Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Phone

+40 256 498 176

Email address

elena.sirbu@e-uvt.ro

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. Universităţii 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 Intelect 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

Street address
Haieu Street

City
Baths 1 Mai

Postal code
417501

Phone
+40 745 883 047

Email
mfmihai27@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Department of Physical Education, Sport and Physiotherapy, University of Oradea

Full name of responsible person
Emilian Tarcău

Street address
No. 1, Universității Street

City
Oradea

Postal code
410087

Phone
+40 770 104 471

Email
emilian.tarcau@yahoo.com

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

Street address
No 4, Parvan Street

City
Timisoara

Province
Timis

Postal code
300233

Phone
+40 744 238 960

Email
elena.sirbu@e-uvt.ro

Person responsible for scientific 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
Street address
No. 4, V Parvan
City
Timisoara
Province
Timis
Postal code
300233
Phone
+40 744 238 960
Email
elena.sirbu@e-uvt.ro

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
Rheumatology
Street address
No. 4, V Parvan
City
Timisoara
Province
Timis
Postal code
300233
Phone
+40 744 238 960
Email
elena.sirbu@yahoo.co.uk

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