Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Examining the effectiveness of amygdala and insula retraining (AIR) program on psychological indicators and sleep patterns in fibromyalgia patients.

Protocol summary

Study aim
Examining the effectiveness of amygdala and insula retraining (AIR) program on psychological indicators and sleep patterns in fibromyalgia patients.

Design
Clinical trials with control group, parallel groups, single-blind, randomized, phase 3, 50 patients

Settings and conduct
This study is a single-blind clinical trial. The statistical population includes patients with fibromyalgia referred to Farabi Hospital in Kermanshah, 50 of whom will be randomly selected and divided into three groups. The first group will receive Amygdala and Insula recovery intervention program, physical activity, and the third group will receive control. All people in all three groups are evaluated by completing the questionnaire at the beginning, 8 weeks later and four weeks after the end of the study in the follow-up test.

Participants/Inclusion and exclusion criteria
Both genders, having an FM diagnostic in accordance with the American College of Rheumatology (ACR) 1990 criteria and provided by a rheumatologist working for the Iranian National Health Service, Being able to read and understand Persian

Intervention groups
The Amygdala and Insula retraining (AIR) intervention group will include psychotherapy focused on improving skills and coping strategies for stressful situations in 8 weeks and 2 sessions per week. The physical activity group will include aerobic exercises in 8 weeks and 2 sessions per week. The protocol of the passive control group will be to meet each other and gather in 8 weeks and 2 times a week.

Main outcome variables
Depression symptoms, Anxiety, Stress, Emotion regulation, Insomnia severity, Sleep quality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210119050079N2**
Registration date: **2023-02-21, 1401/12/02**
Registration timing: **prospective**

Last update: **2023-02-21, 1401/12/02**
Update count: **0**

Registration date
2023-02-21, 1401/12/02

Registrant information

Name
Ebrahim Norouzi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 83 3725 3847

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-25, 1401/12/06

Expected recruitment end date
2023-07-09, 1402/04/18

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Examining the effectiveness of amygdala and insula retraining (AIR) program on psychological indicators and sleep patterns in fibromyalgia patients.

Public title
Examining the effectiveness of amygdala and insula retraining (AIR) program on psychological indicators and sleep patterns in fibromyalgia patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 18 and 70 year Having an FM diagnostic in accordance with the American College of Rheumatology (ACR) 1990 criteria and provided by a rheumatologist working for the Iranian National Health Service Being able to read and understand Persian

Exclusion criteria:
Presence of severe Axis I psychiatric/somatic disorder, autoimmune disease, or the use of corticosteroid medication Participation in a concurrent RCT. As long as the patients agreed not to change their medication dosage during the RCT period, they were not asked to discontinue their regular pattern of medication which was considered part of their usual care. Medication was maintained stable 3 months prior the study and throughout the study.

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Based on a randomized table with 15 blocks designed using Random allocation software, patients are placed in three equal groups (1. Amygdala and Insula recovery intervention, 2. Physical activity, 3. control). In order to randomly assign 50 patients to three groups, first, 10 blocks of 5 different letters A, B, and C are created, which indicate intervention groups for amygdala and insula recovery, physical activity, and control. Then these blocks are numbered from one to ten. In the next step, each of these blocks is randomly selected by drawing 10 times from numbers one to ten. Thus, in each lottery, by choosing a block, a combination of 5 letters A, B, and C is obtained, and at the end of 10 stages of the lottery, after choosing 10 blocks, a total of 50 combinations of letters A and B are obtained, and C will be obtained from the blocks. The obtained combination of letters A, B, and C are placed one by one in 50 separate and sealed envelopes, and one envelope is opened with each patient's visit to determine which group the patient belongs to.

Blinding (investigator's opinion)
Single blinded

Blinding description
Outcome examiners (people who distribute questionnaires among patients) are blind to the type of groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kermanshah University of Medical Sciences

Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences Kermanshah

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Kermanshah

Province
Kermanshah

Postal code
6719851115

Approval date
2023-01-30, 1401/11/10

Ethics committee reference number
IR.KUMS.REC.1401.485

Health conditions studied

1

Description of health condition studied
Fibromyalgia

ICD-10 code
M79.7

ICD-10 code description
Fibromyalgia

Primary outcomes

1

Description
Symptoms of Depression

Timepoint
Before intervention- 8 weeks later- 4 weeks later

Method of measurement
Beck Questionnaire

2

Description
Symptoms of Anxiety
Timepoint
Before intervention- 8 weeks later- 4 weeks later
Method of measurement
Beck Questionnaire

3

Description
Perceived Stress
Timepoint
Before intervention- 8 weeks later- 4 weeks later
Method of measurement
Cohen Questionnaire

4

Description
Emotion Regulation
Timepoint
Before intervention- 8 weeks later- 4 weeks later
Method of measurement
Emotion Regulation Problems Questionnaire

5

Description
Sleep Quality
Timepoint
Before intervention- 8 weeks later- 4 weeks later
Method of measurement
Pittsburgh Questionnaire

6

Description
Sleep Pattern
Timepoint
Before intervention- 8 weeks later- 4 weeks later
Method of measurement
Insomnia Severity Scale and Sleep tables

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the Amygdala and Insula recovery intervention, the hypothesis is that changing emotion and cognition is more effective when the body moves. This psychotherapy approach focuses on improving coping skills and strategies for stressful situations by supposedly interrupting conditioned anxiety or fear responses from the Amygdala. This intervention consists of behavioral and psychological techniques such as cognitive therapy, breathing, meditation and neuro-linguistic programming. The amygdala and insula recovery technique will be practiced in 8 weeks based on the table below.
Category
Behavior

2

Description
Intervention group: The group will receive aerobic exercise in two months. The exercises will include two parts: static aerobic exercise and dynamic aerobic exercise. In general, the exercises will consist of 4 main parts. 1) warm up; It will include stretching movements, hypothetical line movements, cross-arm movements, arm rotations, neck rotations, cross-leg movements, sit-ups, 2) static aerobic exercise; Includes climbers walking, Palank, Palank with knee touch, and ski movement. 3) Dynamic aerobic exercise; It will include jogging at 70% of your maximum heart rate. 4) cooling down; It will include stretching, cross-linking, sitting, lying down and cradle movement. Exercises are performed with behavioral techniques and with the guidance of sports instructors and in a modified manner in accordance with the physical fitness of patients. The intervention will done in 8 weeks and 2 sessions per week. Patients engage in aerobic exercise for 30 to 45 minutes per session
Category
Behavior

3

Description
Control group: Participants in the control condition meet at least once a week at the research center and can talk about their illness and daily life. If they wish, they may also talk to nurses and doctors.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Farabi Hospital
Full name of responsible person
Habibolah Khazaie
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Isar square, Farabi Hospital, Kermanshah, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
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Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
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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
Kermanshah 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
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Full name of responsible person
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Position
Professor
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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
In order to protect the subjects' rights and keep their details confidential
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