Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the Effectiveness of Cognitive-Behavioral Group Therapy, Mindfulness-Based Stress Reduction Group Therapy and Acceptance and Commitment Group Therapy on Impact of Disease, Interoceptive Awareness, Alexithymia, Anxiety Sensitivity and Cognitive Emotion Regulation in Patients with Fibromyalgia

Protocol summary

Study aim
Comparing the Effectiveness of Cognitive-Behavioral Group Therapy, Mindfulness-Based Stress Reduction Group Therapy and Acceptance and Commitment Group Therapy on Impact of Disease, Interoceptive Awareness, Alexithymia, Anxiety Sensitivity and Cognitive Emotion Regulation in Patients with Fibromyalgia

Design
Randomized- consists of control group- three intervention group- each group consists of 20 individuals.

Settings and conduct
The statistical population of this research is women suffering from fibromyalgia disease who refer to pain clinics and sub-specialized rheumatology clinics in Shiraz from July 22, 2024 to November 21, 2024.

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- Not receiving psychological treatment in the last 6 months 4- At least diploma education 5- Age range 20-60

Intervention groups
Cognitive-Behavioral Group Therapy, Mindfulness-Based Stress Reduction Group Therapy and Acceptance and Commitment Group Therapy

Main outcome variables
Impact of Disease, Interoceptive Awareness, Alexithymia, Anxiety Sensitivity and Cognitive Emotion Regulation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20240921063107N1**
Registration date: **2024-09-26, 1403/07/05**
Registration timing: **registered_while_recruiting**

Last update: **2024-09-26, 1403/07/05**
Update count: **0**

Registration date
2024-09-26, 1403/07/05

Registrant information

Name
Armineh Nowzari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 4229 2929

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armineh_nowzari@shu.iaun.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-07-22, 1403/05/01

Expected recruitment end date
2024-11-21, 1403/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparing the Effectiveness of Cognitive-Behavioral Group Therapy, Mindfulness-Based Stress Reduction Group Therapy and Acceptance and Commitment Group Therapy on Impact of Disease, Interoceptive Awareness, Alexithymia, Anxiety Sensitivity and Cognitive Emotion Regulation in Patients with Fibromyalgia

Public title
Comparing the Effectiveness of Cognitive-Behavioral Group Therapy, Mindfulness-Based Stress Reduction Group Therapy and Acceptance and Commitment Group Therapy in Patients with Fibromyalgia
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
diagnosed with Fibromyalgia by a rheumatology specialist willingness and informed consent to participate in the research project not receiving psychological treatment in the last 6 months at least diploma education age range 20-60
Exclusion criteria:
Age
From **20 years** old to **60 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients who meet the conditions for entering the study will be randomly assigned to one of 4 groups by a random allocation method produced by an analyst who is not involved in the registration of patients. 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
کمیته اخلاق دانشگاه آزاد اسلامی واحد خمینی‌شهر
Street address
Khomeinishahr branch, Islamic Azad University, end of Student Blvd., Manzariyeh
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خمینی‌شهر
Province
Isfehan
Postal code
8418148499
Approval date
2024-07-09, 1403/04/19
Ethics committee reference number
IR.IAU.KHSH.REC.1403.048

Health conditions studied

1

Description of health condition studied
Fibromyalgia
ICD-10 code
M79.7
ICD-10 code description
Fibromyalgia

Primary outcomes

1

Description
Impact of Disease
Timepoint
before the start of the intervention- immediately after the end of the intervention- one month after the end of the intervention
Method of measurement
Revised Fibromyalgia Impact Questionnaire (FIQR)

2

Description
Interoceptive Awareness
Timepoint
before the start of the intervention- immediately after the end of the intervention- one month after the end of the intervention
Method of measurement
Multidimensional Assessment of Interoceptive Awareness questionnaire (MAIA)

3

Description
Alexithymia
Timepoint
before the start of the intervention- immediately after the end of the intervention- one month after the end of the intervention
Method of measurement
Toronto Alexithymia Scale (TAS-20)

4

Description
Anxiety Sensitivity
Timepoint
before the start of the intervention- immediately after the end of the intervention- one month after the end of the intervention
Method of measurement
Anxiety Sensitivity Index (ASI)

5

Description
Cognitive Emotion Regulation
Timepoint
before the start of the intervention- immediately after the end of the intervention- one month after the end of the intervention
Method of measurement
Cognitive Emotion Regulation (CERQ)

Secondary outcomes

empty

Intervention groups

1

Description
First Intervention group: Cognitive-Behavioral Group Therapy (CBT). Including 8 sessions, 1 session of 60 minutes per week will be done as a group.
Category
Treatment - Other

2

Description
Second Intervention group: Mindfulness-Based Stress Reduction Group Therapy (MBSR). Including 8 sessions, 1 session of 60 minutes per week will be done as a group.
Category
Treatment - Other

3

Description
Third Intervention group: Acceptance and Commitment Group Therapy (ACT). Including 8 sessions, 1 session of 60 minutes per week will be done as a group.
Category
Treatment - Other

4

Description
Control group: without intervention
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Pain Clinics and Rheumatology Specialist offices
Full name of responsible person
Armineh Nowzari
Street address
University Sq., Najafabad, Isfahan
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8514143131
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Armineh Nowzari
Street address
University Sq., Najafabad, Isfahan
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Phone
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Islamic Azad University- Najafabad branch
Proportion provided by this source
1
Public or private sector
Private
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
Armineh Nowzari

Position
Ph.D. student

Latest degree
Master

Other areas of specialty/work
Psychology

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Assistant professor

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Person responsible for updating data

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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
After the end of the intervention, the data of the participants will be presented separately but without mentioning their identity.

When the data will become available and for how long
One year after publication

To whom data/document is available
Researchers

Under which criteria data/document could be used
The use of information is possible only by mentioning the source

From where data/document is obtainable
Send a message to the researcher's personal email address.

What processes are involved for a request to access data/document
The request and the reason should be raised via email.

Comments