Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

The Effectiveness of Meta-Cognitive Therapy on Cognitive-Attention Syndrome, Pain Catastrophizing and Pain Intensity in Women with Fibromyalgia

Protocol summary

Study aim

The evaluation of the effectiveness of metacognitive therapy on reducing cognitive-attention syndrome, reducing pain intensity and reducing pain catastrophizing in patients affected by fibromyalgia

Design

A random, not blinded clinical trial with a control group design of 42 patients. To make it random, the lottery method is used.

Settings and conduct

Women with fibromyalgia syndrome make up the statistical population in this study. These women will go to rheumatology and orthopedic clinics in Tehran from April 26, 2022 to June 20, 2022.

Participants/Inclusion and exclusion criteria

In this study, the statistical population is women with fibromyalgia syndrome. The inclusion criteria are based on the definitive diagnosis of fibromyalgia by a rheumatologist or orthopedist according to the criteria of the American College of Rheumatology (ACR) and also the absence of rheumatoid arthritis and inflammatory arthritis. Pregnant women, women with a history of hospitalization due to psychotic disorders, women with a history of orthopedic surgery, and patients with multiple sclerosis cannot take part.

Intervention groups

In this study, metacognitive therapy will be performed on the experimental group members individually and the control group members only will participate in the pre-test and post-test part. Treatment will be 60-minute sessions in ten weeks.

Main outcome variables

Reducing cognitive-attention syndrome, reducing pain intensity and pain catastrophizing in patients with fibromyalgia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211031052927N1**
Registration date: **2022-04-20, 1401/01/31**
Registration timing: **prospective**

Last update: **2022-04-20, 1401/01/31**
Update count: **0**

Registration date

2022-04-20, 1401/01/31

Registrant information

Name

Yaser Bodaghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2301 1240

Email address

yaserbodaghi@yahoo.co.uk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-25, 1401/02/05

Expected recruitment end date

2022-05-20, 1401/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effectiveness of Meta-Cognitive Therapy on Cognitive-Attention Syndrome, Pain Catastrophizing and Pain Intensity in Women with Fibromyalgia

Public title
The Effectiveness of Meta-Cognitive Therapy on Cognitive-Attention Syndrome, Pain Catastrophizing and Pain Intensity in Women with Fibromyalgia

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
The definitive diagnosis of fibromyalgia in the patient by a rheumatologist or orthopedist based on the criteria of the American College of Rheumatology (ACR)

Exclusion criteria:
The dismissal of the existence of rheumatoid arthritis and inflammatory arthritis Pregnant women, women with a history of hospitalization due to psychotic disorders, women with a history of orthopedic surgery, and patients with multiple sclerosis cannot take part in the research.

Age
From **20 years** old to **55 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients who meet the conditions to take part in the research are randomly assigned to one of the two groups in a random order by an analyst who is not involved in the participation of the patients. The method used to conceal the diagnosis is the use of a non-transparent sealed envelope. Each random sequence is recorded on a card, and the cards are placed inside the envelopes in order. Based on the order of the entry of eligible participants in the study, one of the envelopes is opened at the beginning of the registration and the assigned group of the participant is revealed.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Participants in this study are divided into experimental and control groups. Psychological intervention is performed on the experimental group and participants in the control group participate in only pre-tests and post-tests.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Semnan University of Medical Sciences (Research Ethics Committee)

Street address
Headquarter of Semnan University of Medical Sciences and Health Services, Bassij Blvd, Semnan, Iran.

City
Semnan

Province
Semnan

Postal code
35147-99442

Approval date
2021-10-26, 1400/08/04

Ethics committee reference number
IR.SEMUMS.REC.1400.193

Health conditions studied

1

Description of health condition studied
Fibromyalgia

ICD-10 code
M79.7

ICD-10 code description
Fibromyalgia

Primary outcomes

1

Description
Cognitive-Attention Syndrome score based on a special questionnaire of Attentive Cognitive Syndrome Scale (CAS-1)

Timepoint
Before beginning the intervention and 7 days after the end of the intervention

Method of measurement
Cognitive-Attention Syndrome score will be based on score and evaluation of the special questionnaire of Attentive Cognitive Syndrome Scale (CAS-1)

2

Description
Pain intensity score in the chronic pain questionnaire of Vonkorff et al.

Timepoint
Before beginning the intervention and 7 days after finishing the intervention

Method of measurement
Pain intensity score will be based on the score obtained as a result of the Vonkorff et al (1992) chronic pain questionnaire

3

Description
Pain Catastrophizing Score Obtained from pain Catastrophizing questionnaire of Sullivan et al.
Timepoint
Before beginning the intervention and 7 days after finishing the intervention.
Method of measurement
Pain Catastrophizing score will be based on the score obtained from the Sullivan et al. (1995) Pain Catastrophizing Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
In this study, metacognitive therapy will be performed on the experimental group members individually and the control group members will participate only in the pre-test and post-test trials. The metacognitive therapy protocol is 8 to 10 weekly sessions of 45-60 minutes; due to the fact that this study is based on three variables and also these patients generally suffer from a lot of pain and bad mood and high anxiety, psychological interventions will be in 10 weekly sessions of 60 minutes. The title of the techniques and activities of each treatment session will be as follows; Session 1: Generate case formulation. Socialize to model. Run suppression experiment. Introduce worry (about pain) postponement. Practice detached mindfulness (DM). Homework: DM and worry postponement. Session 2: Review homework. Continue socialization (if necessary). Begin challenging uncontrollability belief (about pain). Practice detached mindfulness (DM). Attention training technique (ATT) practice. Complete ATT summary sheet. Homework: Postponement of worry (about pain), DM, ATT. Session 3: Review homework. Continue to challenge uncontrollability belief (about pain); giving counterevidence. Explore and ban thought suppression. Explore and ban maladaptive control/avoidance behaviors. Attention training technique (ATT) practice. Homework: Postponement of worry (about pain), DM, ATT. Session 4: Review homework. Continue to challenge uncontrollability belief (about pain), (If necessary). Broaden application of worry/rumination postponement. Continue to explore and ban maladaptive control/avoidance behaviors. Attention training technique (ATT) practice. Homework: Postponement of worry (about pain) and rumination, broaden application of DM, ATT, schedule activities. Session 5: Review homework. Begin to challenge positive beliefs about worry (about pain). Review activity levels and suggest enhancements (explore and ban other unhelpful coping, e.g., excessive sleep, alcohol). Attention training technique (ATT) practice. (increase difficulty). Homework: Postponement of worry (about pain) and rumination, broaden application of DM, ATT, increased activities. Session 6: Review homework. Continue to challenge positive beliefs about worry (about pain). Challenging negative beliefs about worry (about symptoms). Continue reviewing activity levels and suggest enhancements (explore and ban other unhelpful coping, e.g., excessive sleep, alcohol). Attention training technique (ATT) practice. Homework: Postponement of worry (about pain) and rumination, ATT, maintain activities. Session 7: Review homework. Run advantages–disadvantages analysis of threat monitoring. Challenge positive beliefs about threat monitoring. Ban threat monitoring. Suggest alternatives. Attention training technique (ATT) practice. Homework: Practice awareness and abandonment of threat monitoring, ATT, increased activities. Session 8: Review homework. Continue challenging positive beliefs about threat monitoring, banning threat monitoring and suggesting alternatives (If necessary). Work on residual beliefs. Begin work on therapy blueprint. Homework: Patient writes brief summary of treatment. Continue ban on worry/rumination, threat monitoring. Session 9: Review homework. Write out new plan for dealing with intrusions and symptoms.Complete therapy blueprint. Explore and modify fears of recurrence.Homework: Practice implementing new plan. Session 10: Review homework. Reinforce new plan and illustrate with a hypothetical future example. Check for any residual beliefs. Schedule booster session. Homework: Specify continued application.
Category
Treatment - Other

2

Description
Control group: The members will participate only in pre-test and post-test
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Sefibzadeh's clinic
Full name of responsible person
Dr. Mohammad Sefibzadeh
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No 6, 3rd Golzari Alley, Pounak, Tehran
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Dr. Isaac Rahimian Boogar

Street address

Faculty of Psychology and Educational Sciences, Semnan University, Darband, Mahdishahr, Semnan

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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

Semnan University of Medical Sciences

Proportion provided by this source

10

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

Semnan University of Medical Sciences

Full name of responsible person

Dr. Isaac Rahimian Boogar

Position

A˝member of Faculty of Psychology and Educational Sciences, Semanan

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

A member of Faculty of Psychology and Educational Sciences, Semnan University

Latest degree

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Other areas of specialty/work

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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

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

When the data will become available and for how long

August to September of 2022

To whom data/document is available

University lecturers, university students, researchers, psychologists, psychiatrists, orthopedists, rheumatologists

Under which criteria data/document could be used

No special condition is considered

From where data/document is obtainable

Sending an email to researcher`s email address.

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

The request must be sent via email and will be answered within a week

Comments