Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 envelops 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 envelops and shuffled vigorously. Then the envelops 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 intesity
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 30seconds between the sets) and ergonomic advice.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Physiotherapty department,Services Hospital,Lahore
Full name of responsible person
Muhammad Sharif Waqas,Physiotherapist
Street address
Jail road Lahore
City
Lahore
Postal code
54000
Phone
+92 42 99205517
Fax
+92 42 99205513
Email
waqasphysio@gmail.com
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Services Hospital Lahore
Full name of responsible person
Muhammad Sharif Waqas
Street address
Jail Road Lahore

City
Lahore
Postal code
54000
Phone
+92 42 99205517
Email
waqasphysio@gmail.com

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
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
1-Km Raiwind Road, Lahore
City
Lahore
Province
Punjab
Postal code
54000
Phone
+92 42 111 865 865
Email
ashfaq.ahmad@uipt.uol.edu.pk

Person responsible for scientific inquiries

Contact

Name of organization / entity
services Hospital Lahore
Full name of responsible person
Muhammad Sharif Waqas
Position
head of deptt.
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
jail road lahore
City
Lahore
Province
Punjab
Postal code
54000
Phone
+92 42 99205517
Email
waqasphysio@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Services Hospital Lahore
Full name of responsible person
Muhammad Sharif Waqas
Position
cosultant
Latest degree
Master
Other areas of specialty/work
Physiotherapy
Street address
jail road lahore
City
Lahore
Province
Punjab
Postal code
54000
Phone
+92 42 99205517
Email
waqasphysio@gmail.com

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