

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Comparison of the effectiveness of group acceptance and commitment therapy and group schema therapy on perceived stress, pain perception, pain catastrophizing, depression and symptoms severity of women with fibromyalgia

Protocol summary

Study aim

Comparison of the effectiveness of group acceptance and commitment therapy on perceived stress, pain perception, pain catastrophizing, depression and symptoms severity of women with fibromyalgia

Design

The present study is a single-blind clinical trial with parallel groups. The research sample consisted of 60 women with fibromyalgia who will be selected in accessible form and randomly assigned into two experimental groups (each with 20 subjects) and one control group (20 subjects). After the replacement, questionnaires will be provided to subjects and pre-test will be performed. After completing the treatments, the subjects will be exposed again to the post-test.

Settings and conduct

This study will be done at the doctor's office of rheumatology specialist and data collection will be done through questionnaires.

Participants/Inclusion and exclusion criteria

Diagnosis of fibromyalgia by rheumatology specialist, Conscious willingness and willingness to participate in the research project, Age range 25-55, Education higher than diploma, No psychological treatment during the last 6 months; Having mental disorders or other chronic physical illness during the treatment process, Missing more than 2 sessions

Intervention groups

This study has two groups of tests and one control group. In the first test group, group acceptance and commitment therapy will be performed in 8 sessions and at intervals of once a week. In the second experiment group, the group schema therapy will be performed for 10 weeks and once a week. In the control group, placebo treatment will be performed.

Main outcome variables

Perceived stress; Pain perception; Pain catastrophizing; Depression; Symptoms severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181201041810N1**
Registration date: **2019-03-12, 1397/12/21**
Registration timing: **registered_while_recruiting**

Last update: **2019-03-12, 1397/12/21**

Update count: **0**

Registration date

2019-03-12, 1397/12/21

Registrant information

Name

Parisa Soleymani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3327 1340

Email address

p.soleymani@iauardabil.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-06, 1397/12/15

Expected recruitment end date

2019-05-05, 1398/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of group acceptance and commitment therapy and group schema therapy on perceived stress, pain perception, pain catastrophizing, depression and symptoms severity of women with fibromyalgia

Public title

Comparison of the effectiveness of acceptance and commitment therapy and schema therapy in women with fibromyalgia

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of fibromyalgia by rheumatology specialist
Conscious willingness and willingness to participate in the research project
Age range 25-55
Education higher than diploma
No psychological treatment over the past 6 months

Exclusion criteria:

Having mental disorders or other chronic physical illness during the treatment process
Missing more than 2 sessions

Age

From **25 years** old to **55 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of randomization will be simple. The randomization unit will be the person and the randomization tool will be a random number table.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants will not be aware of their assignment to the control group and placebo treatment will be performed on the control group

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Ardabil University of Medical Sciences

Street address

University Ave

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Ardabil

Province

Ardabil

Postal code

5618985991

Approval date

2018-12-23, 1397/10/02

Ethics committee reference number

IR.ARUMS.REC.1397.168

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

Fibromyalgia

ICD-10 code

M79.7

ICD-10 code description

Fibromyalgia

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

Perceived stress

Timepoint

Before the beginning of intervention and after the end of intervention(after 2 months)

Method of measurement

Perceived Stress Scale

2**Description**

Pain perception

Timepoint

Before the beginning of intervention and after the end of intervention(after 2 months)

Method of measurement

Short - form Mc Gill Pain Questionnaire

3**Description**

Pain Catastrophizing

Timepoint

Before the beginning of intervention and after the end of intervention(after 2 months)

Method of measurement

Pain Catastrophizing Scale

4

Description

Depression

Timepoint

Before the beginning of intervention and after the end of intervention(after 2 months)

Method of measurement

Beck Depression Inventory-II

5

Description

Symptoms severity

Timepoint

Before the beginning of intervention and after the end of intervention(after 2 months)

Method of measurement

Riviesed Fibromyalgia Impact Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: group acceptance and commitment therapy that will be performed in 8 sessions and once a week. Along with routine drug therapy

Category

Behavior

2

Description

Intervention group: group schema therapy that will be performed in 8 sessions and once a week. Along with routine drug therapy

Category

Behavior

3

Description

Control group: Plasebo with routine drug therapy

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Office of rheumatologists

Full name of responsible person

Ahad Azami

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Shahriar Physicians Bldg., tava Alley., Sarcheshmeh Sq

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Aref Jalili

Street address

Islamic Azad University of Ardabil Complex., Basij Sq.,

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Parisa Soleymani

Position

Student

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Reza Kazemi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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

Islamic Azad University

Full name of responsible person

Parisa Soleymani

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

Yes - There is 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

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

Information on the main outcome variable

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Researchers

Under which criteria data/document could be used

With references to resources

From where data/document is obtainable

Parisa Soleymani Reza Kazemi

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

Send email to people incharge of providing data

Comments