

# 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

**Postal code**

53720

**Phone**

+92 42 35475709

**Email**

abdulsamad2488@gmail.com

**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

**Street address**

Orchard Heights Plaza, Bahria Orchard phase 1,  
Lahore

**City**

Lahore

**Province**

Punjab

**Postal code**

53720

**Phone**

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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**

Master

**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

**Position**

Clinical Physiotherapist

**Latest degree**

Master

**Other areas of specialty/work**

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**Email**

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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**