# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Investigating the effectiveness of cognitive behavioral stress management on pain perception, chronic treatment and cognitive ability of women with fibromyalgia

## Protocol summary

**Study aim**
Investigating the effectiveness of cognitive behavioral stress management on pain perception, chronic treatment and cognitive ability of women with fibromyalgia

**Design**
A clinical trial with a control group, with factorial groups, randomized in a simple way, with pre-test and post-test, will be conducted on 36 people.

**Settings and conduct**
The experimental groups will undergo cognitive-behavioral stress management group therapy; But the control group does not receive any intervention. Both the experimental group and the control group are measured twice (pre-test-post-test) separately. The statistical population of this research will be all women with fibromyalgia. The performance will be in Tabriz city and for 8 sessions.

**Participants/Inclusion and exclusion criteria**
1- Diagnosed with fibromyalgia by a rheumatology specialist, 2- Willingness and informed consent to participate in the research project, 3- Age range 25-60, 4- At least diploma education, 5- Not receiving psychological treatment in the last 6 months.

**Intervention groups**
18 people will be in the experimental group who will be trained in cognitive-behavioral stress management training classes during 10 90-minute sessions and 18 people will be in the control group who will not receive any intervention.

**Main outcome variables**
Pain perception, chronicity, and cognitive empowerment

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20231122060140N1**
Registration date: **2023-12-20, 1402/09/29**
Registration timing: **retrospective**

Last update: **2023-12-20, 1402/09/29**
Update count: **0**

**Registration date**
2023-12-20, 1402/09/29

**Registrant information**

**Name**
Hossein Rostami

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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rostami.psychologist@gmail.com

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2023-12-02, 1402/09/11

**Expected recruitment end date**
2023-12-09, 1402/09/18

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Investigating the effectiveness of cognitive behavioral stress management on pain perception, chronic

treatment and cognitive ability of women with fibromyalgia

**Public title**
Investigating the effectiveness of cognitive-behavioral stress management of fibromyalgia sufferers
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Diagnosed with fibromyalgia by a rheumatology specialist Willingness and informed consent to participate in the research project Age range 25-60 At least diploma education Not receiving psychological treatment in the last 6 months
**Exclusion criteria:**
**Age**
From **25 years** old to **60 years** old
**Gender**
Female

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **36**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Simple randomization - will be randomly assigned to intervention and control groups, and patients will be randomly assigned to two groups of 18 after meeting the entry criteria. The random selection method will be done by lottery and a number will be assigned to each of the sample people, and then the numbers will be randomly selected with the help of Excel software, which will form the test 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**
Research Ethics Committee of Islamic Azad University- Tabriz branch
**Street address**
IAUT, Pasdaran Highway, Tabriz-East Azerbayjan
**City**
Tabriz
**Province**
East Azarbaijan
**Postal code**
5157944533
**Approval date**
2023-06-23, 1402/04/02
**Ethics committee reference number**
IR.IAU.TABRIZ.REC.1402.274

## Health conditions studied

**1**

**Description of health condition studied**
Investigating the effectiveness of cognitive behavioral stress management on pain perception, chronic treatment and cognitive ability of women with fibromyalgia
**ICD-10 code**
M79.7
**ICD-10 code description**
Fibromyalgia

## Primary outcomes

**1**

**Description**
"Investigating the effectiveness of cognitive behavioral stress management on pain perception" Pain score in the revised McGill Pain Questionnaire
**Timepoint**
The first measurement is by performing a pre-test at the beginning of the study and the second measurement is by performing a post-test after the study
**Method of measurement**
Revised McGill Pain Questionnaire (MPQ) Melzak, (1997)

**2**

**Description**
"Investigating the effectiveness of cognitive behavioral stress management on chronic treatment"Chalder Chronic Fatiguescore in Chalder fatigue scale
**Timepoint**
The first measurement is by performing a pre-test at the beginning of the study and the second measurement is by performing a post-test after the study
**Method of measurement**
Chalder Chronic Fatigue Questionnaire (1993)

**3**

**Description**
"Investigating the effectiveness of cognitive behavioral stress management on cognitive ability" Psychological empowerment score in Spritzer Psychological Empowerment Questionnaire
**Timepoint**
The first measurement is by performing a pre-test at the beginning of the study and the second measurement is by performing a post-test after the study

**Method of measurement**
Spritzer Empowerment Questionnaire (1995)

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: 18 people in the experimental group who will be trained in cognitive-behavioral stress management classes in 10 90-minute sessions. The purpose of stress management training is to empower patients to deal with psychological pressure caused by illness, to obtain information about the sources of psychological pressure that generate individual problems, and to teach effective coping skills, including problem-solving training, muscle relaxation skills training, and adjustment and correction of assessment. are inconsistent with the use of cognitive reconstruction.
**Category**
Treatment - Other

### 2

**Description**
Control group: It does not receive any intervention
**Category**
Treatment - Other

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Rheumatology specialist office
**Full name of responsible person**
Hossein Rostami
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Valiasr West Alley, Manzariyeh Square, Tabriz
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Islamic Azad University
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info@iaut.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**Title of funding source**
Azad University
**Proportion provided by this source**
1
**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**
Islamic Azad University
**Full name of responsible person**
Hossein Rostami
**Position**
Faculty
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Psychology
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## Person responsible for scientific

## inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**
There is no further information

**Study Protocol**
No - There is not a plan to make this available

**Statistical Analysis Plan**
No - There is not a plan to make this available

**Informed Consent Form**
No - There is not a plan to make this available

**Clinical Study Report**
No - There is not a plan to make this available

**Analytic Code**
No - There is not a plan to make this available

**Data Dictionary**
No - There is not a plan to make this available