

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

Sari

Province

Mazandaran

Postal code

4816868890

Phone

+98 11 3336 6552

Email

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

Mazandaran

Postal code

4815733971

Phone

+98 11 3325 7230

Fax

+98 11 3326 1244

Email

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

Street address

No 6 , Mostafavian Clinic , 3th Ave , Razi St

City

Sari
Province
Mazandaran
Postal code
4816868890
Phone
+98 11 3336 6552
Email
z.madani@mazums.ac.ir

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
Sport Medicine
Street address
No 6 , Mostafavian Clinic , 3th Ave , Razi St
City
Sari
Province
Mazandaran
Postal code
4816868890
Phone
+98 11 3336 6552
Email
z.madani@mazums.ac.ir

Person responsible for updating data

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
Street address
No 6 , Mostafavian Clinic , 3th Ave , Razi St
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Mazandaran
Postal code
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Phone
+98 11 3336 6552
Email
z.madani@mazums.ac.ir

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