

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 convenient 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 disability 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

**Postal code**

34200

**Phone**

+92 306 0066879

**Email**

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

**Street address**

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

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**Phone**

+92 42 111 865 865

**Email**

info@uol.edu.pk

**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

**Street address**

House#2 near oasis hotel Jhang road Muzaffargarh

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

The University of Lahore

**Full name of responsible person**

Dr Sana Tauqeer

**Position**

Senior lecturer

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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**Full name of responsible person**

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**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

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**Phone**

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**Email**

sanasagheer14330@gmail.com

## 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 confidentiality

**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.