Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effectiveness of Prone Knee Extension Exercise on Pain Intensity in Patients with Lumbar Disc Herniation: A Randomized Clinical Trial

Protocol summary

Study aim

Effect of Prone Knee Extension Exercise (PKE) on Pain Intensity in Patients with Lumbar Disc Herniation

Design

Design: A Phase 3, randomized, controlled, parallel-group trial. Randomization: Participants were allocated to one of two groups via stratified block randomization using R software (blockrand package), with allocation concealed using SNOSE envelopes. Sample Size: The target was 30 patients; 34 were enrolled to account for potential dropouts.

Settings and conduct

This study will be conducted as a randomized clinical trial at centers affiliated with Mashhad University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Participants had: 1) mechanical low back pain that worsened during load-bearing activities and improved at rest, 2) a confirmed diagnosis of lower lumbar disc herniation via MRI and clinical examination, and 3) sufficient cognitive ability to participate in the study.

Intervention groups

Intervention for the PKE + General Exercise Group: This group, in addition to 10 sessions of standard physiotherapy (including ultrasound, TENS, and heat therapy), received a combined program. This program consisted of structured general exercises (stretching and strengthening for the back and hamstrings) and a specific Prone Knee Extension (PKE) exercise. The PKE protocol was implemented in five progressive stages (from no resistance to adding a 5 kg weight) and included 2-3 sets of 10-15 repetitions per session. Pain and range of motion were monitored, and a home exercise program was also prescribed.

Main outcome variables

Primary outcome: Pain intensity (using the VAS scale). Secondary outcomes: Disability (ODI), quality of life (SF-36), hamstring tightness (SLR test), lumbar lordosis (flexible ruler), lumbar forward flexion range of motion (Schober test), and trunk flexibility. All measures were assessed before and after the treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230212057390N5**
Registration date: **2026-01-26, 1404/11/06**
Registration timing: **registered_while_recruiting**

Last update: **2026-01-26, 1404/11/06**
Update count: **0**

Registration date

2026-01-26, 1404/11/06

Registrant information

Name

Majid Shahbazi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-12-31, 1404/10/10

Expected recruitment end date

2026-07-01, 1405/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effectiveness of Prone Knee Extension Exercise on Pain Intensity in Patients with Lumbar Disc Herniation: A Randomized Clinical Trial

Public title
The Effect of Prone Knee Extension Exercise on Lumbar Disc Herniation Pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Report of increased pain during activities such as forward bending, coughing, sneezing, or prolonged sitting. Pain reduction while lying down Presence of lower lumbar disc herniation on MRI imaging with confirmation by clinical examination Possession of the necessary cognitive abilities to participate in various aspects of the study.

Exclusion criteria:
Acute pain in the hip, back, or knee within the past two weeks Presence of any specific disorder related to the sacroiliac joint and facet joint syndrome History of surgery or fracture in the spine, hip, or knee Presence of pre-existing congenital hip joint disorders Presence of red flags indicating conditions such as tumors, infections, or cauda equina syndrome Presence of cautionary signs related to maladaptive pain coping strategies A score above 37 on the Tampa Scale for Kinesiophobia (TSK) Presence of spinal stenosis History of neurological disorders affecting the musculoskeletal system and other serious conditions associated with impaired joint movement

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **34**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization Method: Blocked (Block Randomization) Method and Description: This study employed block randomization (blocked randomization). In this method, participants are grouped into blocks of fixed or variable sizes, and within each block, allocation to study groups (e.g., intervention and control groups) is performed randomly and in a balanced manner. This ensures that at any point in time, the number of participants in each group is approximately equal, maintaining group balance throughout the study. Unit of Randomization: The unit of randomization in this study was individual. Each eligible participant was independently assigned to one of the study groups. Stratification: Stratified randomization was used in conjunction with the block method. Participants were divided into separate strata based on important outcome-predicting variables (such as age (age categories) and disease severity (mild/moderate/severe)). Within each stratum, an independent block randomization process was conducted to ensure group balance within each key subgroup. Randomization Tool: The allocation sequence was generated using the statistical software R (utilizing specialized packages such as blockrand or randomizeR). This software enables the creation of stratified block randomization sequences with precision and without bias. Sequence Generation Process: An independent statistician, not involved in subsequent stages of the study (such as evaluation or intervention), generated the allocation sequences. The steps were as follows: The block size (e.g., 4, 6, or 8) and the number of groups (2 groups) were defined. For each stratum (a specific combination of age and disease severity variables), a separate block randomization sequence was generated. This sequence specified the exact order of group allocation (e.g., A=intervention, B=control) for each participant in that stratum. Allocation Concealment: To ensure that the enrolling researcher or the participant could not predict or influence future allocation, the Sequentially Numbered, Opaque, Sealed Envelopes (SNOSE) method was used: The generated allocation for each registration number was placed in a separate, opaque, and sealed envelope. The envelopes were arranged in sequential order according to the participants' entry sequence. After obtaining informed consent and final confirmation of eligibility, the enrolling researcher opened the corresponding sequentially numbered envelope and assigned the participant to the designated group as indicated inside the envelope. This process prevented any manipulation or prediction of allocation, thereby enhancing the internal validity of the study.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences

Street address
Shahid Khwarazmi Educational Complex, Faculty of Paramedical Sciences and Rehabilitation, Department of Physiotherapy, University Campus, Azadi Square,

Mashhad.

City
mashhad

Province
Razavi Khorasan

Postal code
9177948964

Approval date
2025-11-16, 1404/08/25

Ethics committee reference number
IR.MUMS.FHMPM.REC.1404.205

Health conditions studied

1

Description of health condition studied
(hernia disc with radiculopathy)

ICD-10 code
51.2M

ICD-10 code description
فتق‌های دیسک بین مهره‌ای با رادیکولوپاتی

2

Description of health condition studied
(hernia disc without radiculopathy)

ICD-10 code
M 51.3

ICD-10 code description
فتق‌های دیسک بین مهره‌ای بدون رادیکولوپاتی

Primary outcomes

1

Description
pain

Timepoint
Before and after the intervention

Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Disability

Timepoint
Before and after the intervention

Method of measurement
Oswestry Disability Index

2

Description
quality of life

Timepoint
Before and after the intervention

Method of measurement
Short Form-36

3

Description
Hamstring tightness

Timepoint
Before and after the intervention

Method of measurement
Active Straight Leg Raise

4

Description
lumbar lordosis

Timepoint
Before and after the intervention

Method of measurement
Flexible ruler

5

Description
lumbar range of motion

Timepoint
Before and after the intervention

Method of measurement
Schober test and trunk flexibility measurement

Intervention groups

1

Description
Intervention group: The intervention group received a combined program of general exercises along with the specific PKE (Prone Knee Extension) exercise. The details were as follows: Common Baseline Treatment: 10 sessions of standard physiotherapy (ultrasound, TENS, superficial heat).General Exercises: A 10-15 minute program including stretching and strengthening exercises for the back and hamstring muscles. Specific PKE Exercise: Performing the Prone Knee Extension exercise for 15-20 minutes per session, following a five-stage progressive protocol (from a no-resistance state to adding a 5 kg weight).Home Program: Performing the PKE exercise at home, twice daily.

Category
Treatment - Other

2

Description
Control group: The control group received only general exercises. The details of this group's intervention are as follows: Common Baseline Treatment: This group, similar to the intervention group, received 10 sessions of standard physiotherapy (including ultrasound, TENS, and superficial heat) three times per week. General Exercises: This group's exercise program was a structured 10 to 15-minute program including the following: Stretching of the back and hamstring muscles. Lumbar extension exercises (such as prone on elbows and prone press-ups).Lumbar flexion exercises (such as double knee-to-chest stretches and posterior pelvic

tilts).Method of Execution: All exercises were individually tailored according to each patient's condition and performed under the direct supervision of a physiotherapist within a pain-free range. Exercise progression was based on the principle of Progressive Overload. No Additional Intervention: This group did not receive the specific PKE (Prone Knee Extension) exercise or its associated home exercise program. Summary: The control group received only the common physiotherapy protocol (including physical modalities and a general exercise program), while the intervention group additionally performed the specific PKE exercise.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Comprehensive Rehabilitation Center

Full name of responsible person
Majid Shahbazi

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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
Vice President for Research, Mashhad University of Medical Sciences- mohsen tafaghodi

Grant code / Reference number
4040492

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

Title of funding source
Mashhad University of Medical Sciences

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
Mashhad University of Medical Sciences

Full name of responsible person
Majid Shahbazi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable