

# 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

##### Phone

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##### Email address

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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

**City**

Baths 1 Mai

**Postal code**

417501

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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

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No. 1, Universităţii Street

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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 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