Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Fascial distortion model on pain , functional disability and Range of motion in patients with chronic low back pain

Protocol summary

Study aim
The previous literature shows lack of studies specifically comparing the effects of routine physiotherapy with and without FDM on pain, functional disability, and ROM in patients with CLBP. Understanding the effects of routine physiotherapy with and without FDM on pain, functional disability, and ROM in patients with CLBP can provide valuable insights into the effectiveness of these interventions and guide evidence-based clinical decision-making. The findings of this study may have implications for the development of more effective treatment protocols for chronic low back pain.

Design
Parallel study with conveniet sampling technique . It is a Randomized Control Trial with single blinding of group division. Data will be collected for 6-9 months after approval

Settings and conduct
Data will be collected from DHQ hospital Muzaffargarh

Participants/Inclusion and exclusion criteria
Inclusion criteria: low back pain of more than 3 months; age 30-65 years old; both male and female. Exclusion criteria: low back pain associated with any structural deformity e.g scoliosis; osteoporosis; spinal fracture; LBP with Radicular symptoms; cauda equina syndrome.

Intervention groups
Fascial distortion model will be implied as Intervention group. There will be a three-week treatment plan with total 6 sessions each group that can be divided into baseline, first week second week and third week, comparing the two interventions.

Main outcome variables
Pain

General information

Reason for update

Acronym
FDM

IRCT registration information
IRCT registration number: **IRCT20240513061772N1**
Registration date: **2024-07-22, 1403/05/01**
Registration timing: **registered_while_recruiting**

Last update: **2024-07-22, 1403/05/01**
Update count: **0**

Registration date
2024-07-22, 1403/05/01

Registrant information

Name
Sana Saghir

Name of organization / entity
University of Lahore

Country
Pakistan

Phone
+92 314 6319023

Email address
sanasagheer14330@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-05-09, 1403/02/20

Expected recruitment end date
2024-11-09, 1403/08/19

Actual recruitment start date
2024-05-09, 1403/02/20

Actual recruitment end date
2024-09-15, 1403/06/25

Trial completion date
2024-11-10, 1403/08/20

Scientific title
Fascial distortion model on pain , functional disability and Range of motion in patients with chronic low back pain

Public title
Fascial distortion model in chronic low back pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Low back pain of more than 3 months Age 30-65 years Both genders
Exclusion criteria:
Low back pain associated with any structural deformity e.g scoliosis Patient with osteoporosis or spinal fractures are not included Low back pain with radicular symptom not included Cauda equina syndrome not included
Age
From **30 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **94**
Actual sample size reached: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple random allocation into two groups through computer generated numbers. Allocation was concealed
Blinding (investigator's opinion)
Single blinded
Blinding description
Study will be single blinded. The participants will be unaware of which group they have been allocated
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of The University of Lahore
Street address
1-Km Defence Road، near Bhuptian Chowk، Lahore, Punjab
City
Lahore
Postal code
54000
Approval date
2024-05-09, 1403/02/20
Ethics committee reference number
REC-UOL-135/8/24

Health conditions studied

1

Description of health condition studied
Low back pain
ICD-10 code
S39.01
ICD-10 code description
Strain of muscle, fascia and tendon of abdomen, lower back and pelvis

Primary outcomes

1

Description
Pain
Timepoint
Before intervention and immediately after treatment and 3 weeks after treatment
Method of measurement
Visual analog pain scale

Secondary outcomes

1

Description
Functional disability
Timepoint
Before and after treatment and At the end of 3rd week of intervention
Method of measurement
Roland-Morris disabilitt questionnaire

2

Description
Range of Motion
Timepoint
Before and after treatment and at the end of 3rd week of intervention
Method of measurement
Inclinometer

Intervention groups

1

Description
Intervention group: Fascial distortion model group
Category
Rehabilitation

2

Description

Control group: Hot pack , TENS , stretching and mobilization exercises

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

DHQ hospital Muzaffargarh

Full name of responsible person

Muhammad Saqib Fareed

Street address

0.5 Km from district courts DHQ hospital Alipur road , Distric Muzaffargarh

City

Muzaffargarh

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dhqmgarh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Lahore

Full name of responsible person

Prof. Dr. Ashfaq Ahmed

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

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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?

Yes

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

Sana Sagheer

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

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Position
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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 comfidentiality
When the data will become available and for how long
Data will be available from feb 2025 to May 2025 after the six months of publication the data sharing plan for a clinical trial (i.e, what data will be shared when and under what conditions) will be publicly available at a third-party site that shares data with and meets the data requirements of WHO's international clinical trials registry platform, this occurs before the first participant is enrolled
To whom data/document is available
Dr Sana tauqeer (corresponding author) senior lecturer at The university of lahore- 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, Dr sana tauqeer and can contact on +92 324 4294807 . Can visit these research engines, you can easily find my study here https://scholar.google.com/
What processes are involved for a request to access data/document
Open-access and there is traditional public data release where anyone can get access to the data with no registration or conditions. The request will be reviewed by director incharge and incase of eligibility , it would be shared in 2 weeks
Comments
I want randomized clinical trial registration.