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Research Protocol

Physical Medicine and Rehabilitation Section

Effect of Ballistic Training on Pain, Range of Motion and Strength in Phase II Rehabilitation of ACL Reconstruction: A Research Protocol of a Randomised Controlled Trial

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ABSTRACT

Introduction: An Anterior Cruciate Ligament (ACL) injury produces a 5-40% reduction in quadriceps strength over time. Neuromuscular electrical stimulation is used to help the quadriceps muscle weaken after ACL surgery. The ACL is the primary stabiliser for anterior tibial displacement and the secondary stabiliser for tibial rotation; an ACL-deficient knee can result in devastating consequences like articular cartilage injuries, meniscus tears, functional instability, and the risk of early-onset osteoarthritis. Following an ACL injury, the goal of ACL restoration is to restore functional knee stability. Journals have indicated an increased interest in combining ACL restoration with extra-articular augmentation in recent years. Several studies have demonstrated that the extra reconstruction not only protects the graft from high loads, but also enhances lateral rotational control. In patients with sore joints after ACL reconstruction, cryotherapy can help by releasing endogenous opiates and decreasing nerve conduction velocity. Exercise performance for the physical qualities of strength and power, like many other sports activities, has a short time element for successful performance. As a result, these workouts are performed at the highest possible speed in the least amount of time.

Need for the study: There are many evidences that theraband exercises are essential for the patients with ACL reconstruction. Even in athletes, there are literature that proves ballistic training is essential for the patients with ACL reconstruction, but there is no literature for the ballistic training in normal population undergoing ACL reconstruction surgery. There is a strong need to perform a study and evaluate them.

Aim: To find out effectiveness of ballistic training in phase II rehabilitation on the patients with ACL reconstruction.

Materials and Methods: This randomised control trial will be conducted from May 2022 to May 2023 in the Outpatient and the Inpatient Department of Physiotherapy, Acharya Vinoba Bhave Rural Hospital, Sawangi (Meghe), Wardha, India, during which 100 patients with ACL reconstruction will be divided into two groups, one group will receive conventional therapy along with theraband exercises and another group will receive conventional therapy exercises along with ballistic training. Treatment will be given for eight weeks, five days in a week. The assessment will be done on day one of the treatment and at the end of treatment that is 8th week. Student's t-test and Chi-square tests will be applied for statistical comparison.

Keywords: Arthroscopy, Conventional therapy, Rehabilitation, Theraband

INTRODUCTION

One of the biggest and extremely complicated joint in the humans is knee joint, which has three different articulating bones which are femur (thigh bone), which is strongest and largest bone in our skeletal system, tibia (shin bone) and patella which forms the knee cap [1]. Primary muscles which are dynamic stabilisers of knee include quadriceps femoris and extensor retinaculum, pes anserinus (semitendinosus, sartorius and gracilis), popliteus, biceps femoris and semimembranosus [2]. Menisci is the structure which helps in improving weight bearing distribution, which increase contact between tibia and femur and also acts as a shock absorber [1]. The capsule of the joint, menisci, and various ligaments act as passive stabilisers, but the five extracapsular ligaments support the capsule: the Medial Collateral Ligament (MCL) and Lateral Collateral Ligament (LCL) the ligament of patella, the oblique popliteal ligament, and the arcuate popliteal ligament [2]. The joint is passively supported by two sets of intracapsular structures, comprising fibrocartilagenous menisci [2] and cruciate ligaments [2]: ACL and Posterior Cruciate Ligament (PCL). The ACL runs from the posterior medial aspect of lateral femoral condyle in the intercondylar notch which limits the forward movement of tibia relative to femur [2], it acts as a passive constraint on the femur's anterior tibial translation and has mechanoreceptors that send information through sensory pathways which result in reflex contraction of the hamstrings and provide protection in the form of dynamic stability to knee [3].

The ACL injuries can result in tear of the ligament which can be partial or complete, avulsion of the ligament from the upper or lower leg bone, or avulsion fracture. Another part of the knee, such as the pads that cushion the knee joints (menisci), another knee ligament, or the tissue that covers the ends of bones, can be injured at the same time as the menisci (cartillage) [4]. A pop is frequently heard, followed by pain, the knee becomes oedematus due to blood from the cruciate ligament haemorrhage and effusion and knee pain develops over next few days or weeks and the diagnosis is confirmed by computed tomography, magnetic resonance imaging, X-rays [1,4]. Cruciate ligament injury does not generate discomfort when the knee is at rest. When any weight is placed on it, however, it will seem unstable, and patients feel as if their knee is not under control and can result in further lesions which also lead to decreased mobility and muscular function [4]. Rupture of ACL is treated through reconstruction of ACL, which target to regenerate a mechanically strong ligament and restore knee kinematics and stability of the joint while preventing chronic osteoarthritis [5].

Quadriceps is the muscle which commonly goes into weakness after the ACL reconstruction surgery, for which neuromuscular electrical stimulation is applied to prevent atrophy and restore their strength [6]. There are also evidences that cryotherapy is beneficial for this

inhibition effect of quadriceps muscle [7]. Followed by theraband exercises which are used for strengthening of the muscle where the load is progressed from no load to 90% of load of the healthy leg [6]. Ballistic training which is also known as power training is also given to the patients for the person to enhance the presentation of the lower extremities exercises and ADL [8]. Rehabilitation continues to evolve as there are advances in the clinical and basic science knowledge [4]. Rehabilitation has a significant impact on the functional results of the extremities after ACL restoration. All of these requirements are emphasised in current ACL rehabilitation procedures [9].

There are many evidences that theraband exercises are essential for the patients with ACL reconstruction, even there are literature that proves ballistic training is essential for the patients with reconstruction of the ACL. There is no research regarding ballistic training in the general population undergoing ACL reconstruction. Therefore there is a strong need to perform a study and evaluate them.

Aim of the study is to study effectiveness of the ballistic training over theraband exercises.

The objectives of the study are:

1) To determine the effectiveness of ballistic exercises on the patients with ACL reconstruction;
2) To determine the effectiveness of theraband training exercises on the patients with ACL reconstruction;
3) To compare the effectiveness of ballistic training exercise over theraband exercises in the patients with ACL reconstruction in the normal population.

The null hypothesis of the study is that there will be no significant difference in the effectiveness of the ballistic training and theraband exercises.

The alternate hypothesis of the study is that there will be significant difference in the effectiveness of the ballistic training and theraband exercises.

Review of Literature

The protocol will be followed to determine effectiveness of ballistic training versus theraband. In the ballistic training the patient will be given high intensity exercises to perform which will be given for the patient to quickly return back to activities of daily living which will be given five days a week and for 30 minutes and lower extremity functional scale will be assessed.

A study conducted in 2019 on the feasibility, safety and effectiveness of ballistic training in the patients with neurological impairments and conducted a review of five studies and came to the conclusion that ballistic training is safe and feasible for the neurological patients and also has positive effect on the strength and power with the help of resistance training [10].

Another Study done in the year 2015 for the concepts of ACL repair in athletes the aim of the protocol was to return the particular athlete to the preinjury level and the rehabilitation protocol was administered and it was found to be useful for the athletes to bring back as they were before the ligament injury [9], while another study in 2012 was done for the accelerated recovery of the ACL patients, where they evaluated the joint position sense and muscle strength which was found to be beneficial for the patients to return to sport after the injury [5].

A review conducted in the year 2021 concluded that, targeting motor control deficiencies is an important part of ACLR rehabilitation. Changing how attention is directed when completing motor activities in the early, middle, and late periods of rehabilitation could help enhance neuromuscular control. An outward focus of attention is a strategy for automatic movement control that is more effective than an internal focus of attention in terms of performance and learning. To promote appropriate mobility patterns throughout rehabilitation procedures, clinicians are recommended to adopt an exterior rather than an internal centre of attention in their practise. Furthermore, when defining attentional focus interventions in experimental designs, researchers should attempt to utilise identical terms [11].

MATERIALS AND METHODS

This Randomised controlled trial will be conducted at the Department of Musculoskeletal Outpatient Department (OPD), Ravi Nair College of Physiotherapy, Datta Meghe Institute of Medical Sciences, Sawangi Wardha, India from May 2022 to May 2023.The research place will be AVBRH Sawangi, Wardha's Outpatient and Inpatient Physiotherapy Departments. The trial has been registered in the Clinical Trial Registry of India (CTRI) with the reference number CTRI/2022/07/044268. The participant will be given informed consent on a paper form with signatures and confirmation of confidentiality.

Prior to the start of the study, all participants will be informed about the intervention, research, and data confidentiality. Those that meet the inclusion criteria (n=100) will be enrolled in the study. After obtaining ethical clearance for the study {DMIMSU(DU)/IEC/2022/893}, the study will be carried out.

Inclusion and Exclusion criteria: The individuals aged 20-40 years of males and females, with ACL reconstruction will be included in the study while the patient with fracture, patients elder than 40 years of age and the patients with other knee conditions such as osteoarthiritis, immune compromised disease, overweight patients, osteoporosis will be excluded from the study.

Sample size calculation: A total of 50 individuals in group A and 50 individuals in group B will be included. Sample size was calculated using Cochran's formula:

$$n=\frac{Z^2_{\alpha/2}.p.\ (1-p)}{E^2}$$

Where,

$Z^2_{\alpha/2}$ is the level of significance at 5% that is 95%

Confidence interval=1.96

P=Incidence of tears=44%=0.44 [12]

E=Error of margin=10%=0.10

$$N=\frac{1.96^2\times0.44\times(1-0.44)}{0.10^2}$$

=94.65=100 patients will be needed in the study

Both the groups, group A and group B will consist of 50 patients in each group out of which one will be the control and another will be the experimental group.

Group A

This group will be receiving treatment for one hour per day, five days a week and will be continued for eight weeks.

4 weeks of conventional therapy: It starts from the 1st day after ACL reconstruction which includes – Cryotherapy for the patients with elevation of leg, as much as, possible. SLR in sitting, standing and supine position to achieve active and passive ranges.

For 2-4 weeks: Functional exercises passive exercises and stretching which are continued with pain control, range and gait training, balance and proprioception exercises and next four weeks ballistic training will be given.

Ballistic exercises: This group will be receiving ballistic exercises for 30 minutes per day, five times a week for four weeks. This group includes group of exercises such as:

Box jump: Jump over the box. Depending on the patient's skills, the exercise comprises jumping up to a box or a surface of a specified height.

Kettle bell exercises: When performed correctly, this ballistic exercise produces a regular pattern hip-hinge, which is needed for

the performance (technically) of numerous lower-extremity exercises and activities. This exercise necessitates a faster execution speed and the deceleration skills that introduce high velocity exercise, that are required for stopping, landing, and changing directions.

Bunny hops: These are of low impact, done by pushing the balls away from the feet while flexing the knees slightly at the surface of ground. This modified ankling exercise can be progressed to ankling exercises in which the patient alternates plantar and dorsi flexion of each foot while landing on the ball of the foot and propelling themselves forward in a modified straight leg cycling pattern. During exercise performance, the knee and hip musculature play a little role in forward movement.

Group B

Conventional therapy is administered for four weeks, same as in group A

Theraband exercises: This group will be receiving theraband exercises for 30 minutes per day, five times a week for four weeks. This group includes group of exercises such as:

Glute bridge exercises: A resistance banded hip bridge will be indicated to ensure appropriate gluteus maximus activation. The patient was asked to-Begin by reclining on your back, knees bent and feet flat on the floor. Wrap a theraband around your thighs just above the knees. Complete a hip bridge while slightly abducting your legs. Return to your starting position slowly, keeping your knees apart. Perform three sets of ten repetitions each.The weakening of the external rotators of hip and gluteus maximus can potentially cause valgus collapse of the knee. The clam shell exercise helps to reduce hip rotator weakness, lowering the chance of injury.

Calm shell with theraband: Patient will start by lying on their side by using theraband around their knees, knees in same position and bent to 90°. Patients were asked to raise their upper part of knee while keeping their feet together. They will keep elevating the knee until it reaches the point where the pelvis starts to shift. They will present three sets of 10 repetitions each. Hamstring musclework in tandem with the quadriceps to assist support the tibia against the quadriceps' anterior demands. A leg curl with a stability ball will be an excellent Open Kinetic Chain (OKC) exercise that's been proven to increase activities in Electromyography in hamstring muscles, will be contracting simultaneously the core muscles.

One fourth squat with theraband side steps: Start by wrapping a Theraband around your thighs, right above your knees. Maintain a comfortable distance between your feet and knees so that the band can resist you. Squat down at a 14° angle with both your weight is supported by your feet. Maintain a squatting position and move your body weight to one leg completely. With your other/unweighted leg, take a lateral step. Side steps are taken first in one direction and then to another. When landing with less than a 45° flexion angle in the knees, there is an additional risk of damage. Long Jumps are utilised to develop suitable landing patterns. To begin with plyometrics as it is a great technique because it's comparable to the Tuck Jump test but in forward motion.

Outcome

Outcome measures used for this are divided into two groups that are primary outcomes and another one is the secondary outcome. Primary outcome measures will include Numerical Pain Rating Scale (NPRS), Range Of Motion (ROM), 1 Repetition Maximum (RM) and the secondary outcome measures include Lower Extremity Function Scale (LEFS), International Knee Disability Classification (IKDC) [13].

Randomisation sequence: The patients are randomised on the basis of the random numbers which are generated through the random numbers, during which the number are provided by the opaque sealed envelope and the patient is allowed to pick the envelope. Depending on the number the patient will be assigned to the intervention.

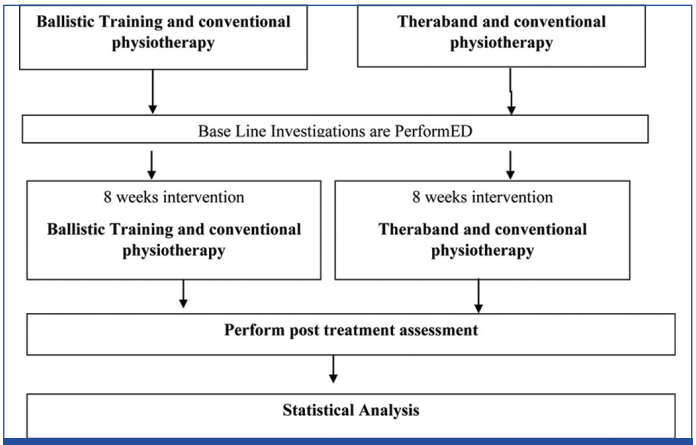
Allocation: Sequence generation- The sequence allocation was done using simple random sampling using the chit method, during which random numbers are generated with the help of computer. The number will be sealed in the opaque envelope through which the patient would not be able to see the allocation of the group and the intervention the patient will be receiving.

Implementation: Randomisation will be overseen by the research coordinator and main investigator. For recruitment into either group, participants will be requested to manually select from an envelope with a sealed group allocation.

Blinding: To assign the participants to the groups, the tester(s) will be blindfolded. Subjects will be required not to give any details about their therapy to the tester in order to ensure blindness.

Dependent variables: Pain and ROM

Independent variables: Theraband and Ballistic training [Table/Fig-1].



[Table/Fig-1]: Showing recruitment of subjects in the study.

STATISTICAL ANALYSIS

The statistical software used for the study will be Statistical Package for the Social Sciences (SPSS), version 27.0 and GraphPad Prism 7.0. Student's t-test and chi-square test will be used to compare the parameters in the both the groups.

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