Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of Pilates versus McGill exercises on pain, flexibility, core stability and functional disability in patients with chronic mechanical low back pain

Protocol summary

Study aim

To compare the effects of Pilates Exercise versus McGill's Exercise on Pain, Flexibility, Core Stability and Functional Disability in patients with chronic mechanical low back pain.

Design

The trial will be conducted at Zainab Siddique Poly Clinic Engineer Town Lahore. The participant will be blinded by concealment of the technique that will be used on the participant.

Settings and conduct

Randomized clinical trial, single blinded study, two parallel groups with 32 patients from Zainab siddique Poly Clinic Engineer Town Lahore .

Participants/Inclusion and exclusion criteria

INCLUSION CRITERIA: Both male and Female Age between 20 and 40 years (11) Having mechanical low back pain without radiation to lower limbs, for more than 6 weeks were enrolled in the study. EXCLUSION CRITERIA : Patients with any systemic disorder or who were undergoing intervention Patients having a history of spine surgery were also not included.(11) Have a pacemaker or a history of serious cardiac event or of cardiorespiratory dysfunction. Participants who have a history of uncontrolled hypertension or arrhythmias. Participants who are currently participating in another clinical trial. Participants who have not undergone any recent surgical intervention for low back pain within the last six months.

Intervention groups

Group A : The Pilates group in the study will follow a six-week exercise regimen, where they will participate in Pilate's sessions twice a week with 6-10 repetition : Single leg lower Straight-leg bicycle Oblique double knee tucks Oblique tucks Group B The Mc Gill group in the study will follow a six-week exercise regimen, where they will participate in Pilate's sessions twice a week with 6-10 repetition : Curl-Up, Bird-Dog, Side Plank

Main outcome variables

Pain , Flexibility ,Core Stablity and functional disability are the main outcomes variable .

General information

Reason for update

Acronym

mlbp

IRCT registration information

IRCT registration number: **IRCT20190717044238N12**
Registration date: **2024-05-06, 1403/02/17**
Registration timing: **prospective**

Last update: **2024-05-06, 1403/02/17**
Update count: **0**

Registration date

2024-05-06, 1403/02/17

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

2024-05-06, 1403/02/17

Expected recruitment end date
2024-07-30, 1403/05/09
Actual recruitment start date
2024-05-12, 1403/02/23
Actual recruitment end date
2024-08-02, 1403/05/12
Trial completion date
2024-08-10, 1403/05/20

Scientific title
Effects of Pilates versus McGill exercises on pain, flexibility, core stability and functional disability in patients with chronic mechanical low back pain

Public title
Effects of Pilates versus McGill exercises on pain, flexibility, core stability and functional disability in patients with chronic mechanical low back pain
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Both male and Female Age between 20 and 40 years . Having mechanical low back pain without radiation to lower limbs, for more than 6 weeks were enrolled in the study. Participants should obtain clearance from their primary healthcare provider or a physician to participate in a physical activity program like Pilates or McGill's Protocol.
Exclusion criteria:
Patients with any systemic disorder or who were undergoing intervention Patients having a history of spine surgery were also not included Have a pacemaker or a history of serious cardiac event or of cardiorespiratory dysfunction Severe cognitive impairment or aphasia leading to difficulty in communication, Participants who have any significant musculoskeletal or orthopedic problems that would interfere with their ability to participate in the physical therapy program. Participants who have a history of uncontrolled hypertension or arrhythmias.
Age
From **20 years** old to **40 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **42**
Actual sample size reached: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done by use of sealed envelops which involves assigning participants to different groups by randomly selecting an envelope that contains their group assignment. This will ensure reduce biasness 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 lessor 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 Commitee 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 mechanical low back pain
ICD-10 code
M54.5
ICD-10 code description
Low Back Pain

Primary outcomes

1

Description
Pain
Timepoint
Before intervention, 6 weeks
Method of measurement
Numeric pain rating scale (NPRS)

2

Description
Flexibility
Timepoint
Before intervention, 6 week
Method of measurement
Sit and reach test score

3

Description
Core stability
Timepoint
Before intervention ,6 week
Method of measurement
Sahrmann core stability test

4

Description
Funtional disability
Timepoint
Before intervention, 6 week
Method of measurement
Urdu version of Oswestry Disability index (ODI)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1 : The Pilates group in the study will follow a six-week exercise regimen, where they will participate in Pilate’s sessions twice a week. Pilates is a form of exercise that focuses on core strength, flexibility, and controlled movements. As the weeks progress, the intensity and complexity of the Pilates exercises will be increased, aiming to gradually build the participants' physical capabilities and enhance their health outcomes. This structured approach will allow the patients to adapt to the exercise difficulty over time, potentially improving their effectiveness.: Pilate’s exercises emphasize core muscle activation :□ Single leg lower□ Straight-leg bicycle□ Oblique double knee tucks □ Oblique tucks□ Kneeling side bending.
Category
Rehabilitation

2

Description
Intervention group 2 :The Mc Gill group in the study will engage in a six-week exercise protocol specific to the Mc Gill method, attending sessions twice a week. With 10 minutes of heating pad This program is expected to concentrate on exercises that promote back health and core stability. With each passing week, the exercises will become more challenging, with the goal of methodically enhancing the participants' endurance, strength, and overall well-being. This progressive strategy will be designed to allow participants to gradually adjust to the increasing demands of the exercises, which is anticipated to improve the efficiency and benefits of the intervention .The Big Three: McGill has popularized three specific exercises that are often included in his approach. These exercises are the McGill □ Curl-Up, □ Bird-Dog,□ Side Plank
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Zainab siddeque Poly Clinic lahore
Full name of responsible person
Sabra Ghulam Rasool
Street address
Zainab siddeque Poly Clinic engineer town lahore
City
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Postal code
54000
Phone
+92 310 4143346
Email
sabra.ksr@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
City
Lahore
Postal code
54000
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?
Yes
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

Sabra Ghulam Rasool

Position

MS student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Full name of responsible person

Fareeha Amjad

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Sabra Ghulam Rasool

Position

MS sudent

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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City

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Postal code

54000

Phone

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Email

sabra.ksr@gmail.com

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 asked at following email sabra.ksr@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