

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effects of sacroiliac mobilization versus high velocity low amplitude thrust manipulation on pain and functional disability in female patients with sacroiliac joint dysfunction: A randomized controlled trial

#### Protocol summary

##### Study aim

the aim of study is to compare the effects of mobilization and manipulation on pain and functional disability in female patients with Sacroiliac joint dysfunction and to check whether or not one technique is more effective than other.

##### Design

two arm parallel group randomized trial with blinded outcome assessment

##### Settings and conduct

study will be conducted in Islam central hospital Sialkot. it will be double blinded study as the care giver and assessor will be unaware of treatment given

##### Participants/Inclusion and exclusion criteria

INCLUSION CRITERIA: (1)Females from age 25 to 50 (2)Patients with confirmed clinical diagnosis of sacroiliac joint dysfunction (3)Patients presenting with acute pain from last four weeks in low back or Sacroiliac joint of iliac origin (4)Patients with the complain of hypomobility of sacroiliac joint. EXCLUSION CRITERIA: (1)Patients with vertebral bone pathology,radiculopathy,sciatica, recent fracture (2)Patients with history of recent surgery in lumbosacral or pelvic area (3)Pregnant women, or those who had recent infection (4)Females with history of osteoporosis or cancer

##### Intervention groups

experimental group 1 will receive mobilization along with routine physical therapy experiential group 2 will receive manipulation along with routine physical therapy

##### Main outcome variables

Pain Functional Disability

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211117053085N1**

Registration date: **2021-12-20, 1400/09/29**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-12-20, 1400/09/29**

Update count: **0**

##### Registration date

2021-12-20, 1400/09/29

##### Registrant information

###### Name

Nusrat Qamar

###### Name of organization / entity

University of Lahore

###### Country

Pakistan

###### Phone

+92 52 3544112

###### Email address

msptm02193002@student.uol.edu.pk

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-08-04, 1400/05/13

##### Expected recruitment end date

2022-01-05, 1400/10/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of sacroiliac mobilization versus high velocity low amplitude thrust manipulation on pain and functional

disability in female patients with sacroiliac joint dysfunction: A randomized controlled trial

## Public title

Effects of sacroiliac mobilization versus thrust manipulation on pain and functional disability in female patients with sacroiliac joint dysfunction

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with confirmed clinical diagnosis of sacroiliac joint dysfunction will be included Patients presenting with acute pain from last four weeks in low back or Sacroiliac joint of iliac origin Patients with the complain of hypomobility of sacroiliac joint Will be included in our study Females from age 25 to 50 years will be included in our study

### Exclusion criteria:

Patients with vertebral bone pathology, radiculopathy, sciatica, recent fracture will not be included in our study Patients with history of recent surgery in lumbosacral or pelvic area Females with history of osteoporosis or cancer or any other bone pathology will not be included Pregnant women, or those who had recent infection will not be included in our study

## Age

From **25 years** old to **50 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

- Care provider
- Outcome assessor

## Sample size

Target sample size: **72**

More than 1 sample in each individual

Number of samples in each individual: **5**

data will be collected at baseline, 1, 2, 3 and 4 weeks of intervention

## Randomization (investigator's opinion)

Randomized

## Randomization description

computer generated randomization method will be used to allocate our participants in 2 groups. We will use computer software which will randomly allocate our subjects into either experimental group 1 or experimental group 2. Experimental group 1 will receive Mobilization along with Routine physical therapy while Experimental Group 2 will receive High Velocity Low Amplitude Thrust Manipulation along with routine physical therapy.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

the care giver and outcome assessor will be unaware of treatment given to participants. We will not disclose to the care giver or the outcome assessor about the type of treatment given to patient. In this way they will be blinded

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of University of Lahore

##### Street address

1km off defence road

##### City

Lahore

##### Postal code

54590

#### Approval date

2021-10-27, 1400/08/05

#### Ethics committee reference number

992

## Health conditions studied

### 1

#### Description of health condition studied

Sacroiliac joint Dysfunction

#### ICD-10 code

M46.1

#### ICD-10 code description

Sacroiliitis, not elsewhere classified

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

outcome will be measured at baseline, 1st, 2nd and 4th weeks post intervention

#### Method of measurement

pain will be measured using Numeric pain rating scale

### 2

#### Description

Functional Disability

#### Timepoint

Outcome will be measured at baseline, 1st, 2nd and 4th weeks post interventions

#### Method of measurement

Functional disability will be measured using Oswestry Disability Index Questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: 1 will receive Mobilization along with Routine physical therapy. In routine physical therapy we will use electro therapeutic modalities and simple pelvic stabilization exercises. The intervention will be applied 3 sessions per week for 4 weeks.

#### Category

Treatment - Other

### 2

#### Description

Intervention group: 2 will receive High Velocity Low Amplitude Thrust Manipulation along with routine physical therapy. In routine physical therapy we will use electro therapeutic modalities and simple pelvic stabilization exercises. The intervention will be applied 3 sessions per week for 4 weeks

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

islam central hospital, Sialkot

##### Full name of responsible person

Dr. Majid Saeed

##### Street address

Commissioner Road Sialkot

##### City

Sialkot

##### Postal code

51310

##### Phone

+92 52 3310611

##### Email

mabdul166@gmail.com

### 2

#### Recruitment center

##### Name of recruitment center

Sialkot college of physical therapy

##### Full name of responsible person

Dr. Wajida Perveen

##### Street address

Defence Road, Sialkot

##### City

Sialkot

##### Postal code

51310

##### Phone

+92 52 3250520

##### Email

wajopri@gmail.com

##### Web page address

<https://scholar.google.com/citations?user=7IAZykAAAJ&hl=en&oi=ao>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

university of Lahore

##### Full name of responsible person

dr. Ashfaq Ahmed

##### Street address

1 km off defence road

##### City

Lahore

##### Postal code

53700

##### Phone

+92 52 3310611

##### Email

hod@uipt.uol.edu.pk

##### Grant name

postgraduation research

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

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

Sialkot college of physical therapy

##### Full name of responsible person

Dr. Wajida Parveen

##### Position

Associate Professor

##### Latest degree

Master

##### Other areas of specialty/work

Physiotherapy

##### Street address

Defence Road Sialkot

##### City

Sialkot  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
Nusrat Qamar  
**Position**  
Lecturer  
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## Person responsible for updating data

### Contact

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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

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

Effects of Sacroiliac Mobilization versus high velocity low amplitude thrust manipulation on Pain, and functional Disability in female patients with Sacroiliac joint Dysfunction: A randomized controlled trial All collected Deidentified IPD will be shared

### When the data will become available and for how long

it will be available after the completion of work for three years upon request to the person involved in scientific inquiries

### To whom data/document is available

People working in academic institutes or involved in doing research work

### Under which criteria data/document could be used

it can be used for citations

### From where data/document is obtainable

data can be obtained through email using mail address of dr.nusratqamar55@gmail.com

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

data can be obtained through e mail to dr.nusratqamar55@gmail.com

### Comments