

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### The effect of exercise therapy on pain and disability indicators of patients with non-specific back pain in patients referred to the pain clinic

#### Protocol summary

##### Study aim

Determining the effect of exercise therapy on improving back pain

##### Design

A clinical trial with a control group with parallel groups without blinding, randomized, letter cards were used for randomization, 50 patients were included in the study and were followed up for 3 months.

##### Settings and conduct

This study will be conducted at the Yasai Pain Clinic in Fasa, patients under 20 years old and over 60 years old and patients who do not agree to participate in the study will be excluded from the study. they announce

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age 20 to 60 years, with VAS back pain intensity higher than 3 Exclusion criteria: no uncontrollable underlying disease and back pain without specific symptoms

##### Intervention groups

In this study, the effect of exercise on improving disabilities caused by back pain will be investigated. Including two groups, the first group will receive only medicine and the second group will receive medicine and exercise

##### Main outcome variables

the amount of primary disability; the level of patient satisfaction; The rate of improvement of the patient's pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220830055833N1**

Registration date: **2022-09-12, 1401/06/21**

Registration timing: **retrospective**

Last update: **2022-09-12, 1401/06/21**

Update count: **0**

##### Registration date

2022-09-12, 1401/06/21

##### Registrant information

###### Name

Maryam Marzbanfard

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 5334 3202

###### Email address

m.marzbanfard95@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-08-30, 1401/06/08

##### Expected recruitment end date

2022-09-07, 1401/06/16

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of exercise therapy on pain and disability indicators of patients with non-specific back pain in patients referred to the pain clinic

##### Public title

The effect of exercise therapy on pain and disability in patients with low back pain

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Age 20 to 60 years Severity of back pain with VAS criteria higher than 3

**Exclusion criteria:**

Not having an uncontrollable underlying disease  
Presence of back pain without specific symptoms

**Age**

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

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, we prepare cards for the sample size of 50 people, we write the letter A on 25 of the cards and the letter B on the other 25. We put these in a closed envelope. Then we ask the patient to choose one of the cards at the time of visit. If the patient gets card A, he will be in the intervention group, and if he gets card B, he will be in the control group.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Fasa University of Medical Sciences

**Street address**

Ibn Sina Square

**City**

Fasa

**Province**

Fars

**Postal code**

7461453493

**Approval date**

2022-08-30, 1401/06/08

**Ethics committee reference number**

IR.FUMS.REC.1401.076

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

Back pain

**ICD-10 code**

M54.5

**ICD-10 code description**

Low back pain

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

Pain score in Oswestry Disability Index

**Timepoint**

Examining the improvement of patient's pain 6 weeks after doing sports exercises

**Method of measurement**

Oswestry Disability Index Questionnaire

**Secondary outcomes****1****Description**

Patient satisfaction score from 0 to 10

**Timepoint**

Pain score after 6 weeks of exercise

**Method of measurement**

Patients were asked to rate their satisfaction with exercise from 0 to 10

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

Intervention group: The intervention group of 25 patients with back pain will be followed up by giving Williams and McKenzie exercises. Exercises are performed during two stages of 6 weeks, in which the first 6 weeks are 6 days a week and the second 6 weeks are 3 days a week, every other day for a total of 12 weeks, and the patients visit the pain clinic monthly. This group also uses uniflex tablets once a day, wishca cream three times a day and meloxicam tablets 15 mg every 12 hours in case of pain. Uniflex tablets contain calcium carbonate, methylsulfonylmethane, vitamin D and K, magnesium and zinc. Methylsulfonylmethane is anti-inflammatory and antioxidant, and it has been shown that it has cartilage-building and collagen-building effects, which is useful for our study considering the cause of wear and tear, which is cartilage breakdown.

**Category**

Rehabilitation

## 2

### Description

Control group: The control group also uses uniflex tablets once a day, wishca cream three times a day and meloxicam tablets 15 mg every 12 hours in case of pain. Uniflex tablets contain calcium carbonate, methylsulfonylmethane, vitamin D and K, magnesium and zinc. Methylsulfonylmethane is anti-inflammatory and antioxidant, and it has been shown that it has cartilage-building and collagen-building effects, which is useful for our study considering the cause of wear and tear, which is cartilage breakdown. Community Verified icon

### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dastghib Yasai Pain Clinic

##### Full name of responsible person

Maryam Marzbanfard

##### Street address

Ibn Sina Square

##### City

Fasa

##### Province

Fars

##### Postal code

7461453493

##### Phone

+98 71 5334 3202

##### Email

m.marzbanfard95@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Fasa University of Medical Sciences

##### Full name of responsible person

Bordbar Zare

##### Street address

Ibn Sina Square

##### City

Fasa

##### Province

Fars

##### Postal code

7461453463

##### Phone

+98 71 5334 3202

##### Email

m.marzbanfard95@gmail.com

##### Grant name

##### Grant code / Reference number

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

No

### Title of funding source

Fasa 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

Fasa University of Medical Sciences

#### Full name of responsible person

Maryam Marzbanfard

#### Position

intern

#### Latest degree

Medical doctor

#### Other areas of specialty/work

General Practitioner

#### Street address

No. 4, Alley 1, Shahid Hashemi Nesab St., Shahid Azadian Blvd., Feshar ghavi Square, Phase 2, Golestan, Fasa Community Verified icon

#### City

Fasa

#### Province

Fars

#### Postal code

7461453493

#### Phone

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#### Email

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## Person responsible for scientific inquiries

### Contact

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Fasa University of Medical Sciences

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Golestan, Fasa Community Verified icon

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Fasa

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Fars

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**Contact**

**Name of organization / entity**

Fasa University of Medical Sciences

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**Province**

Fars

**Postal code**

7461453493

**Phone**

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**Email**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

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

Only a part of the data, such as the information related to the main outcome or the like, can be shared.

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

Access starts 6 months after the results are published

**To whom data/document is available**

Academic and scientific institutions

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

The data can be used for additional work and research expansion.

**From where data/document is obtainable**

Maryam Marzbanfard 09352998417

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

The applicant can access the information after contacting Maryam Marzban Fard.

**Comments**