

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Effects of Multimodal intervention on Pain, Range of motion and Trunk Endurance in patients with Hamstring Strain Injury

Protocol summary

Study aim

To determine the effects of multimodal intervention on pain, range of motion and trunk endurance in patients with hamstring strain injury.

Design

Single blinded randomized controlled trial. Randomization will use and done by one of the research team members who will be blinded and not involve in patient recruitment or assessment or data analysis. Randomization will be done through computer generated and random number table. Total Sample Size is 72

Settings and conduct

Data will be collected from Pakistan Sports Board, Lahore. The study population will be consisted of patients with non specific pain. The study is single blinded. One of the research team members who will be blinded and not involve in patient recruitment or assessment or data analysis.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age between 18 to 30 years. Both Genders. Previous hamstring strain in last year Athletes diagnosed with hamstring strain injury. Grade I and II patients with hamstring strain injury will be included. Exclusion Criteria: Muscular pain or illness in other than hamstring muscles. Lumbopelvic or lower limb surgery. History of fracture due to hamstring strain injury. History of Lower limb fracture

Intervention groups

Intervention Group: Multimodal intervention will be applied on the patients with hamstring strain injury. This study will assess the impact of multimodal intervention on hamstring strain injury in overall physical performance. Control Group: This group will receive conventional physical therapy (CPT).

Main outcome variables

Pain, Range of motion and Trunk endurance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231119060113N1**

Registration date: **2023-12-09, 1402/09/18**

Registration timing: **prospective**

Last update: **2023-12-09, 1402/09/18**

Update count: **0**

Registration date

2023-12-09, 1402/09/18

Registrant information

Name

Hiba Saeed

Name of organization / entity

The University Of Lahore

Country

Pakistan

Phone

+92 309 7158785

Email address

hibasaeed992@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-10, 1402/09/19

Expected recruitment end date

2024-02-01, 1402/11/12

Actual recruitment start date

2023-12-10, 1402/09/19

Actual recruitment end date

2024-02-01, 1402/11/12

Trial completion date

2024-02-04, 1402/11/15

Scientific title

Effects of Multimodal intervention on Pain, Range of motion and Trunk Endurance in patients with Hamstring Strain Injury

Public title

Effects of Multimodal intervention on Pain, Range of motion and Trunk Endurance in patients with Hamstring Strain Injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 to 30 years. Both genders. Previous hamstring strain in last year. Athletes diagnosed with hamstring strain injury. Grade I and II patients with hamstring strain injury will be included.

Exclusion criteria:

Muscular pain or illness in other than hamstring muscles. Lumbopelvic or lower limb surgery. History of fracture due to hamstring strain injury. History of Lower limb fracture

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

2

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **72**

More than 1 sample in each individual

Number of samples in each individual: **36**

Empty

Actual sample size reached: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Lottery method of randomization will use and done by one of the research team members who will be blinded and not involve in patient recruitment or assessment or data analysis. Allocation assignments will be kept in opaque and sealed envelope and will be unsealed by researcher after baseline assessment. Participants are randomly allocated into two groups through drawing a number.

Blinding (investigator's opinion)

Single blinded

Blinding description

The study is single blinded and the participants did not know while they are receiving experimental or conventional treatment.

Placebo

Not used

Assignment

Factorial

Other design features

Trunk flexor musculature, Lateral and posterior trunk musculature used for trunk stability.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee

Street address

1-Km Defence Road,, near Bhuptian Chowk,, Lahore, Punjab

City

Lahore

Postal code

54000

Approval date

2023-10-16, 1402/07/24

Ethics committee reference number

REC-UOL-542-10-2023

Health conditions studied

1

Description of health condition studied

Hamstring Strain Injury

ICD-10 code

M79.8

ICD-10 code description

Other specified soft tissue disorders

Primary outcomes

1

Description

Pain will be measured by visual analogue scale

Timepoint

Before intervention, During intervention (3rd week) and after intervention(6th week).

Method of measurement

Visual Analogue Scale

2

Description

Range of motion

Timepoint

Before intervention, During intervention (3rd week) and after intervention(6th week).

Method of measurement

Range of motion will be measured by Goniometer.

Secondary outcomes

1

Description

Trunk Endurance

Timepoint

Before and 6th week after intervention.

Method of measurement

Trunk endurance will be measured by Trunk flexor musculature, Lateral trunk musculature and Posterior trunk musculature

Intervention groups

1

Description

Intervention group: Participants will receive tens and ultrasound therapies after that strengthening exercises will be applied. For 6th weeks, All participants received a total of 18 treatment sessions over a six week period which consisted of 3 treatment sessions per week.

Category

Rehabilitation

2

Description

Control group: This group will receive conventional physical therapy. Participants will receive regular physiotherapy interventions which includes 10 minutes of hot pack followed by TENS which continues till 6th week. After applying modalities patients will receive manual therapy sessions of stretching as well as strengthening exercises of hamstring muscles.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Pakistan Sports Board

Full name of responsible person

Mr. Abdul Majeed

Street address

G85J+V6V, Lahore - Kasur Rd, Block E 2 Gulberg III,
Lahore, Punjab

City

Lahore

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54000

Phone

+92 42 99230383

Email

psblahore@hotmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Lahore

Full name of responsible person

Prof. Dr. Ashfaq Ahmad

Street address

1-Km Defence Road,, near Bhuptian Chowk,, Lahore,
Punjab

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Email

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Web page address

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

Grant name

Grant code / Reference number

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

No

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

Hiba Saeed

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Physiotherapy

Street address

1-Km Defence Road,, near Bhuptian Chowk,, Lahore,
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Person responsible for scientific inquiries

Contact

Name of organization / entity

The University of Lahore

Full name of responsible person

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Position

Student

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Demographic data and data related to final outcome will be shared by maintaining the confidentiality.

When the data will become available and for how long

Data will be available from 15 June 2024 to 15 Dec 2024 after 6 month of publication

To whom data/document is available

Hiba Saeed, University of Lahore

Under which criteria data/document could be used

For research purpose

From where data/document is obtainable

To the corresponding author of the study, Hiba Saeed and can contact on +923097158785, hibasaeed992@gmail.com

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

Open access and there is the traditional public data release where anyone can get access to the data with no registration

Comments

I want randomized controlled trials registration