Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effectiveness of exposure therapy and cognitive behavioral therapy for insomnia on psychological distress and well-being in women with fibromyalgia

Protocol summary

Study aim

Determining the effectiveness of exposure therapy and cognitive behavioral therapy for insomnia on psychological distress and well-being in women with fibromyalgia. Comparison of the effectiveness of exposure therapy and cognitive behavioral therapy for insomnia on psychological distress and well-being in women with fibromyalgia

Design

Three arm parallel group, randomized trial, single-blind, distribution of 60 patients randomly among 3 groups

Settings and conduct

Virtual social networks will be used to select sample groups. First, in order to achieve the goals of the research and according to the specified entry criteria, 60 people will be selected based on Purposive sampling. Then they will be divided into two intervention groups and one control group of 20 people in a completely simple random manner. It should be noted that the samples will be coded from number 1 to 60 and then will be placed in intervention or control groups based on the table of random numbers. Psychotherapy sessions will be through the Internet.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Female gender; At least 18 years old; Diagnosis of fibromyalgia by a specialist doctor ;Willingness and informed consent to participate in the research; Education at least diploma. Exclusion criteria: Receiving psychological intervention currently or within the past 6 months; Suffering from a severe mental or physical illness such as schizophrenia or cancer; Addiction

Intervention groups

First group: Exposure therapy Second group: Cognitive Behavioral Therapy for Insomnia (CBTI) Third group: the control group that does not receive any intervention

Main outcome variables

psychological distress; well-being

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240104060609N1**
Registration date: **2024-02-17, 1402/11/28**
Registration timing: **registered_while_recruiting**

Last update: **2024-02-17, 1402/11/28**
Update count: **0**

Registration date

2024-02-17, 1402/11/28

Registrant information

Name
Amir Ghorbanzade BorBor
Name of organization / entity
Urmia University
Country
Iran (Islamic Republic of)
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+98 44 3337 9600
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-14, 1402/11/25

Expected recruitment end date

2024-02-19, 1402/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of exposure therapy and cognitive behavioral therapy for insomnia on psychological distress and well-being in women with fibromyalgia

Public title

Effectiveness of cognitive behavioral therapy for insomnia and exposure therapy for fibromyalgia patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Female gender At least 18 years old Diagnosis of fibromyalgia by a specialist Willingness and informed consent to participate in research Education at least diploma

Exclusion criteria:

Patients who are receiving a psychological intervention, or who have received this within the preceding 6 months Suffering from a severe mental or physical illness such as schizophrenia, cancer, addiction

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Considering that we previously had a research with the cooperation of fibromyalgia patients and we have access to them through social networks, first, to achieve the goals of the research and according to the specified inclusion criteria, 60 people will be selected based on Purposive sampling. Then to achieve equality in the number of members of the groups, block randomization method will be done with a block size of 3. For each of the 6 possible modes, the numbers will be assigned as follows: ABC(1), ACB(2), BAC(3), BCA(4), CAB(5), CBA(6). Random sequence will be generated using random number table and the following website (www.graphpad.com/quickcalcs/randomize1/). numbers will be selected for each block, and based on that, the group (exposure therapy, cognitive behavioral therapy for insomnia, control) is determined for each participant.

Blinding (investigator's opinion)

Single blinded

Blinding description

First, the participants will be explained about the objectives of the study, and after they agree to participate in the study, they will be selected as the study samples. In this study, only the person responsible for analyzing the data will be kept blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Urmia University

Street address

11th km of SERO Blvd. Urmia, West Azarbayjan, Iran

City

Urmia

Province

West Azarbaijan

Postal code

5756151818

Approval date

2023-05-31, 1402/03/10

Ethics committee reference number

IR.URMIA.REC.1402.004

Health conditions studied

1

Description of health condition studied

Fibromyalgia

ICD-10 code

M79.7

ICD-10 code description

Fibromyalgia

Primary outcomes

1

Description

Psychological distress based on DASS21 scale score

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

The Depression, Anxiety and Stress Scale - 21 Items (DASS-21)

2

Description

well-being score in keyes Mental health continuum short form (MHC-SF)

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
Mental health continuum short form (MHC-SF)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: An important feature of exposure therapy is that avoidance is defined by the function of the behavior, not its topography. That is, behaviors that act as avoidance for some people, may not act as avoidance for others. In fact, in many cases, the same behavior that acts as avoidance for some patients (for example, physical activity), is considered a form of exposure for other patients. Participants in the exposure therapy group will receive eight online intervention sessions. The content is mainly based on text and is divided into 8 parts, which the participants will gradually access by completing the assignments. Treatment progress will be Carefully monitored by a therapist, and participants will be contacted regularly (about 1-3 times per week) via asynchronous text messages (no chat or video conferencing will be used). The main task of the therapist will be to guide the participants during the treatment and help to solve the problems if needed. The therapist responds to people's messages 24 hours a day on working days. If a participant is inactive for 4 days, the therapist will text or call the participant to remind and encourage them to continue treatment and to contact the therapist to resolve any potential issues. Sessions include description of treatment, presentation of psychoeducation (general knowledge) about fibromyalgia and exposure-based therapy, role of avoidance behaviors and their impact on hypervigilance, attention, and long-term consequences on pain-related distress. Exercises and worksheets: Encourage and train participants to identify their avoidance behaviors and place them in the context of therapy. Participants also record their behaviors daily and practice mindfulness as a way to direct attention to physical symptoms. Addressing the role of cognitions and emotions in relation to fibromyalgia symptoms and/or pain-related distress will also be taught and intervened.
Category
Treatment - Other

2

Description
Intervention group 2: 8 sessions (each session 50 minutes) of cognitive behavioral therapy for insomnia will be done in a group through the Internet on the google meet platform. Session 1: sleep education: participants will be taught about the stages of sleep. Session 2: sleep hygiene: sleep hygiene is discussed and participants are told to follow the following rules: (1) avoid caffeine in the afternoon, (2) avoid exercise, nicotine, alcohol, and heavy meals 2 hours before sleep (3) avoid watching screen 1 hour before sleep. The goal of sleep hygiene is to eliminate sleep-disturbing behaviors. Session 3: stimulus control and brief relaxation: stimulus control is discussed and participants are asked to adhere to advice such as: do not use the bed/bedroom for anything other than sleep (or sex). Session 4: sleep restriction: a sleep duration prescription is adjusted based on the reported daily average of total sleep time plus 30 minutes. If this value is less than 5 hours, the sleep duration is set to 5 hours. The purpose of sleep restriction is to regulate the sleep-wake cycle and reduce the time of waking up in bed. Session 5: monitoring automatic thoughts. Session 6: challenging/replacing negative thoughts. Session 7: practical recommendations. Session 8: review and maintenance
Category
Treatment - Other

3

Description
Control group: No intervention
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Social media
Full name of responsible person
Amir Ghorbanzade BorBor
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Sponsors / Funding sources

1

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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Urmia 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
Urmia University
Full name of responsible person
Amir Ghorbanzade BorBor
Position
PhD student in psychology
Latest degree
Master
Other areas of specialty/work
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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
Due to confidentiality and privacy of personal data

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

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

Clinical Study Report

Yes - There is 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

Only part of the data, such as the information related to the main outcome, can be shared.

When the data will become available and for how long

The access period starts 6 months after the results are published.

To whom data/document is available

researchers working in academic institutions

Under which criteria data/document could be used

In order to conduct similar scientific studies and researches

From where data/document is obtainable

Amir Ghorbanzade BorBor via email address: a.ghorbanzadeh@urmia.ac.ir

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

1. Complete introduction of the applicant who must be among the researchers of academic institutions. 2. Sending the researcher resume to the mentioned email address 3. Responding to the researcher's request via email within 3 weeks

Comments