

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparative effect of Mulligan two leg rotations and bend leg raise techniques in improving pain intensity and hamstring dynamics in subjects with chronic low back pain

Protocol summary

Study aim

To check the comparative effects of Mulligan two leg rotations and bend leg raise techniques in pain intensity and hamstring dynamics in subjects with chronic low back pain. Secondary objective was to compare the disability in patients with chronic low back pain.

Design

Single blind, parallel assigned, bi-center, randomized clinical trial that will be done on 34 patients with history of pain for more than 12 weeks. Patients will be assigned by using the lottery method of simple random sampling.

Settings and conduct

Hussain memorial hospital Lahore and The Physiotherapy Clinic of The University of Lahore.

Participants/Inclusion and exclusion criteria

Patients with age from 20 to 45 years. Both male and female were included. Subjects with pain above 3 on numeric pain rating scale. Pain more than 12 weeks. Score more than 30% and less than 65% on the Modified Oswestry disability questionnaire. Subjects not willing to participate. Patients with Sciatica pain.. Fracture of the Lumber, pelvic and all the spinal regions. Slipping of vertebra or complete tears of intervertebral disc. Recent history of trauma within six months. Patients with Surgical History. Radiating pain to the legs and buttocks. Spinal pathologies i.e. degenerative changes, spinal T.B, discitis, Osteoporosis and neoplasm. Disc herniation at any spinal region. Females with Pregnancy.

Intervention groups

Group A: Warmup before the treatment will be given as baseline treatment. Mulligan two leg rotation technique will be applied. Group B: As a baseline treatment warmup before the treatment will be done by the use of hot pack. Then the bend leg raise technique will be applied.

Main outcome variables

Pain intensity, Hamstring Flexibility on both sides and

disability

General information

Reason for update

Because I have to update recruitment dates

Acronym

IRCT registration information

IRCT registration number: **IRCT20210813052159N1**

Registration date: **2021-08-24, 1400/06/02**

Registration timing: **prospective**

Last update: **2021-10-10, 1400/07/18**

Update count: **1**

Registration date

2021-08-24, 1400/06/02

Registrant information

Name

Abdul Samad

Name of organization / entity

The University of Faisalabad and The University of Lahore

Country

Pakistan

Phone

+92 46 2528198

Email address

abdulsamad2488@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-25, 1400/06/03

Expected recruitment end date

2021-09-05, 1400/06/14

Actual recruitment start date

2021-08-27, 1400/06/05
Actual recruitment end date
2021-09-07, 1400/06/16
Trial completion date
2021-10-10, 1400/07/18

Scientific title

Comparative effect of Mulligan two leg rotations and bend leg raise techniques in improving pain intensity and hamstring dynamics in subjects with chronic low back pain

Public title

Comparison of Mulligan techniques in chronic low back pain patients

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

• Patients with age from 20 to 45 years • Both male and female were included • Subjects with pain above 3 on numeric pain rating scale. • Pain more than 12 weeks • Score more than 30% and less than 65% on the Modified Oswestry disability questionnaire

Exclusion criteria:

• Subjects not willing to participate • Patients with Sciatica pain • Fracture of the Lumber, pelvic and all the spinal regions • Slipping of vertebra or complete tears of intervertebral disc • Recent history of trauma within six months • Surgical History • Radiating pain to the legs and buttocks • Spinal pathologies i.e. degenerative changes, spinal T.B, discitis, Osteoporosis and neoplasm • Disc herniation at any spinal region • Pregnancy

Age

From **20 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **34**

Actual sample size reached: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients will be randomly assigned, using the simple random sampling technique by lottery method. Out of the screened patients, 34 patients those who fulfill the inclusion criteria were assigned a number. The walk-in patients will be assigned by even numbers and odd numbers. Patients coming at the even numbers will be included in Group A (Two Leg Rotation) and those with odd numbers will be included in the Group B (Bend Leg Raise). 17 patients will be included in the Group A and 17 patients will be assigned to the Group B.

Blinding (investigator's opinion)

Single blinded

Blinding description

Information about the details of both programs will not

be provided except for similarities across both groups (exercise regime). Both programs will be personalized to the patient's abilities to ensure all eligible patients could complete the program. Patients will not be informed about the treatment protocols within the group they are enrolled in. Patient will not be aware whether they are included in the Group A or Group B and they will not be aware that they are receiving Two Leg Rotation or Bend Leg Raise technique within the group. Patient will not be aware of the maximum outcome measures possible after the treatment. Within two groups, the treatment will be given at the hospital or rehabilitation clinic during the one-hour therapy session.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics and Technical committee of The University of Faisalabad

Street address

University town, Sargodha road Faisalabad

City

Faisalabad

Postal code

38000

Approval date

2021-05-25, 1400/03/04

Ethics committee reference number

TUF/DR/SA/MSPP/2021/237-246

Health conditions studied

1

Description of health condition studied

Chronic Low Back Pain patients with decreased hamstring flexibility

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Pain Intensity

Timepoint

Before the Intervention, after 4 weeks of intervention

Method of measurement

Numeric Pain Rating Scale

2**Description**

Hamstring flexibility

Timepoint

Before the Intervention, after 4 weeks of intervention

Method of measurement

Active Knee Extension Test

Secondary outcomes**1****Description**

Disability in Low back pain patients

Timepoint

Before the treatment, 4 weeks after the treatment

Method of measurement

Modified Oswestry disability questionnaire

Intervention groups**1****Description**

Intervention group: Group A (Mulligan Two Leg Rotation)
Patient will be in supine lying and therapist will stand on the limited side of hamstring flexibility. Therapist will move both the legs into hip flexion and knee flexion to the maximum until both the feet are off the table. Upper extremity of the patient will be fixed to the plinth by using the belt or assistant. Then both the legs will be moved to the limited hamstring flexibility side. Upon reaching the limit this position will be maintained for 30 seconds and over pressure may be applied. 3 repetitions will be given and same procedure will be applied on the other side. Devices used will be Mulligan belts and plinths.

Category

Treatment - Other

2**Description**

Intervention group: Group B (Mulligan Bend Leg Raise)
Patient will be in supine lying position. Knee will be placed on the therapist shoulder in 90-degree hip and knee flexion. Therapist would be standing on the patient side which is going to be treated. Both the hands will be placed on the lower end of thigh. Knee would rest on the therapist shoulder under the popliteal fossa and distraction will be added along the longitudinal axis of femur by using the both hands. Ask the patient to push against the shoulder with his leg and then asked to relax voluntarily. During this relaxation period bent knee will be pushed through its available range in the direction of shoulder in pain free range. Stretch will be maintained for 30 seconds and 3 repetitions will be given. If the pain is decreased and range of motion increased the hip will be moved into more flexion and procedure will be

repeated. Devices used will be Mulligan belts and plinths.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hussain Memorial Hospital

Full name of responsible person

Umar Javed Alvi

Street address

105, Multan road, Lahore

City

Lahore

Postal code

54500

Phone

+92 42 37505082

Email

info@hussainmemorialhospital.com

Web page address**2****Recruitment center****Name of recruitment center**

Physiotherapy clinic, The University of Lahore

Full name of responsible person

Haider Ullah Khan

Street address

1- KM off thokar niaz baig, raiwind road, Lahore

City

Lahore

Postal code

53700

Phone

+92 42 35963428

Email

Haiderullah.khan@uipt.uol.edu.pk

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

ABS Physiotherapy Clinic

Full name of responsible person

Abdul Samad

Street address

Orchard Heights Plaza, Bahria Orchard phase 1, Lahore

City

Lahore

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53720

Phone

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Grant name

Grant code / Reference number

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

No

Title of funding source

ABS Physiotherapy Clinic

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

ABS Physiotherapy Clinic

Full name of responsible person

Abdul Samad

Position

Clinical Physiotherapist

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

ABS Physiotherapy Clinic

Full name of responsible person

Abdul Samad

Position

Clinical Physiotherapist

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

ABS Physiotherapy Clinic

Full name of responsible person

Abdul Samad

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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

As we have signed and assured the patients that their data will not be shared and updated elsewhere other than the current study

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Primary and secondary outcome measures will be shared

and no other personal information will be shared.

When the data will become available and for how long

Starting from January 2022 and it will be available for indefinite period of time

To whom data/document is available

To everyone related to the field of study

Under which criteria data/document could be used

Anyone who will request for the data

From where data/document is obtainable

Through email address

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

An email that will state the use of data will be obliged

Comments