

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effects of routine physical therapy with and without core stability in improving pain, functional mobility and quality of life in patients with iliotibial band syndrome

Protocol summary

Study aim

Primary aim of this study is to evaluate effectiveness of core stability exercises with and without routine physical therapy (RPT) on pain and functional mobility in patients with iliotibial band (ITB) syndrome. Secondary aim, evaluate effectiveness of core stability exercises on quality of life in iliotibial band syndrome (ITBS)

Design

Single center, parallel group, concealed, double blind, randomized controlled trial of 40 participants

Settings and conduct

University Physical Therapy and Rehabilitation Clinic, University of Lahore. Participants and outcome assessor blinded.

Participants/Inclusion and exclusion criteria

Participants were included if age between 18-50 years in both the gender, presence of local tenderness over the lateral epicondyle, positive noble compression test and modified ober's test. Participants with systemic illness, peripheral nerve involvement and any type of Arthritis in lower limb, Tumor and history of previous knee trauma and surgery were excluded.

Intervention groups

In control group participants follows RPT that includes 1- Specific stretching exercises of ITB, tensor fascia latae, and gluteus medius 2- Soft tissue and medial patella mobilizations 3- Active release soft-tissue mobilization and myofascial release 5- Strengthening exercises for ITBS 6- Cryotherapy, Phonophoresis, While interventional group participants follow RPT and core stability exercise , which includes: Transversus abdominus (30 reps with 8s hold) Bracing with heel slides, Abdominal bracing, bridging, standing, standing row, walking, leg lifts. Paraspinals/multifidi (30 reps with 8s hold). Quadruped legs lifts and arm lifts with bracing, Quadruped alternate legs and arms lifts with bracing. Quadratus lumborum and obliques (30 reps with 8s hold). Side plank with

knees flexed and extended Trunk curl

Main outcome variables

Numeric Pain Rating Scale and Lower Extremity Functional Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200211046456N1**

Registration date: **2020-08-16, 1399/05/26**

Registration timing: **retrospective**

Last update: **2020-08-16, 1399/05/26**

Update count: **0**

Registration date

2020-08-16, 1399/05/26

Registrant information

Name

Rabia Saeed

Name of organization / entity

The University of Lahore

Country

Pakistan

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-05, 1397/04/14

Expected recruitment end date

2019-07-30, 1398/05/08

Actual recruitment start date

2018-08-10, 1397/05/19

Actual recruitment end date

2019-06-18, 1398/03/28

Trial completion date

2019-08-02, 1398/05/11

Scientific title

Effects of routine physical therapy with and without core stability in improving pain, functional mobility and quality of life in patients with iliotibial band syndrome

Public title

Effect of core stability exercise in treatment of iliotibial band syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The age between 18-50 years in both the gender
 Presence of local tenderness over the lateral epicondyle
 Subjects with Positive Noble compression test
 Subjects with Positive modified ober's test

Exclusion criteria:

Systemic illness
 Peripheral nerve involvement in lower extremity
 Any type of Arthritis of lower limb
 Tumor
 History of previous knee trauma and surgery

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

This study was designed to be a parallel group randomized controlled trial. Random numbers were generated, without stratification, from 1-40 using an online random numbers generator in two sets by an independent statistician. Set 1 was assigned routine physical therapy and set 2 was assigned core stability exercises and routine physical therapy. Opaque, sealed envelope method was used to randomly assign patients (in a 1:1 ration) into both groups and unsealed by a researcher after baseline testing. Outcome assessors were unaware of group assignment.

Blinding (investigator's opinion)

Double blinded

Blinding description

After randomisation, patients were told about their treatment regime by their therapist, keeping blind about the other group treatment. Patients were only informed about treatment programme similarities in both groups (soft tissue, cryotherapy, stretching and strengthening

exercises). Both treatment programmes were tailored to the patient's abilities to make sure all eligible patients could complete the trial. Outcome assessors and data analyzers were masked to group allocation. Patients were told not to talk about the treatment protocol they were given during the trial with the outcome assessors and could contact their therapist in case of any problems during trial participation. Besides, if two or more study participants were in the clinic at the same time, they were assigned to different treatment areas without any opportunity to observe each other or their treatment times were rearranged to prevent unintended crossover.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Institutional Review Board of University of Lahore

Street address

1-KM Defence Road, Off Bhubatian Chowk, Lahore

City

Lahore

Postal code

54000

Approval date

2018-05-31, 1397/03/10

Ethics committee reference number

IRB-UOL-FAHS/347/2018

Health conditions studied**1****Description of health condition studied**

Iliotibial Band Syndrome

ICD-10 code

M76.3

ICD-10 code description

Iliotibial band syndrome

Primary outcomes**1****Description**

Pain

Timepoint

At baseline (before intervention), 3 weeks of treatment and at end of treatment (6 weeks)

Method of measurement

Numeric Pain Rating Scale

2

Description

Functional Mobility

Timepoint

At baseline (before intervention), 3 weeks of treatment and at end of treatment (6 weeks)

Method of measurement

Lower Extremity Functional Scale

Secondary outcomes

1

Description

Quality of Life

Timepoint

At baseline (before intervention) and at end of treatment (6 weeks)

Method of measurement

Short Form (36) Health Survey

Intervention groups

1

Description

Intervention group: This group include combination of routine physical therapy and core stability exercises as part of treatment. Core stability exercise includes: 1- Transversus abdominus (perform 30 reps with 8s hold) Bracing with heel slides, Abdominal bracing, bridging, standing, standing row, walking, leg lifts. 2- Paraspinals/multifidi (perform 30 reps with 8s hold). Quadruped legs lifts and arm lifts with bracing, Quadruped alternate legs and arms lifts with bracing. 3- Quadratus lumborum and obliques ((perform 30 reps with 8s hold). Side plank with knees flexed and extended. 4- Trunk curl. (Conventional) Routine physical therapy protocol include 1- specific stretching exercises focused on the ITB, tensor fascia latae, and gluteus medius. 2- soft tissue and medial patella mobilizations. 3- active release soft-tissue mobilization techniques. 4- foam roller as a myofascial release tool. 5- strengthening exercises for ITBS. 6- cryotherapy. 7- phonophoresis. 8- immobilization. Total treatment duration was 40 mins per session, 3 days a week (on alternate basis) for 6 weeks.

Category

Rehabilitation

2

Description

Control group: In this group participant only received (Conventional) Routine physical therapy protocol include 1- specific stretching exercises focused on the ITB, tensor fascia latae, and gluteus medius. 2- soft tissue and medial patella mobilizations. 3- active release soft-tissue mobilization techniques. 4- foam roller as a myofascial release tool. 5- strengthening exercises for ITBS. 6- cryotherapy. 7- phonophoresis. 8- immobilization. Total treatment duration was 40 mins per

session, 3 days a week (on alternate basis) for 6 weeks.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

University Physical Therapy and Rehabilitation Clinic,
University of Lahore

Full name of responsible person

Prof Dr. Ashfaq Ahmad, PT

Street address

1-KM Raiwind Road, Lahore

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ashfaq.ahmad@uipt.uol.edu.pk

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Lahore

Full name of responsible person

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Web page address

<https://www.uol.edu.pk/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

The University of Lahore

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity

The University of Lahore

Full name of responsible person

Rabia Saeed

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Study protocol, statistical analysis plan, informed consent form will be shared for primary and secondary outcome measure with interested research after considering the ethics and confidentiality.

When the data will become available and for how long

Data will be available after 9 months of publication for 2 consecutive years.

To whom data/document is available

Data will only be shared with individual researcher and academic researchers working with sports/orthopedic injuries. Data will not be shared for any commercial purposes/businesses for any reasons.

Under which criteria data/document could be used

Data can be used under confidentiality and medical ethics

From where data/document is obtainable

Data can be obtained by emailing at rabiasaeed534@gmail.com.

What processes are involved for a request to access data/document

Simple email can do this. But this can take up to 6 weeks

depends on busy schedule of researcher.
Comments