention and cognitive task may improve automatic control and return to normal motor skills.[5] Adding cognitive task is one method to remove attention from postural control.[8] Cognitive tasks can be continuous or discrete. Discrete task requires intermittent attention and attention directed to postural control at interval times. Instead, continuous cognitive task results in continuously diverting attention from postural control. Results of a study have demonstrated that continuous cognitive task reduces postural sway more than discrete cognitive task.[9] External focus (EF) of attention is another method that usually recommended to divert attention away from postural control.[10] After anterior cruciate ligament reconstruction, due to disorder in postural control, there is a possibility of developing osteoarthrite in knee which will increase the risk of further injurey. The use of principle of motor learning as the cognitive task and

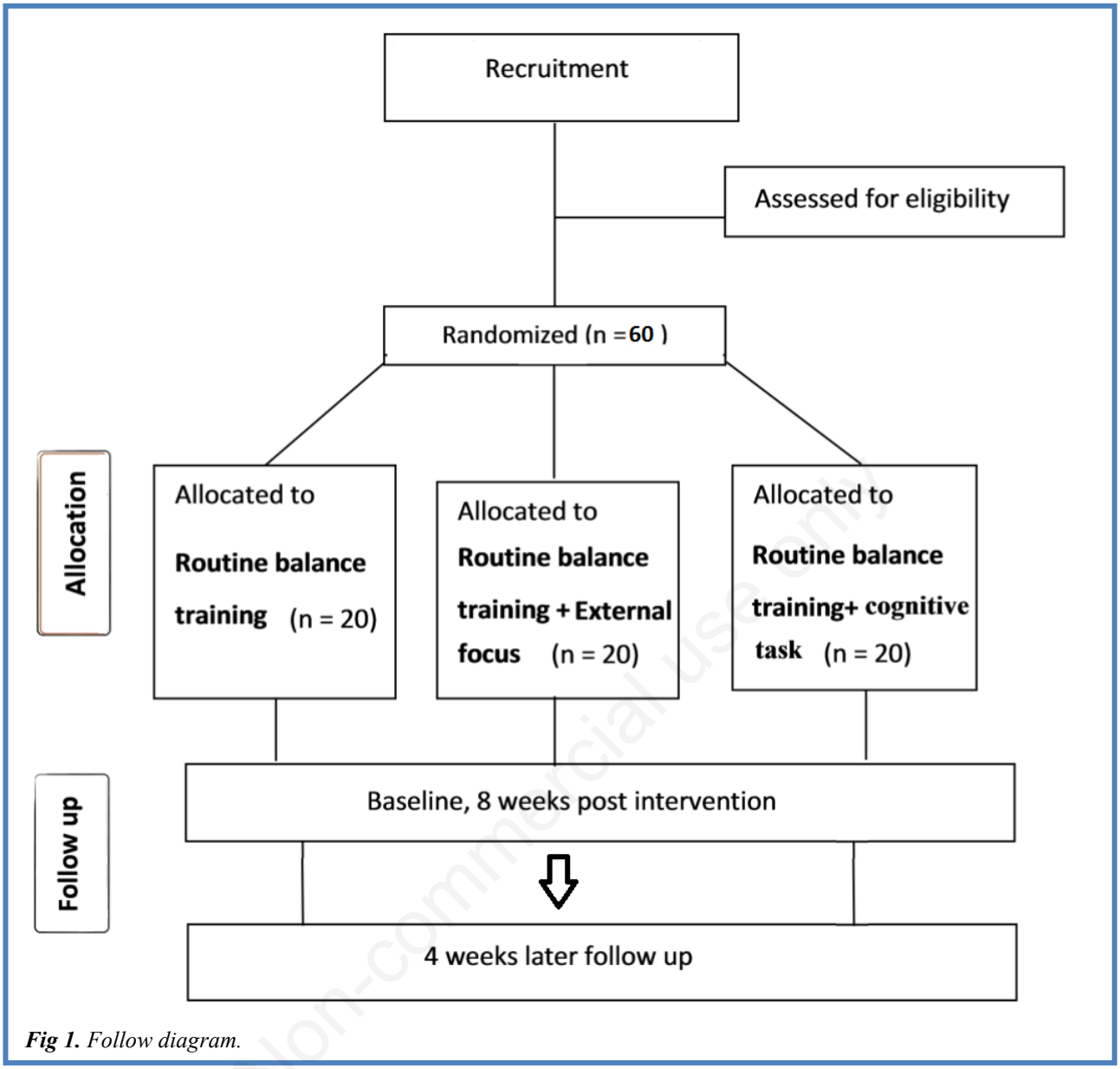

Fig 1. *Follow diagram.*

external focus of attention with balanced exercises may have a significant impact on outomatic control of individual, thereby reducing the risk of injury and possibility of knee OA and preventing the injury of anterior cruciate ligament.[2,5] Yet, randomized clinical trials will be found to investigate the effects of balancing exercises with cognitive task compared to external focus on the postural control of individuals with anterior cruciate ligament reconstruction. This study protocol describes a clinical study in which three groups are examined in terms of balance exercises type. A long-term follow-up assessment will be conducted 6 months after the start of the study. Our study aims to investigate the effects of balance training with cougnitive task. It is performed in people with anterior cruciate ligament reconstruction. Second, we aim to provide new clinically integrated motor learning principles to support neuroplasticity. Our hypothesis is that providing this protocol may improve functional performance and hopefully reduce the risk of re-injury.

Materials and Methods

Study Design

This study is a double-blind, parallel-group randomized controlled trial that will be conducted on patients referred to physiotherapy clinics located in Khuzestan, Iran. The study protocol follows the recommendations of SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guideline.[11] In addition, specific interventions are based on the TIDieR (Template for Intervention Description and Replication) checklist,[12] and CERT (Consensus on Exercise Reporting Template) checklist.[13] The study was approved by the ethics committee of the Ahvaz Jundishapur University of Medical Sciences (IR.AJUMS.REC.1400.335), and all procedures were in

Table 1. *SPIRIT figure showing the schedule of enrollment, interventions, and assessments.*

	STUDY PERIOD				
	Enrolment	**Allocation**	**Post-allocation**		**Close-out**
TIMEPOINT**	$-t_1$	**0**	t_0	t *post intervention*	T_4 *weeks*
ENROLMENT:					
Eligibility screen	**X**				
Informed consent	**X**				
Allocation		**X**			
INTERVENTIONS:					
[Routine balance training]	←	—	→		
[Routine balance training + External focus	←	—	→		
[Routine balance training + Cognitive tasks	←	—	→		
ASSESSMENTS:					
[local stability test]			**X**	**X**	**X**
[global stability test]			**X**	**X**	**X**
[Star excursion balance test]			**X**	**X**	**X**

accordance with the latest version of the Declaration of Helsinki. The trial identifier code is IRCT20211004052666N1 and was registered on November 23, 2021. Prior to participation, written informed consent was obtained from all participants and their parents/legal guardians after a comprehensive explanation of the study procedures.

Inclusion and Exclusion criteria and screening

The inclusion criteria of patients include age between 18 and 47 years;[5] more than 6 months after surgery;[14] Range of Motion After Knee Replacement Surgery;[3] Non-participation of people in another treatment program in the last 6 weeks.[7]

Exclusion criteria include: Have a history of posterior cruciate ligament rupture, contralateral lower limb surgery or injury; Have a history of surgery or traumatic injury to any of ankle and hip joints;[15] Have a complaint about instability;[15] Have a history of neurological, vestibular and uncorrected visual disorders;[16] Have a history of diabetes, use of medication affecting balance and confusion, musculoskeletal problems in the back and neck;[17] traumatic injury or surgery other than ACL reconstruction in the operated side;[5] Giving way;[15] Recent neck and back pain;[5] Joint effusion and pain.[3] Tegner activity rating scale was used to evaluate activity level.[18] Evaluation of disability was conducted with the Knee Injury and Osteoarthritis Outcome Score (KOOS). KOOS score range is from 0 to 100, in which higher scores represent less disability.[19]

Recruitment, randomization, blinding and treatment allocation

Individuals who met inclusion criteria will randomly be allocated to one of three training groups: (i) Routine balance training (ii) balance training with external focus of attention (iii) balance training with cognitive task, using computer-generated random numbers in stratified permuted block (block size of 4 and 6) (Figure 1) The allocation will be concealed in an opaque, sealed envelope. A research assistant opens them and assigns patients to the intervention groups. The randomization will be conducted after signing the informed consent and baseline assessments. The outcome assessments

Table 2. *SPIRIT figure showing the schedule of enrollment, interventions, and assessments.*

Phase	**Type of balance exercise**
Phase 1 (1-4 session)	1- Foreward lunge on foam with 3 cm thicness 2- Foreward lunge on foam with 6 cm thicness 3- Double leg squat exercise on foam with 3 cm thicness Double leg squat exercise on foam with 6 cm thicness 4-
Phase 2 (5-8 session)	1- Double leg stance on the balanc board with instability in the mediolateral direction 2- Double leg stance on the balanc board with instability in the antroposterior direction 3- Double leg stance stance on the wobble board with instability in the all directions 4- Double leg stance stance on the trampolin board with instability in the all direction
Phase 3 (9-12 session)	1-Single leg sstance exercise with non-operated limb on foam with 3 cm thickness 2-Single leg squat exercise with operated limb on foam with 3 cm thicness 3-Single leg sstance exercise with non-operated limb on foam with 6 cm thickness 4-Single leg squat exercise with operated limb on foam with 6 cm thicness
Phase 4 (13-16 session)	1-Single leg squat exercise with non-operated limb on a foam with 3 cm thickness 2-Single leg squat exercise with operated limb on a foam with 3 cm thicness 3-Single leg squat exercise with non-operated limb on a foam with 6 cm thickness 4-Single leg squat exercise with operated limb on a foam with 6 cm thicness
Phase 5 (17-20 session)	1-Single leg stance with non-operated limb on balanc board in the mediolateral direction 2-Single leg stance with operated limb on balanc board in the antroposterior direction 3-Single leg stance with operated limb on balanc board in the mediolateral direction 2-Single leg stance with operated limb on balanc board in the antroposterior direction
Phase 6 (21-24 session)	1-Single leg stance stance with non-operated limb on wobble board 2-Single leg stance with operated limb on wobble board
Phase 7 (25-28 session)	1-Single leg stance stance with non-operated limb on trampolin 2-Single leg stance with operated limb on trampolin
Phase 8 (1-4 session)	1-Single leg squat with non-operated limb on wobble board 2-Single leg squat exercise with operated limb on wobble board 3-Single leg squat exercise with non-operated limb on trampolin 4-Single leg squat exercise with operated limb on trampolin

will be performed by a physiotherapist who is blinded toward treatment allocation. Additionally, patients will be blinded toward treatment groups. Demographic measures include gender, age, height, weight, and comorbidities.

Timeline

The scheduling will be such that in the first TIMEPOINT (.-t1) the entry conditions and informed consent of patients will be confirmed. At t0, baseline measurements are taken by the outcome evaluator and allocation will be made. Then, the same researcher who enrolled the subject in study will divide people into aforementioned groups with specific exercises. In Post-allocation and Close-out, the outcomes and data collection for this study will be completed (Table 1).

Routine balance training intervention

First group (Routine balance training group) will practice conventional balance training without cognitive task and external focus of attention according to Table 2. To carry out these balance programs, the following

Table 3. *Balance training with cognitive task.*

			Attention Intervention	**cognitive task**
Phase 1 (1-4 session)	1	Foreward lunge 3 cm thicness	Reach toward the cone with your knee	Discrete cognitive task with low cognitive load
	2	Foreward lunge 6 cm thicness		
	3	Double leg 3 cm thicness		
	4	Double leg 6 cm thicness		
	2	Double leg antroposterior direction		
	3	Double leg on the wobble in the all directions		
	4	Double leg on the trampolin in the all direction		
Phase 3 (9-12 session)	1	Single leg with non-operated with 3 cm thickness	Keeping the bar horizontal, Which is maintained by the Opposite hand	Discrete cognitive task with low cognitive load
	2	Single leg with operated limb with 3 cm thicness		
	3	Single leg stance exercise with non-operated with 6 cm thickness		
	4	Single leg squat exercise with operated with 6 cm thicness		
Phase 4 (13-16 session)	1	Single leg with non-operated with 3 cm thickness	Stand on 1 leg and reach slowly toward the cone with your knee while bending your knee	Discrete cognitive task with low cognitive load
	2	Single leg with operated limb with 3 cm thicness		
	3	Single leg squat exercise with non-operated with 6 cm thickness		
	4	Single leg squat exercise with operated with 6 cm thicness		
Phase 5 (17-20 session)	1	Single leg with non-operated in the mediolateral direction	Paying attention to red light, shining on the wall from the laser on person's head.	Continuous cognitive task with relatively high cognitive load
	2	Single leg with operated in the antroposterior direction		
	3	Single leg with operated in the mediolateral direction		
	4	Single leg with operated in the antroposterior direction		
Phase 6 (21-24 session)	1	Single leg stance stance with non-operated limb on wobble board	Paying attention to the red light shining on the wall from the laser on the person's head.	Continuous cognitive task with relatively high cognitive load
	2	Single leg stance with operated limb on wobble board		
Phase 7 (25-28 session)	1	Single leg stance stance with non-operated limb on trampolin	Paying attention to red light shining on the wall from the laser on the person's head.	Continuous cognitive task with relatively high cognitive load
	2	Single leg stance with operated limb on trampolin		
Phase 8 (29-32 session)		1-Single leg squat with non-operated limb on wobble board	Paying attention to the red light shining on the wall from the laser on the person's head	Continuous cognitive task with relatively high cognitive load
		2-Single leg squat exercise with operated limb on wobble board		
		3-Single leg squat exercise with non-operated limb on trampolin		
		4-Single leg squat exercise with operated limb on trampolin		

five general principles should be considered: (i) Exercises should be safe and challenging at the same time. (ii) Exercises should stress person in several planes of motion. (iii) Adopt a method in which several senses of the person are involved. (iv) These exercises should be upgraded from static to dynamic, from two-legged to one-legged, and from stable levels to more unstable levels.[20]

Balance training with external focus of attention ntervention

The second group will practice balance exercise with external focus of attention. In this study, several types of balance exercises with external focus of attention are use as describe in Table 3. In most rehabilitation cases where movement skills must be learned or relearned, patients receive instructions to perform correct movement techniques. These orders specifically refer to individual's body movement's coordination, including the program, form, and timing of various body movements. Directing a person's attention towards movement effects on environment (external focus of attention) makes more appropriate and useful movements.[4,14,21,22]

Balance training with cognitive task intervention

Individuals will practice balance exercises along with cognitive tasks that will be performed in the same situations as the postural tasks of routine balance exercises. These types of balance exercises will be performed with eyes open and will progress from simple to complex. The task that will be used in these exercises will be a discrete and continuous cognitive task because this task is completely mental that does not cause mechanical disturbances. Balance exercises with cognitive task will be change progressively in 32 sessions. In sessions 1 to 4, people are asked to perform a movement task with a simple discrete cognitive task. In the next 5 sessions, people are asked to do different types of discrete cognitive tasks with higher difficulty. In sessions 9 to 12, a more difficult discrete cognitive task is added to the balance exercises. In sessions 13 to 16, people are asking to perform a simple continuous cognitive task and in the sessions 17 to 20, continuous cognitive tasks with moderate difficulty are added to their balance exercises. From session 21 to 24, a more difficult cognitive task is added to one's exercises (Table 3). A type of continuous cognitive task will be used in this study consists of a string of three-digit numbers, each number being presented for 3 seconds by an audio tape during the test. Before the exercise, a figure is chosen randomly and people are asked to focus on predetermined figure and at the end of exercise, provide the total number of determined figure repetitions. A different numerical string is use for each exercise. The subjects will not be allowed to use their fingers for counting and calculating because it can affect the body swing and the maximum cognitive effort of the person. Another type of continuous cognitive task that will be used in this study includes a number of simple mathematical equations (for example, 3÷3×5+2) where each equation is present at an interval of 3 seconds by an audio tape during each exercise. A different set of equations will be used for each of the balance exercises.[3,5,7]

Interventions

The recruitment is announced for patients with anterior cruciate ligament reconstruction from public physiotherapy clinics, and the screening will be based on the predefined inclusion and exclusion criteria. The participants will be evaluated before, 8 weeks after intervention, and 4 weeks later.

Balance training will be performed by one expert physiotherapist. All intervention groups will receive 32 sessions, 4 times a week. Patients in three groups will practice the balance exercise for 8 weeks, 3 times per week, with 45 minute per session. In the first practice session, Prior to the start of the program, people will be doing 5 minute stretching exercises to warm themselves.[14,20]

Outcomes

Outcome measurements will be assessed in a random order at baseline, 8 weeks post interventions, and 4 weeks later.

Postural control tests

We will use a force plate (Kistler 40×60, 9286BA, Kistler, Switzerland) at the sampling frequency of 100 Hz to evaluate Postural control. We will use a Thera Band green sponge placed on the force plate to evaluate postural control (Figure 1). The tests will be doing in three stages; before starting the balance training program, after doing 8 weeks of balance training and 4 weeks later in standing positions on one leg without using foam and using foam randomly. In total, to check the local and global stability of the posture, there will be 8 random test modes. Each test mode will be repeated three times. In total, information was collected 24 times. One minute rest was given between each test.[3,5]

Local stability test

To evaluate local dynamical stability, subjects are asked to stand on the force plate with full-extended knee and arms placed on chest such that contralateral leg is semi-flexed for 60 seconds without foam support and with foam support, and maintain their balance on the force plate. To assess the local stability, each participant is randomly face with 4 conditions: (i) standing without foam support on force plate with operated foot; (ii) standing on foam that is place on force plate with the operated foot; (iii) standing without foam on the force plate with the healthy leg; (iv) standing with foam on the force plate with the healthy leg (5). Each condition will be repeated three times. Each data collection took 30 seconds. The order of the conditions will be randomized to decrease learning effects. Lyapunov exponent, as the slope of the divergence curve of neighboring trajectories in the reconstructed state space will be calculated to represent local dynamical stability of standing balance. Time delay to reconstruct the state space will be the first local minimum of mutual information algorithm. Also, the dimension of the reconstructed state space will be the median of false nearest neighbor algorithm among all subjects and all conditions. After 8 weeks of completing the exercise program and 4 weeks later, a local dynamical stability of postural control will be conducted again for all three groups.[5,7,20,23]

Global stability test

This test will also be conducted before starting the balance training program, immediately after 8 weeks of balance training and 4 weeks after the training program is finished, for all three groups. To evaluate global stability, subjects are asked to stand on the force plate with full-extended knee and arms are place on the chest such that the contralateral leg is semi-flexed for 60 seconds without foam support and with foam support, and maintain their balance on the force plate. In order to check the overall stability of the posture, there are 4 test conditions: (i) standing on the operated leg with extended knee without foam and with external perturbation; (ii) standing on the operated leg with extended knee with foam and with external perturbation; (iii) standing on the healthy leg with extended knee without foam and with external perturbation; (iv) Standing on the healthy leg with extended knee on foam with external perturbation. The external perturbation, 10% of subject's weight, will be applied using a servomotor attached to the back of the subject. System will apply a backward pulling force to the individual at an unpredictable time; a belt is tie at the level of the patient's pelvis. The belt will be connected to the motor pulley behind the person's head through a horizontal cabl.[5,7,20,23,24] The amount of applied force is normalize based on the weight of the patients and is equal to ten percent of the weight of the individual. Each data collection took 30 seconds.[3,5]

Star Excursion Balance Test

This balance test is a valid and reliable test to check dynamic stability and as a tool to predict the probability of injury. In this test, the displacement of foot is measured in anterior, posterior-external and posterior-internal directions. Before the start of test, subject's superior leg is determined, so that if the right leg is superior, the test will be performed counter-clockwise, and if the left leg is superior, the test will be performed clockwise. At the beginning of the test the examiner first measures the length of the subject's lower limbs from the end of the anterior-superior spine to the end of the ankle. Lines in the shape of English letter Y will be drawn on the floor in three directions: anterior, posterior internal, posterior external. Then, the subject stand at the center of intersection of these lines so that the big toe of the subject's foot was lower than the center of intersection and his hands will be on the hip joint. In this situation, the person would try to move the opposite leg as far as possible on each of the lines and return to the normal position on both legs. During the test, the sole of the weight bearer's foot had to keep its contact with the ground. While standing on one leg, the person will move the farthest possible point with foot toe until he do not commit a mistake in any of the designated directions and perform the act of reaching. While performing this test, the person should not lean on anyone or anything and should not fall. The distance from the contact point to the center will be the reach distance, which will be recorded in centimeters. Each subject performs each direction three times. In addition, after each attempt, the subject will give a 30-second rest, and finally, the average maximum displacement in each direction will be calculated and divided by the length of the foot, and then multiplied by 100 to obtain the normalized reach distance.[25]

Trial Steering Committee

The title page presents trial steering committee members. All members participated in the conception of the study design and procured funding. The principal investigator (Hosein Kouhzad Mohammadi) is coordinating ongoing trial. The trial steering committee reviews the progress of the trial and agrees to the necessary changes in the protocol if any.

Knowledge translation

What is "already known" in this topic. No randomized control trial study examined the effects of balance training with and without cognitive task and external focus of attention on postural control in individuals with anterior cruciate ligament reconstruction.

What this article will add

In this study, the effects of balance training with and without cognitive task and external focus of attention on postural control will be investigated on people with anterior cruciate ligament reconstruction.

Data Collection and Management

All obtained results will be collected using a test score protocol or fulfilling questionnaires and, after that, entered into Excel (version 2016, Microsoft Corporation, Redmond, WA, USA). All collected test score protocols and questionnaires will be kept in a locked place as backup. Access to study data is restricted only for investigators and anyone cannot be accessed without permission. Data will be pseudonymized and stored in paper and digital format in accordance with regulations regarding public authority archives and the General Data Protection Regulation.

Sample Size

The sample size was calculated using the G-power software, version 3.1.10. Applying a significance level of 0.05, effect size of 0.8, and a power of 80%, the calculation revealed that 20 patients would be required in each group. Since a 10% of patient loss due to follow-up is presumed, a total of 25 patients will include in each group.

Statistical analysis

Data will be analyzed using the Statistical Package for the Social Sciences (SPSS) version 26.0 (SPSS, Chicago, Ill., USA). The statistical analysis of the primary outcome measures will be performed according to an intention-to-treat analysis to handle non-adherence subjects. Statistical tests will be dependent on data distribution. In case of normal data distribution, we will proceed with a repeated measures mixed model with patients as random effect and time (baseline, 8 weeks after treatment, and 4 weeks later) and treatment arm (balance training with and without cognitive task and

external focus of attention) as fixed effects, and with adjustments for baseline imbalance. No imputation will take place. Secondary outcomes and other endpoints will be analyzed similarly to the primary outcome.
The frequency of adverse events will be compared between groups at the 4-weeks follow-up using a Poisson regression model with robust error variance. Categorical outcomes will be analyzed using a X2 test, Fisher exact test, or a Mann-Whitney U test as appropriate. A per-protocol analysis will be performed for the primary outcome, excluding patients who had poor adherence to the intervention, defined as participating in less than 75% of the exercise sessions and not attending both balance training sessions. A 95% confidence interval (CI) will be interpreted as a lack of a clinically meaningful difference between groups. P values and 95% CIs will be presented. All authors will have access to the final anonymized trial dataset.

Adverse events

The frequency of side effects during the 4-week follow-up period in all groups will be recorded and reported in this this study.

Trial Status

The patient recruitment process initiated on June 2021 and was expected to be completed by December 2021.

Discussion

To the best of our knowledge, this is the first clinical trial conducted to evaluate the potential impact of balance training with cognitive task and external focus of attention in these groups of patients. This study will determine whether the combination of balance training with cognitive task and external focus of attention could regulate postural control of patients with ACL reconstruction. The trial will be conducted using randomized allocation, double-blinded method, and clinically applicable interventions. The study interventions are conducted in clinical settings, thereby enhancing the possibility of programs future implementation in health care systems. These would be strengths of this trial.
On the limitation's aspects, it is noteworthy that the outcomes will be measured 8 weeks after the interventions and 4 weeks later. Since the ACL reconstruction postural control deficit is a chronic condition, longer follow-up periods would be beneficial to detect the impacts of interventions that could appear subsequently and also allows comparing the outcomes in various periods. Another thing is that some parameters such as weight and age can affect protocol effectiveness,[26,27] which is important to pay attention to it. In this regard, it will be noted that the groups are well justified during the protocol. The results obtained from this trial can help improve quality of life and health of ACL reconstruction patients as a risk-free solution, and the knowledge gained from this research can be effective in increasing our understanding exercises role on motor and cognitive performance.

List of acronyms

ACL - Anterior Cruciate Ligament
CERT - Consensus on Exercise Reporting Template
CI - Confidence Interval
EF - External Focus
KOOS - Knee Injury and Osteoarthritis Outcome Score
TIDieR - Template for Intervention Description and Replication

Contributions of Authors

All authors participated in idea formation, data gathering, data analysis and interpretation, manuscript drafting and revising. All authors have read and approved the final edited typescript.

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Conflict of Interest

The authors declare no conflicts of interest.

Ethical Publication Statement

We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

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