

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

EFFECTS OF SPINAL MANIPULATION VERSUS ROUTINE PHYSICAL THERAPY ON THORACIC SPINAL PAIN; A RANDOMIZED CONTROLLED TRIAL

Protocol summary

Study aim

- To determine the effect of Spinal Manipulative Therapy on Thoracic Spinal Pain, ROM & QoL

Design

A double blind randomized controlled trial.

Settings and conduct

This RCT will be conducted according to CONSORT guidelines. A parallel group RCT with 1:1 allocation ratio will be conducted at physical therapy department of Services Hospital Lahore. Patients will be asked to sign an informed consent. The assessor & patients will be blinded to allocation of treatment groups.

Participants/Inclusion and exclusion criteria

Inclusion: • Age between 40 and 60 years. • Mid line upper back pain, • Decreased thoracic range of motion
Exclusion: • Severe spinal deformity • Any systemic disease e.g. cardiovascular or neurological etc. • Traumatic history and any other red flags of spinal pain

Intervention groups

Experimental group will be managed with spinal manipulative therapy while the control group will be managed with routine physiotherapy and both the groups will receive ergonomic advice. The treatment will be given maximum for four weeks; three sessions per week. Then patients will be followed up at 8th and 12th week of treatment to check the consistency of effects.

Main outcome variables

□ The Pain threshold will be measured with VAS □ Quality of pain and the sensory dimensions will be assessed with McGill Pain Questionnaire □ The subjective outcome of pain and disability will be obtained with the Oswestry Back Pain Disability Index □ Objective measurement of ROM in the thoracic spine will be measured with the Goniometer. □ Chest expansion will be measured by Measurement Tape □ HR will be recorded by pulse oximeter and BP recording will be done by Digital sphygmomanometer. □ QOL improvement will be judged by using QOL questionnaire .

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190327043125N1**

Registration date: **2019-06-08, 1398/03/18**

Registration timing: **prospective**

Last update: **2019-06-08, 1398/03/18**

Update count: **0**

Registration date

2019-06-08, 1398/03/18

Registrant information

Name

Muhammad Sharif Waqas

Name of organization / entity

The University of Lahore

Country

Pakistan

Phone

+92 42 99200600

Email address

waqasphysio@gmail.com

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2640-06-21, 2019/03/31

Expected recruitment end date

2641-12-20, 2020/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

EFFECTS OF SPINAL MANIPULATION VERSUS ROUTINE PHYSICAL THERAPY ON THORACIC SPINAL PAIN; A RANDOMIZED CONTROLLED TRIAL

Public title

EFFECTS OF SPINAL MANIPULATION ON THORACIC SPINAL PAIN

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Only patients who will receive a diagnosis of thoracic spine pain from the researcher will be accepted into the study. Diagnosis will be made by questioning and examining the subject . • Age between 40 and 60 years
Midline back pain
Mobility deficit in thoracic range of motion
Pain with compression into spine extension
Patients without any known cause of TSP

Exclusion criteria:

Patient with neurological signs & symptoms
Osteoporosis
Severe spinal deformity
Any systemic disease e.g. cardiovascular or neurological etc
Traumatic history and any other red flags of spinal pain

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

1

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization: Subjects suitable for inclusion will be randomly allocated into two groups; group A/ Experimental group and group B/ control group using coin toss method and allocation sequence will be concealed through sealed envelopes. Concealment of allocation: Allocation concealment will be achieved with sequentially numbered, opaque, sealed, envelopes (SNOSE). SNOSE will be used according to guidelines of Doig and Simpson (25). An independent researcher with no clinical involvement in the trial will make the concealed envelopes. 100 Envelopes will be made. Half envelopes will contain folded papers with Treatment A written on them and the remaining half will contain folded papers with Treatment B written on them. A carbon paper will be inserted in each envelop with carbon side facing the paper so the allocation sequence, patient name, date of birth of participant and other information can be transferred onto allocation paper inside the envelope. A piece of tin foil is also inserted into envelop so the treatment card cannot be read against light. Envelops will be sealed and signed by the maker. A unique randomized number will be allocated to

these envelopes and shuffled vigorously. Then the envelopes will be arranged sequentially and handed over to another independent researcher. Assessor will pretest the participant and if eligible envelope will be allocated to subject. Therapist will record the information on the envelope and open it afterwards to maintain the concealment. Assessor will record the post treatment findings and another independent analyst will analyze the data. This allocation of concealment will ensure the unpredictability of treatment allocation by investigators and patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

In these patients assessor will be blinded to allocation of treatment groups in this study. Patient will be blinded to treatment allocation as treatment will be given in separate rooms for each group. Therapist who is not blinded will not take the outcome measurements.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethical committee/Institutional Review Board, The University of Lahore

Street address

1-Km raiwin Road Lahore

City

Lahore

Postal code

54000

Approval date

2018-09-20, 1397/06/29

Ethics committee reference number

IRB-UOL-FAHS/373-IIV/2018

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

Thoracic Spinal Pain effecting Quality of Life

ICD-10 code

M54.6

ICD-10 code description

Pain in thoracic spine

Primary outcomes

1

Description

Thoracic spine pain intensity

Timepoint

before and after treatment session and 8 & 12 weeks after treatment

Method of measurement

visual analogue scale to measure pain

Secondary outcomes

1

Description

chest expansion

Timepoint

before and after intervention and 8, 12 weeks after intervention

Method of measurement

measuring tape

2

Description

range of motion

Timepoint

before and after intervention and 8, 12 weeks after intervention

Method of measurement

goniometer

3

Description

Quality of Life

Timepoint

before and after intervention and 8, 12 weeks after intervention

Method of measurement

Quality of Life questionnaire

4

Description

blood pressure

Timepoint

before and after intervention and 8, 12 weeks after intervention

Method of measurement

digital sphygmomanometer

5

Description

heart rate

Timepoint

before and after intervention and 8, 12 weeks after intervention

Method of measurement

pulse oximeter

Intervention groups

1

Description

Intervention group: Subjects in experimental group will be managed with spinal manipulative therapy (a single attempt of high-velocity low-amplitude thrust in prone position) & ergonomic advice. The manipulation technique will be considered successful if an auditory or palpable release is perceived by the therapist and if an improved movement of that joint will be noted on post manipulative motion palpation besides the decrease in pain on visual Analogue Scale

Category

Other

2

Description

Control group: Subjects in the control group will be managed with routine physiotherapy (therapeutic exercises of thoracic spinal muscles with three sets of 10 repetitions with the rest period of 30 seconds between the sets) and ergonomic advice.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy department, Services Hospital, Lahore

Full name of responsible person

Muhammad Sharif Waqas, Physiotherapist

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Services Hospital Lahore

Full name of responsible person

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Grant name
N/A
Grant code / Reference number
N/A
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Services Hospital 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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
The University of Lahore
Full name of responsible person
Dr Ashfaq Ahmed
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Professor
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Ph.D.
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available