

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### **Effect of 4-week physical therapy with and without National Academy of Sports Medicine (NASM) on pain intensity, functional disability, muscle endurance, low back mobility and quality of life in low back pain with discopathy.**

#### **Protocol summary**

##### **Study aim**

Effect of 4-week physical therapy with and without National Academy of sport medicine NASM on pain intensity, Functional disability, muscle endurance, low back mobility and quality of life in low back pain with discopathy.

##### **Design**

This single-blinded randomized clinical trial (RCT) includes a control group, treatment (intervention) group. Each group consists of 14 participants who are randomly assigned to their group using Block Randomization with block size four, which results in six possible sequences: AABB, ABAB, ABBA, BAAB, BABA, BBAA. We would then build our full sequence randomly picking, for 7 iterations, one of the previously mentioned sequences to cover all 28 trial participants.

##### **Settings and conduct**

This controlled trial performed in Zanjan and physical therapy clinic. We will have two groups: physical therapy with and without NASM. They will assess before beginning of intervention with pretests and then after 4 weeks and intervention again will assess with tests. Results will be analyzed after statistical review.

##### **Participants/Inclusion and exclusion criteria**

Inclusion criteria: 1- At least 3-month-long low back pain with radiological findings and diagnostics approved by an orthopedic surgeon. 2- between 18 to 55 years of age.  
Exclusion criteria: 1-pregnant woman 2-patients absence for more than three consecutive sessions.

##### **Intervention groups**

Intervention group 1 includes patients with low back pain from discopathy who will undergo physical therapy including core stability and low-power laser. Intervention group 2 includes patients with low back pain from discopathy who will undergo physical therapy with corrective exercise.

#### **Main outcome variables**

pain

#### **General information**

##### **Reason for update**

##### **Acronym**

lbp pt

##### **IRCT registration information**

IRCT registration number: **IRCT20210921052547N1**

Registration date: **2022-01-03, 1400/10/13**

Registration timing: **retrospective**

Last update: **2022-01-03, 1400/10/13**

Update count: **0**

##### **Registration date**

2022-01-03, 1400/10/13

##### **Registrant information**

##### **Name**

Mahdis Hamidi

##### **Name of organization / entity**

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

+98 24 3346 0725

##### **Email address**

mahdis.hamidi61@gmail.com

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

##### **Expected recruitment start date**

2021-11-21, 1400/08/30

##### **Expected recruitment end date**

2021-12-06, 1400/09/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of 4-week physical therapy with and without National Academy of Sports Medicine (NASM) on pain intensity, functional disability, muscle endurance, low back mobility and quality of life in low back pain with discopathy.

**Public title**

Effect of physical therapy in low back pain

**Purpose**

Other

**Inclusion/Exclusion criteria****Inclusion criteria:**

People with a history of low back pain who have been tested and diagnosed by an orthopedic surgeon. No sign of lower limb deformity. At least 3-month-long Low back pain. No limit for undergoing exercise therapy. No lower extremity sensory impairment. No sensory and movement disorders. No autoimmune disease like such as Rheumatoid arthritis. having filled the consent documents. between 18 to 55 years of age.

**Exclusion criteria:**

Pregnancy for woman. Absence in 3 secessions consecutive. consent of continuing. Any of disease in process that make it difficult for participants to continuing . Low back injury or lower extremity.

**Age**

From **18 years** old to **55 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **28**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this resurch we will use 4 letters block which are combined from 2 letters A and B.in every block, every letter repeat 2 times and we will have 6 block that they are put in 6 pockets.pockets will numbered from 1 to 6.we will have 28 cases so we will select 7 times.and base on sequence of A and B, cases goes to A and B groups.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Other

**Other design features**

Participants are randomly divided into two equal group,

and each group will perform physiotherapeutic treatment including core stability exercise and low-power laser therapy.One of the groups will, in addition, perform exercise based on American Academy of Sports medicine.The first group will be considered the controlled group and the second the treatment group.( experimental group).

**Secondary Ids**

empty

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

zanjan medical science university

**Street address**

mahdavi bulvar

**City**

zanjan

**Province**

Zanjan

**Postal code**

4513964841

**Approval date**

2021-09-21, 1400/06/30

**Ethics committee reference number**

IR.ZUMS.REC.1400.256

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

discopathy

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

pain

**Timepoint**

4 week after intervention.

**Method of measurement**

visual analogue scale

**2****Description**

functional disability

**Timepoint**

At the begining and end (after 4 week) of intervention.

**Method of measurement**

Oswestry disability index

## Secondary outcomes

### 1

**Description**

muscle endurance

**Timepoint**

At the beginning and end( after 4 week) of intervention.

**Method of measurement**

sorenson test

### 2

**Description**

low back mobility

**Timepoint**

At the beginning and end( after 4 week) of intervention.

**Method of measurement**

goniometer

### 3

**Description**

quality of life

**Timepoint**

At the beginning and end( after 4 week) of intervention.

**Method of measurement**

whoqol-bref

## Intervention groups

### 1

**Description**

Intervention group1 :Physical therapy that people goes to physiotherapy for 4 week 3 session 1 hour consist of core stability exercise and low power laser.

**Category**

Rehabilitation

### 2

**Description**

Intervention group: The second group that receive physiotherapy with national academy of sport medicine for 4 week 3 session 1 hour consist of core stability exercise and low power laser and NASM.

**Category**

Rehabilitation

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

farabi physical therapy clinic

**Full name of responsible person**

Mahdis Hamidi

**Street address**

kochmeshki

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zanjan

**Province**

Zanjan

**Postal code**

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**Phone**

+98 24 3347 2754

**Email**

mahdis.hamidi61@gmail.com

**Web page address**

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Mahdis Hamidi

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no101-first south 4-way-koochmeshki

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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**

zanjan medical science university

**Proportion provided by this source**

100

**Public or private sector**

Private

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Other

## Person responsible for general inquiries

**Contact****Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Mahdis Hamidi

**Position**

physiotherapist

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

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**Position**

physiotherapist

**Latest degree**

Bachelor

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**Latest degree**

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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**

Undecided - It is not yet known if there will be a plan to make this available

**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**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available