

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effects of McGill versus Lee Stabilization Exercises on Pain, Disability, Range of motion, Quality of life and Endurance in Patient with Chronic Nonspecific Low Back Pain

Protocol summary

Study aim

To compare the effects of Mc Gill versus Lee stabilization exercises on pain, disability, range of motion, quality of life and endurance in patient with chronic nonspecific low back pain

Design

The trial will be conducted at Sir Ganga Ram Hospital, Lahore. The participant will be blinded by the concealment of the technique that will be used on them.

Settings and conduct

Randomized clinical trial, single blinded study, two parallel groups with 32 patients from Sir Ganga Ram Hospital, Lahore.

Participants/Inclusion and exclusion criteria

Inclusion criteria Both male and female patient Age 30-50 years Patient with a history of 3 months nonspecific low back pain Pain intensity (3-7) according to NPRS score Exclusion Criteria Any lumbar surgery Spinal stenosis Neurological dysfunction Systemic disease Pregnancy

Intervention groups

Intervention group 1 :The Mc Gill group in the study will follow a six-week exercise regimen, where they will participate in sessions thrice a week week with 6-10 repetition : □ Curl-Up, □ Bird-Dog, □ Side Plank
Intervention group 2: The Lee Stabilization group in the study will follow a six-week exercise protocol specific to the Lee Stabilization method, attending sessions three times a week. The main exercises will be Upper-Body Extension, Alternate Arm and Leg Lift, Alternate Arm and Leg Extension on All Fours, Diagonal Curl Up and Curl up with arms at sides, tilt pelvis to flatten back.

Main outcome variables

Pain, disability, range of motion, quality of life and endurance

General information

Reason for update

Acronym

nlbp

IRCT registration information

IRCT registration number: **IRCT20190717044238N14**

Registration date: **2024-05-18, 1403/02/29**

Registration timing: **prospective**

Last update: **2024-05-18, 1403/02/29**

Update count: **0**

Registration date

2024-05-18, 1403/02/29

Registrant information

Name

Fareeha Amjad

Name of organization / entity

The University of Lahore

Country

Pakistan

Phone

+92 42 99200600

Email address

fari_fairy22@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-20, 1403/02/31

Expected recruitment end date

2024-07-29, 1403/05/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of McGill versus Lee Stabilization Exercises on Pain, Disability, Range of motion, Quality of life and Endurance in Patient with Chronic Nonspecific Low Back Pain

Public title

Effects of McGill versus Lee Stabilization Exercises on Pain, Disability, Range of motion, Quality of life and Endurance in Patient with Chronic Nonspecific Low Back Pain

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient with a history of 3 months nonspecific low back pain Pain intensity (3-7) according to NPRS score Age: 30-50 years Both male and female patients

Exclusion criteria:

Any lumbar surgery Spinal stenosis Neurological dysfunction Systemic disease Pregnancy Infections Carcinoma Any fracture or deformity

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done by using sealed envelopes which involves assigning participants to different groups by randomly selecting an envelope that contains their group assignment. This will ensure reduced bias in allocation of interventions. Simple randomization method is used to allocate participants to different groups

Blinding (investigator's opinion)

Single blinded

Blinding description

In the trial the participant(who are willing to participate) is blinded by not knowing or being unaware which intervention they are receiving , but the researcher (physiotherapist) know. This trial will be single blinded. Researcher will be responsible for care for participants during the trial, data collectors, outcome assessors, and with lesser importance Data Safety .

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research and ethics Committee Riphah College of Rehabilitation and Allied Health Sciences

Street address

Riphah International University Gulberg campus lahore

City

Lahore

Postal code

54000

Approval date

2024-04-03, 1403/01/15

Ethics committee reference number

REC/RCR&AHS/23/0190

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

chronic non specific low back pain

ICD-10 code

Low Back P

ICD-10 code description

M54.5

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

Pain

Timepoint

Before intervention, 6 weeks

Method of measurement

Numeric pain rating scale (NPRS)

2**Description**

Functional disability

Timepoint

Before intervention, 6 weeks

Method of measurement

Urdu version of Oswestry Disability index (ODI)

3**Description**

Range of motion

Timepoint

Before intervention, 6 weeks

Method of measurement

Inclinometer

4

Description

Endurance

Timepoint

Before intervention, 6 weeks

Method of measurement

Sorensen Test

5

Description

quality of life

Timepoint

Before intervention, 6 weeks

Method of measurement

SF-36 Urdu version

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mc Gill group

Category

Rehabilitation

2

Description

Control group: Lee Stabilization

Category

Rehabilitation

Recruitment centers

1

Recruitment center**Name of recruitment center**

Sir Ganga Ram Hospital, Lahore

Full name of responsible person

Hafiza Sumbal Liaqat

Street address

Sir Ganga Ram Hospital, Lahore

City

Lahore

Postal code

54000

Phone

+92 332 0459833

Email

sumballiaqat10@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Riphah International University Lahore

Full name of responsible person

Fareeha Amjad

Street address

Riphah International University Lahore Gulberg green campus

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Lahore

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Phone

+92 334 3372779

Email

fari_fairy22@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Riphah International University 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**

Riphah International University Lahore

Full name of responsible person

Hafiza Sumbal Liaqat

Position

MS student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Riphah International University Lahore

Full name of responsible person

Fareeha Amjad

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

Contact

Name of organization / entity

Riphah International University Lahore

Full name of responsible person

Hafiza Sumbal Liaqat

Position

MS student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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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

confidentiality of participants

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not 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

Consent form in its original format with no information about any participant study protocol -how the intervention was given to both groups

When the data will become available and for how long

Data would be available after the completion of the research

To whom data/document is available

People working in an academic and clinical setting can have access to the above mentioned information/documents

Under which criteria data/document could be used

Data can be used for research paper

From where data/document is obtainable

Data can be requested at following email:
sumballiaqat10@gmail.com

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

One can ask for data at the given email address and it would be provided after knowing the general implications of sharing that particular data

Comments