

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### The effect of modified protocol of exercise therapy with psychological interventions specified for army staff with discogenic low back pain: A randomized clinical trial

#### Protocol summary

##### Study aim

The effect of modified protocol of exercise therapy with psychological interventions among army staff with discogenic low back pain

##### Design

Randomized control trial, based on society, parallel, single blind.

##### Settings and conduct

This study will be a single blind study as the assessor is not aware about the intervention protocols in groups and it will be conducted in Aja University of Medical Sciences, Tehran, Iran.

##### Participants/Inclusion and exclusion criteria

Class 11,1 ASA age 18-60 Chronic low back pain for more than 3 months with at least two symptoms of discogenic low back pain having difficulties in lifting heavy loads or feeling pain during changing the position feel pain during bending Absence of radicular pain in lower limb during physical test Absence of disc tearing Presence of low intensity signals between vertebral area and absence of joint burst in MRI report

##### Intervention groups

1- Exercise therapy : (doing Williams and Mackenzie exercises) 2- Exercise + psychological therapy: (doing Williams and Mackenzie exercises followed by relaxation techniques) 3- control : : No intervention

##### Main outcome variables

pain intensity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171111037388N3**

Registration date: **2018-07-08, 1397/04/17**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-07-08, 1397/04/17**

Update count: **0**

##### Registration date

2018-07-08, 1397/04/17

##### Registrant information

###### Name

Ardalan Shariat

###### Name of organization / entity

TUMS

###### Country

Iran (Islamic Republic of)

###### Phone

+98 939 861 4772

###### Email address

a-shariat@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-06-22, 1397/04/01

##### Expected recruitment end date

2018-12-22, 1397/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of modified protocol of exercise therapy with psychological interventions specified for army staff with discogenic low back pain: A randomized clinical trial

##### Public title

The effect of modified protocol of exercise therapy with psychological interventions specified for army staff with

discogenic low back pain: A randomized clinical trial

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Class 11,1 ASA Age 18-60 Chronic low back pain for more than 3 months with at least two symptoms of discogenic low back pain Having difficulties in lifting heavy loads or feeling pain during changing the position Feel pain during bending Absence of radicular pain in lower limb during physical test Absence of disc tearing Presence of low intensity signals between vertebral area and absence of joint burst in MRI report

### Exclusion criteria:

Using of steroids or corticosteroid drugs Absence of agreement for participation or continue the study Absence of agreement for participation or continue the study Having radicular pain in beginning or during of study Having radicular pain in beginning or during of study

## Age

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

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Investigator

## Sample size

Target sample size: **72**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The participants will be divided to three groups randomly based on the random block.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The assessors are not aware from the protocols of cycling done by participants in each groups.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Aja Medical University

##### Street address

Fatemi, Sindokht

##### City

Tehran

## Province

Tehran

## Postal code

1411718541

## Approval date

2018-06-09, 1397/03/19

## Ethics committee reference number

IR.AJAUMS.REC.1397.004

## Health conditions studied

### 1

#### Description of health condition studied

Discogenic low back pain

#### ICD-10 code

S30.8

#### ICD-10 code description

Other supe

## Primary outcomes

### 1

#### Description

pain intensity

#### Timepoint

Baseline- after 6 weeks, after 12 weeks

#### Method of measurement

11 grade NRS

## Secondary outcomes

### 1

#### Description

Quality of life

#### Timepoint

Baseline, after 6 weeks, and after 12 weeks from baseline

#### Method of measurement

Quality of Life Scale (QOLS)

### 2

#### Description

Anxiety and depression

#### Timepoint

Baseline, after 6 weeks, and after 12 weeks from baseline

#### Method of measurement

Hospital Anxiety and Depression Scale (HADS)

### 3

#### Description

Back pain-related functional limitation

#### Timepoint

Baseline, after 6 weeks, and after 12 weeks from baseline

#### Method of measurement

FRI scale

## Intervention groups

### 1

#### Description

Intervention group: Exercise therapy (doing Williams and Mackenzie exercises)

#### Category

Rehabilitation

### 2

#### Description

Intervention group: Modified exercise therapy (doing Williams and Mackenzie exercises followed by relaxation techniques)

#### Category

Rehabilitation

### 3

#### Description

Control group: No intervention

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Aja University of Medical sciences

##### Full name of responsible person

Dr.Reza Alizade

##### Street address

West Fatemi, Shahid etemadzade

##### City

tehran

##### Province

Tehran

##### Postal code

1411718541

##### Phone

+98 21 8802 8350

##### Email

rezalizadeh@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Artesh University of Medical Sciences

##### Full name of responsible person

Dr. Reza Alizade

##### Street address

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##### City

Tehran

##### Province

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##### Postal code

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##### Phone

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##### Email

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#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Artesh 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

Artesh University of Medical Sciences

##### Full name of responsible person

Dr.Reza Alizade

##### Position

Associate professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

##### Street address

West Fatemi, Shahid etemadzade

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## Person responsible for scientific inquiries

#### Contact

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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**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is 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**

Yes - There is 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

**Title and more details about the data/document**

We will publish the results as a scientific article without any name from participants

**When the data will become available and for how long**

After finish the protocol, the article will be published and will be available permanently

**To whom data/document is available**

After finish the protocol, the article will be published and will be available permanently

**Under which criteria data/document could be used**

As an article for academic purposes

**From where data/document is obtainable**

As an article for academic purposes

**What processes are involved for a request to access data/document**

Call to the corresponding author directly:  
Ardalansh2002@gmail.com

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Artesh University of Medical Sciences

**Full name of responsible person**

Dr.Reza alizade

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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