

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

COMPARISON OF DRY NEEDLING AND SPINAL MANIPULATIVE THERAPY VERSUS SPINAL MANIPULATIVE THERAPY ALONE ON PAIN AND DISABILITY IN PATIENTS WITH NON-SPECIFIC CHRONIC LOW BACK PAIN

Protocol summary

Study aim

To determine the effects of dry needling combined with spinal manipulative therapy versus spinal manipulative therapy alone on pain, disability, lumbar range of motion (ROM) and muscle endurance in patients with non-specific chronic low back pain.

Design

Two arm parallel group randomised trial with blinded outcome assessment

Settings and conduct

Setting is Sindh Institute of Physical Medicine and Rehabilitation. Outcome assessor will be blinded to the treatment intervention.

Participants/Inclusion and exclusion criteria

Patients diagnosed as having chronic nonspecific low back pain will be included in the study. Any serious spinal pathology will be excluded

Intervention groups

After random allocation of the participants into two groups, experimental group will receive spinal manipulative therapy and dry needling while the control group will receive spinal manipulative therapy alone.

Main outcome variables

Pain, lumbar range of motion, disability and lumbar muscle endurance

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200826048530N1**

Registration date: **2023-10-01, 1402/07/09**

Registration timing: **retrospective**

Last update: **2023-10-01, 1402/07/09**

Update count: **0**

Registration date

2023-10-01, 1402/07/09

Registrant information

Name

Kashmala Khan

Name of organization / entity

University of Lahore+Dow university of health science

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Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-04, 1397/11/15

Expected recruitment end date

2022-12-29, 1401/10/08

Actual recruitment start date

2019-02-04, 1397/11/15

Actual recruitment end date

2022-12-29, 1401/10/08

Trial completion date

2022-12-29, 1401/10/08

Scientific title

COMPARISON OF DRY NEEDLING AND SPINAL MANIPULATIVE THERAPY VERSUS SPINAL MANIPULATIVE THERAPY ALONE ON PAIN AND DISABILITY IN PATIENTS WITH NON-SPECIFIC CHRONIC LOW BACK PAIN

Public title

DRY NEEDLING AND SPINAL MANIPULATIVE THERAPY VERSUS SPINAL MANIPULATIVE THERAPY ALONE IN NON-SPECIFIC CHRONIC LOW BACK PAIN

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients willing to be part of the study
Patients diagnosed as having chronic nonspecific low back pain
Age 18 -60 years Both male and female
History of non-specific LBP without referral into the lower extremity
Score 4 points on the Roland Morris Disability Questionnaire
Have not received physical therapy within the last 3 months
Exhibit at least 1 active TrP reproducing their symptom in quadratus lumborum , gluteus medius and paraspinal muscle

Exclusion criteria:

Any serious spinal pathology (e.g. inflammatory or infectious condition of the spine, metastatic fracture, cauda-equina syndrome etc)
Compromised nerve root
Any history of spinal surgery
Any other conditions that would affect the active participation in the treatment.
Long term steroid use
Any neurological condition
Osteoporosis

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **128**

Actual sample size reached: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

The subjects are randomly assigned to one of two groups by using simple randomization method using computer-generated random numbers and the random sequence is built with the computer generated software. The unit of the randomization is individual patient. The allocation concealment is carried out.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a single blinded randomized controlled trial in which assessor (another PT) will not be aware of the treatment groups. The principal investigator has to perform all the treatment sessions so it would not be possible to be blinded. Also, the participant cannot be blinded because of the different nature of interventions.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Review Board of the University of Lahore

Street address

1-Km Defence Road., near Bhupian Chowk.

City

Lahore

Postal code

54000

Approval date

2019-01-07, 1397/10/17

Ethics committee reference number

IRB-UOL-FAHS/670-1/2019

Health conditions studied

1

Description of health condition studied

Non-specific chronic low back pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Pain intensity

Timepoint

before intervention and 4, 8 weeks, 6 months after intervention

Method of measurement

Visual Analogue Scale (VAS-0 to 10cm) for pain intensity.
increase in scores suggests increase in pain intensity and decrease suggests decrease in pain intensity.

2

Description

Range of motion of lumbar spine

Timepoint

before intervention and 4, 8 weeks, 6 months after intervention

Method of measurement

Modified-modified Schöber Test to measure flexion of lumbar spine.

3

Description

Disability

Timepoint

before intervention and 4, 8 weeks, 6 months after intervention

Method of measurement

Ronald Morris Disability Questionnaire (RMDQ) for disability

Secondary outcomes

1

Description

Lumbar muscle endurance

Timepoint

before intervention and 4, 8 weeks, 6 months after intervention

Method of measurement

Sorensen test for lumbar muscle endurance

Intervention groups

1

Description

Intervention group: Spinal manipulative therapy and dry needling (DN). Participants allocated to this group will receive both Spinal manipulative therapy and dry needling. For the spinal manipulative therapy, patient will be treated with joint mobilization or manipulation techniques applied to the spine or pelvis. The particular dose and techniques will be at the discretion of the treating physical therapist, based on each participant's physical examination findings. After this the Active TrPs located in the gluteus medius and quadratus lumborum muscles will be treated with DN. These muscles will be chosen because active TrPs are prevalent in patients with chronic mechanical LBP. The disposable stainless steel needles (0.25 × 32 mm and 0.25 × 32 mm) that will be inserted through the skin over the active TrP. In this study, the fast-in and fast-out technique described by Hong will be applied. After locating an active TrP, the overlying skin will be cleaned with alcohol, and the needle will be subsequently inserted, penetrating the skin and muscle till 16 to 20 mm into the TrP. The position of the patient will be side lying. Once inserted into the TrP, the needle will be moved in multiple directions until the first local twitch response is obtained. Once the first local twitch response will be obtained, the needling will be performed in an up and down fashion, at approximately 1 Hz for 25 to 30 seconds with the aim of eliciting different local twitch responses. The interventions will be provided by a clinician with 10 years of experience. Total number of intervention session is 12 with intervention duration is set is 8 weeks, comprising of an hourly session with a frequency of two session per week for manipulative therapy including one day treatment of DN till 4th week and after that one session of manipulative therapy plus DN per week.

Category

Rehabilitation

2

Description

This group will receive spinal manipulative therapy only. The patient will be treated with joint mobilization or

manipulation techniques applied to the spine or pelvis. The particular dose and techniques will be at the discretion of the treating physical therapist, based on each participant's physical examination findings.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Sindh Institute of Physical Medicine and Rehabilitation

Full name of responsible person

Kashmal Khan

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Chand Bibi Rd, near Mujahid Masjid, Deli Colony
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sindh Institute of Physical Medicine and Rehabilitation

Full name of responsible person

Prof. Dr. Nabila Najam Soomro

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Grant name

Grant code / Reference number

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

No

Title of funding source

context and facilities for the conduct of trial

Proportion provided by this source

100

Public or private sector

Public
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
Sindh Institute of Physical Medicine and Rehabilitation
Full name of responsible person
Kashmala
Position
Assistant Professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Results will be published by the investigators in academic journals. Sharing of generated study data will be carried out in several different ways. We plan to make our results available to researchers and potential collaborators interested in physical medicine rehabilitation and low back pain.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available