Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effects of non-surgical decompression in addition to routine physical therapy in patients with lumber radiculopathy; A Randomized Controlled Trial

Protocol summary

Study aim
To compare the effects of non-surgical spinal decompression therapy in addition to routine physical therapy in patients with lumber radiculopathy.

Design
A single blinded randomised controlled trial, conducted on 60 patients, equally divided into two groups, single centered study

Settings and conduct
Pain Center, single blinded study (patient will be blinded to the recruited group)

Participants/Inclusion and exclusion criteria
Inclusion Criteria Both male and female patients, Age between 25-55 years, Clinically and radiologically diagnosed patients (by neuro-surgeon) of lumbar radiculopathy, Unilateral radiating low back pain (LBP) for at least 3 months, Willing to participate in the study Exclusion Criteria Recent fracture or dislocation of lumber vertebra, History of surgery on lumber spine, hip or pelvis, Spinal tumors or infections in the intervertebral disc, Inflammatory diseases such as rheumatism, Spinal deformity such as scoliosis, Spondylolysthesis, Osteoporosis below first lumber vertebra (L1), Patients taking medications e.g Non-Steroidal Anti-Inflammatory Drugs (NSAIDS) for pain, Severe disc degeneration, Pregnant females, Having three or more herniation

Intervention groups
60 patients will be randomly divided into control and experimental groups. The control group will receive routine physical therapy while the experimental group will receive spinal decompression therapy alongwith the routine physical therapy.

Main outcome variables
1. Pain intensity 2. Level of disability 3. Quality of life 4. lumber Range of motion 5. Endurance

General information

Reason for update
data collection has been completed

Acronym
RCT

IRCT registration information
IRCT registration number: **IRCT20190717044238N1**
Registration date: **2019-12-23, 1398/10/02**
Registration timing: **prospective**

Last update: **2021-07-06, 1400/04/15**
Update count: **2**

Registration date
2019-12-23, 1398/10/02

Registrant information

Name
Fareeha Amjad
Name of organization / entity
The University of Lahore
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Pakistan
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-20, 1397/07/28

Expected recruitment end date
2020-03-20, 1399/01/01

Actual recruitment start date
2020-01-01, 1398/10/11

Actual recruitment end date

2021-04-01, 1400/01/12

Trial completion date

2021-06-01, 1400/03/11

Scientific title

The effects of non-surgical decompression in addition to routine physical therapy in patients with lumber radiculopathy; A Randomized Controlled Trial

Public title

The effects of non-surgical decompression in addition to routine physical therapy in patients with lumber radiculopathy; A Randomized Controlled Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Both male and female patients Age between 25-55 years Clinically and radiologically diagnosed patients (by neuro-surgeon) of lumbar radiculopathy Radiating Low Back Pain for at least 3 months Willing to participate in the study

Exclusion criteria:

Recent fracture or dislocation of lumber vertebra History of surgery on lumber spine, hip or pelvis Spinal tumors or infections in the intervertebral disc Inflammatory diseases such as rheumatism Spinal deformity such as scoliosis Spondylolysthesis Osteoporosis below L1 Patients taking medications e.g NSAIDS for pain Severe disc degeneration Pregnant females Having three or more herniation

Age

From **25 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

By using computer generated random number table, patients will be randomly assigned into two groups. All those random numbers will be enclosed in sealed envelopes. A third person (who will further not be the part of research) will open envelops and the patients will be allocated to the mentioned group accordingly.

Blinding (investigator's opinion)

Single blinded

Blinding description

An independent assessor, who will be a senior and experienced physiotherapist and further will not be the part of study will perform the assessment of patients

Placebo

Not used

Assignment

Parallel

Other design features

no

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Review Board

Street address

The University of Lahore,Pakistan

City

Lahore

Postal code

54000

Approval date

2018-09-20, 1397/06/29

Ethics committee reference number

IRB-UOL-FAHS/373-X/2018

Health conditions studied

1

Description of health condition studied

Lumber Radiculopathy

ICD-10 code

M54.16

ICD-10 code description

Radiculopathy, lumbar region

Primary outcomes

1

Description

Pain Intensity

Timepoint

before intervention and after 4 weeks of intervention

Method of measurement

Visual Analogue Scale

2

Description

Lumber range of motion

Timepoint

before intervention and after 4 weeks of intervention

Method of measurement

Clinical Test (Modified-Modified Schober's Test)

Secondary outcomes

1

Description

Quality of Life

Timepoint
before intervention and after 4 weeks of intervention
Method of measurement
SF 36 scoring calculator will be used

2

Description
Level of disability
Timepoint
before intervention and after 4 weeks of intervention
Method of measurement
ODI scoring calculator

3

Description
Endurance
Timepoint
before intervention and after 4 weeks of intervention
Method of measurement
Stop Watch will be used to calculate the endurance time

Intervention groups

1

Description
Control group: The control group will receive conventional physiotherapy including electrotherapy and trunk stability exercises. The treatment will be performed as follows:1) Electrotherapy components will consist of 5 minutes of therapeutic ultrasound and 15 minutes of continuous transcutaneous electrical nerve stimulation with concurrent hot pack 2) Trunk stability Exercises
Category
Treatment - Other

2

Description
Intervention group: In addition to the interventions given in control group, participants in the experimental group will also receive spinal decompression therapy. The treatment session of 20 minutes will be given three days a week, for a total of 4 weeks. For non-surgical spinal decompression therapy of lumbar spine, the patient will be in supine lying position on a motorized table, which has movable lower half. A harness is placed around the hips and is attached to the lower table near the feet. The upper part of the table remains in a fixed position while the lower part, to which the patient is harnessed, slides back and forth to provide the traction and relaxation. Decompression isolates the distraction forces to a specific motor unit of the spine and affects a specific disc level.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Pain Center
Full name of responsible person
Fareeha Amjad
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The University of Lahore
Full name of responsible person
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https://www.uol.edu.pk
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
The University of Lahore
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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
The University of Lahore
Full name of responsible person
Fareeha Amjad
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)
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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All collected identified IPD
When the data will become available and for how long
Data will be available after the completion of study and will remain available till 6 months
To whom data/document is available
Data will be available for other people almost 6 months after the completion of study
Under which criteria data/document could be used
The data/document could be used by communicating with the principle investigator "Fareeha Amjad" on email address: fari_fairy22@yahoo.com
From where data/document is obtainable
Fareeha Amjad, fari_fairy22@yahoo.com
What processes are involved for a request to access data/document
Data/document can be accessed through communicating with principle investigator "Fareeha Amjad" on institutional email address: fari_fairy22@yahoo.com
Comments
N/A