Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 assesor 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
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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 spinemetastatic 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
Instituitional Review Board of the University of Lahore
Street address
1-Km Defence Road، near Bhuptian 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
Pian intensity
Timepoint
before intervent 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 intervent 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 intervent 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 intervent 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 recieve 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 and0.25 × 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 willl 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 recieve 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 Ranchore Lane
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

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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