

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Effectiveness of educating stretching exercise on impact and Quality of Life in Patients on drug therapy with Fibromyalgia

#### Protocol summary

##### Study aim

Determining the effectiveness of stretching exercises on the effect of the disease and quality of life in patients with fibromyalgia undergoing drug treatment

##### Design

Randomized clinical trial with control group with parallel groups and impossibility of blinding on 50 patients with fibromyalgia

##### Settings and conduct

Medical clinics of Mazandaran University of Medical Sciences / Patients are identified by a rheumatologist and referred to a psychiatric clinic and then to a sports medicine clinic for intervention. The intervention group is trained in static stretching exercises by a sports medicine specialist. Every week during the phone call, the process of doing exercises, possible complications and stopping criteria are checked. Patients fill in their sports logbook for each session. Questionnaire are completed in weeks 0, 5 and 10.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who have been diagnosed by a rheumatologist and are being treated with Sertraline or Fluoxetine or Duloxetine/Female gender/Age over 18 years/Have consent to participate in the study/Be literate/Lack of suicidal thoughts/Do not take corticosteroids/No secondary fibromyalgia/Not participating in another clinical trial in the last six months/Do not have heart disease, uncontrolled blood pressure and diabetes and other rheumatic diseases/Failure to start with any neurological, metabolic or orthopedic problems prevents all sports-related sports/Not abusing drugs, cigarettes and other substances according to the statement of the person or companion/Not pregnant or breastfeeding/A maximum of 3 months have passed since the start of drug treatment and drug treatment remains constant during the plan

##### Intervention groups

control: Pharmacotherapy Intervention;  
Pharmacotherapy+exercise therapy

#### Main outcome variables

Quality of life;the effect of fibromyalgia

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200131046322N3**

Registration date: **2021-04-26, 1400/02/06**

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

Last update: **2021-04-26, 1400/02/06**

Update count: **0**

##### Registration date

2021-04-26, 1400/02/06

##### Registrant information

##### Name

Zahra Madani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3360 8570

##### Email address

z.madani@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-21, 1400/02/01

##### Expected recruitment end date

2021-07-21, 1400/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Effectiveness of educating stretching exercise on impact and Quality of Life in Patients on drug therapy with Fibromyalgia

**Public title**

Effectiveness of educating stretching exercise on impact and Quality of Life in Patients on drug therapy with Fibromyalgia

**Purpose**

Treatment

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

Patients with fibromyalgia diagnosed by a rheumatologist, referred to a psychiatric clinic and treated with sertraline or fluoxetine or duloxetine Female gender Age over 18 years Have consent to participate in the study. Be literate Lack of suicidal thoughts Do not take corticosteroids No secondary fibromyalgia Not participating in another clinical trial in the last six months Do not have heart disease, uncontrolled blood pressure and diabetes and other rheumatic diseases Not to have any neurological, metabolic or orthopedic problems prevents all sports-related sports Not abusing drugs, cigarettes and other substances according to the statement of the person or companion Not pregnant or breastfeeding A maximum of 3 months have passed since the start of drug treatment and drug treatment remains constant during the plan

**Exclusion criteria:****Age**

From **18 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients according to the inclusion criteria are assigned to the following blocks, respectively (assuming the presence of 14 new patients per month): so that the first and second person according to the blocks are part of the intervention group and the third and fourth person are control group and similarly random Making is done. The last block is less and the cause of randomization is the homogenization of the two groups in terms of number. 0001: Case 0005: Placebo 0009: Case 0013: Placebo 0002: Case 0006: Placebo 0010: Case 0014: Placebo 0003: Placebo 0007: Case 0011: Case 0004: Placebo 0008: Case 0012: Placebo

0015: Case 0019: Placebo 0023: Case 0027: Placebo 0016: Case 0020: Case 0024: Placebo 0028: Placebo 0017: Case 0021: Placebo 0025: Placebo 0018: Case 0022: Placebo

0026: Case \_\_\_\_\_

0029: Placebo 0032: Placebo 0035: Case 0038: Case 0030: Case 0033: Placebo 0036: Case 0039: Placebo 0031: Case 0034: Placebo 0037: Placebo 0040: Case 0041: Case 0042: Placebo

0043: Case

0045: Case 0047: Placebo 0049: Case 0044: Placebo 0046: Case 0048: Placebo 0050: Placebo

**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 Mazandaran University of Medical Sciences

**Street address**

Fanavarihayeh Novin University, next to Bagheban clinic, Shahid beheshti boulevard

**City**

Sari

**Province**

Mazandaran

**Postal code**

4816895475

**Approval date**

2020-12-02, 1399/09/12

**Ethics committee reference number**

IR.MAZUMS.REC.1399.780

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

Fibromyalgia

**ICD-10 code**

M79.7

**ICD-10 code description**

Fibromyalgia

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

Quality of Life

**Timepoint**

0,5,10 weeks

**Method of measurement**

SF-36 questionnaire

**2****Description**

Effect of fibromyalgia

**Timepoint**

0,5,10 weeks

**Method of measurement**

Fibromyalgia Impact Questionnaire (FIQ)

**Secondary outcomes**

empty

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

Intervention group: exercise therapy. 5-week period, static stretching exercises including neck flexor & extensor stretch, wrist extensor stretching, hip abductor stretch, gluteus maximus stretch, hip adductor stretch and piriformis stretching (taken from the book Rehabilitation techniques for sports medicine and athletic training-6th edition. William E Prentice). Each movement 2 days a week and repeated 3 times, the first week 10 seconds and a 5 second increase in subsequent weeks (fifth week 30 seconds) and to the extent of feeling unwell

**Category**

Treatment - Other

**2****Description**

Control group: Pharmacotherapy

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Rheumatologic Clinic and Sport Medicine Center of Imam Khomeini Hospital

**Full name of responsible person**

Zahra Madani

**Street address**

Sport Medicine Center , Mostafavian Clinic , 3th Ave, Razi St

**City**

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Mazandaran

**Postal code**

4816868890

**Phone**

+98 11 3336 6552

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z.madani@mazums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Majid Saeedi

**Street address**

Deputy of Research and Technology, Moallem Square

**City**

Sari

**Province**

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4815733971

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+98 11 3326 1244

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pajoheshi@mazums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mazandaran 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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Zahra Madani

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Sport Medicine

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Zahra Madani  
**Position**  
Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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## Person responsible for updating data

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Mazandaran University of Medical Sciences  
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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

Not applicable

### Data Dictionary

Not applicable