

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effects of Complex Rehabilitation Program on Reducing Pain and Disability in Patients with Lumbar Disc Protrusion. Is Early Intervention the Best Recommendation?

Protocol summary

Study aim

The main objective of this study was to determine the complex physiotherapy program effectiveness versus electrotherapy-only intervention on pain and disability reduction, and increased muscle strength and mobility in patients with lumbar disc protrusions. The second objective was to investigate if there is a correlation between early rehabilitation intervention and pain and disability.

Design

A non-randomized, controlled, parallel groups on 60 patients, single-blind (outcome assessment)

Settings and conduct

Ceres Hotel Treatment Centre from Băile 1 Mai, Romania. Single blinded (the evaluator has no information about the patients or about the study protocol)

Participants/Inclusion and exclusion criteria

Inclusion criteria: 25-80 years of age, low back pain for more than three months, an MRI confirmed diagnosis of lumbar disc protrusion (without dural compression), ability to perform a physical therapy program. Exclusion criteria: indication for acute surgery, previous surgery on the same lumbar spinal level, sciatica, presence of severe spinal pathology (spinal tumor, spinal fracture, spinal stenosis or radiculopathy, fibromyalgia, inflammatory and infectious spinal diseases). Chronic pain relief drug users, refusal to participate in the research, any sort of neoplasm, severe comorbidity, mental illness.

Intervention groups

The control group (Gr A) received only a classical electrotherapy program. In addition, the patients in the experimental group (Gr B) received a complex individualized physical exercise therapy program associated with hydrotherapy and electrotherapy.

Main outcome variables

Spinal mobility, pain, muscle strength, Oswestry

Disability Index (ODI)

General information

Reason for update

Acronym

CRP

IRCT registration information

IRCT registration number: **IRCT20200422047172N2**

Registration date: **2022-03-21, 1401/01/01**

Registration timing: **retrospective**

Last update: **2022-03-21, 1401/01/01**

Update count: **0**

Registration date

2022-03-21, 1401/01/01

Registrant information

Name

Elena Sirbu

Name of organization / entity

West University of Timisoara,

Country

Romania

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-21, 1400/04/30

Expected recruitment end date

2022-01-31, 1400/11/11

Actual recruitment start date

2021-07-21, 1400/04/30

Actual recruitment end date

2022-01-21, 1400/11/01

Trial completion date

2022-01-31, 1400/11/11

Scientific title

Effects of Complex Rehabilitation Program on Reducing Pain and Disability in Patients with Lumbar Disc Protrusion. Is Early Intervention the Best Recommendation?

Public title

Effects of Complex Rehabilitation Program on Reducing Pain and Disability in Patients with Lumbar Disc Protrusion.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

25-80 years of age low back pain for more than three months MRI confirmed diagnosis of lumbar disc protrusion (without dural compression) ability to perform a physical therapy program

Exclusion criteria:

indication for acute surgery previous surgery on the same lumbar spinal level sciatica presence of severe spinal pathology (spinal tumour, spinal fracture, spinal stenosis or radiculopathy, fibromyalgia, inflammatory and infectious spinal diseases) chronic use of pain killer drugs refusal to participate in the research neoplasms of any sort, severe comorbidities mental illness refusal to participate in the research

Age

From **26 years** old to **76 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

All assessments were made before intervention and 6 months later by the same physiotherapist, who was blinded to the treatment groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Local Ethics Committee, University of Oradea

Street address

Str. Universității nr. 1

City

Oradea

Postal code

410087

Approval date

2021-07-14, 1400/04/23

Ethics committee reference number

1947/14.07.2021

Health conditions studied**1****Description of health condition studied**

Low back pain

ICD-10 code

M51.86

ICD-10 code description

Other intervertebral disc disorders, lumbar region

Primary outcomes**1****Description**

pain

Timepoint

before intervention and 6 months after intervention

Method of measurement

Short Form McGill Pain Questionnaire (SF-MPQ) and visual analogue scale (VAS)

2**Description**

disability

Timepoint

before intervention and 6 months after intervention

Method of measurement

Oswestry Disability Index (ODI)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group 1/Experimental group: 30 patients received a complex individualized physical therapy (PT) program associated with hydro-therapy(HT) and

electrotherapy (ET). Hydrotherapy was performed in a therapeutic pool for 30 min a day, 5-days a week for a total duration of 10 days. The PT program was given to all patients for 45 min a day, 5-days a week for a total duration of 10 days. After completing the exercise PT program, electrotherapy ET was applied to each patient. The electrotherapy ET procedures consisted of: 1) Transcutaneous electrical nerve stimulation (TENS) in conventional mode, symmetric biphasic, 90 Hz, for 15 min; 2) Interferential current (IFC) in quadripolar mode, at 100 Hz frequency, for 10 min; 3) Magnetic field therapy in continuous form (sedative effect), for 15 min. TENS and IFC were performed using the Chattanooga Intellect Neo combined de-vice. The magnetic field was delivered through a Physiomed MAG-Expert device with a field strength of 1-100 Gauss (adjustable in steps of one Gauss) and a frequency range from 1 to 100 Hz, with two completely independent channels and a treatment timer.

Category

Rehabilitation

2**Description**

Intervention group/Control group: 30 patients received classical electrotherapy program (ET) for 10 days. The electrotherapy ET protocol was the same as for the experimental group (TENS, IFC, Magnetic field therapy)

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ceres Hotel Treatment Centre

Full name of responsible person

Florin Marcu

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Haieu Street

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Baths 1 Mai

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Department of Physical Education, Sport and Physiotherapy, University of Oradea

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

Department of Physical Education, Sport and Physiotherapy, University of Oradea

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**

West University of Timisoara

Full name of responsible person

Elena Sirbu

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Rheumatology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data

Contact

Name of organization / entity

West University of Timisoara

Full name of responsible person

Elena Sirbu

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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

There is no further information

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

Not applicable

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available