Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

The Effectiveness of Metacognitive Therapy on Believability of Anxious Feeling and Thought, Emotional Distress Tolerance and Medication Adherence in Patients with Generalized Anxiety Disorder

Protocol summary

Study aim

The aim of the present study is to determine the effectiveness of cognitive therapy on the Believability of Anxious Feeling and Thought, Emotional Distress Tolerance and Medication Adherence in patients with generalized anxiety disorder.

Design

A clinical trial with a control group, with parallel, unblinded, randomized groups, on 32 patients, was selected to randomize the control and intervention groups as one among the participants.

Settings and conduct

This study will be conducted at Zare Hospital in Sari city. The control and experimental groups will complete questionnaires on cognitive beliefs, anxiety, emotional distress tolerance, and medication adherence before and immediately after the intervention.

Participants/Inclusion and exclusion criteria

The inclusion criteria for the study are: Willingness and ability to participate in therapy sessions Diagnosis of generalized anxiety disorder (scoring above the cutoff point on the Generalized Anxiety Disorder 7-item scale (GAD-7) and initial clinical interview) Literacy in reading and writing Age between 18 and 50 years Need for medication treatment The exclusion criteria are: Individuals with a history of psychotic symptoms and psychosis diagnosed by a psychiatrist History of hospitalization in a psychiatric hospital Concurrent alcohol use and substance use disorder Major psychiatric disorders such as major depressive disorder, bipolar disorder, major cognitive disorders Significant physical illness Participation in simultaneous psychotherapy sessions.

Intervention groups

The experimental group will receive 8 sessions of cognitive therapy, and the control group will not receive any treatment.

Main outcome variables

Believability of Anxious Feeling and Thought, Emotional Distress Tolerance and Medication Adherence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231128060213N1**
Registration date: **2024-01-05, 1402/10/15**
Registration timing: **retrospective**

Last update: **2024-01-05, 1402/10/15**
Update count: **0**

Registration date

2024-01-05, 1402/10/15

Registrant information

Name

Mobina Khalilnezhadevati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3325 8799

Email address

khalilnezhd@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-15, 1402/08/24

Expected recruitment end date

2023-12-15, 1402/09/24

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effectiveness of Metacognitive Therapy on Believability of Anxious Feeling and Thought, Emotional Distress Tolerance and Medication Adherence in Patients with Generalized Anxiety Disorder

Public title
Investigating the effect of cognitive behavioral therapy on patients with generalized anxiety disorder.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having informed consent and the ability to participate in therapy sessions Having generalized anxiety disorder (scoring above the cutoff point on the Generalized Anxiety Disorder 7-item scale (GAD-7) and initial clinical interview) Having literacy in reading and writing Being aged 18 to 50 Needing medication treatment.
Exclusion criteria:
Individuals with a history of psychiatric symptoms and psychosis diagnosed by a psychiatrist history of hospitalization in a neurology and psychiatry hospital Simultaneous use of alcohol and substance abuse disorder Major psychiatric disorders such as major depressive disorder, bipolar disorder, and major cognitive disorders Suffering from a significant physical illness Participating in psychotherapy sessions simultaneously.
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, 32 people are selected using GPOWER software in an accessible way. Then random replacement is done by lottery method (one number is assigned to each sample). We write down the numbers on the paper, fold them and put them in the container. We mix and stir the papers completely. Then we take out the papers one by one and put one number in the first group and one number in the second group. Then random application will be done. In this way, one group is known as "control group" and the other group is known as "intervention group". The lottery will be done by putting the two groups obtained from the previous step (random replacement step) into two separate envelopes and placing them in a container. Then we randomly take out an envelope that contains 16 numbers from the container and assign it to the "intervention group" and the other envelope that also contains 16 numbers to the "control group". Finally, the intervention group: receive 8 sessions of 120 minutes of metacognitive therapy for generalized anxiety of Wells, and the second group, as a control group, does not receive any psychological treatment.
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
Ethics committee of Islamic Azad University - Sari branch
Street address
5th floor, Medical Building, Azad University, Farah Abad Road, Khazar Square ,Sari.
City
Sari
Province
Mazandaran
Postal code
4816119318
Approval date
2023-11-14, 1402/08/23
Ethics committee reference number
IR.IAU.SARI.REC.1402.207

Health conditions studied

1

Description of health condition studied
Patients with Generalized Anxiety Disorder
ICD-10 code
F41.1
ICD-10 code description
Generalized anxiety disorder

Primary outcomes

1

Description
Believability of Anxious Feeling and Thought
Timepoint
Before the study and immediately after the intervention
Method of measurement

questionnaire Believability of Anxious Feeling and Thought

2

Description
Emotional Distress Tolerance
Timepoint
Before the study and immediately after the intervention
Method of measurement
questionnaire Emotional Distress Tolerance

3

Description
Medication Adherence
Timepoint
Before the study and immediately after the intervention
Method of measurement
questionnaire Medication Adherence

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this study, there is an experimental group and a control group. Before the intervention, research participants will undergo pre-tests of credible beliefs and anxiety-related variables, emotional distress tolerance, and medication adherence. After this stage, participants in the experimental group will receive 8 sessions of 120-minute cognitive-behavioral therapy for generalized anxiety, while the control group will not receive any training. Subsequently, participants from both the experimental and control groups will undergo post-tests. The content of the sessions is as follows: 1. Pre-test execution, preparation, and introduction to cognitive-behavioral therapy, presentation of cognitive-behavioral therapy rationale. 2. Familiarization with cognitive attention syndrome and its impact on the continuity of mental disorders, questioning about the effectiveness of self-regulatory behaviors (coping), suppression of thoughts experiment. 3. Challenging negative cognitive beliefs related to uncontrollable thoughts, negative thoughts, and emotions, teaching independent mindfulness exercises, independent mindfulness exercises about neutral thoughts. 4. Continued challenge with uncontrollability beliefs (examining opposing evidence), delaying thoughts experiment, loss of control experiment in therapy session. 5. Challenging positive cognitive beliefs related to uncontrollability of danger and harm, introduction to verbal methods and behavioral experiments. 6. Challenging positive cognitive beliefs, presenting non-matching and inconsistency strategies, modifying cognitive thought experiments. 7. Presentation of a new processing plan including: identifying the process of thoughts-anxieties-stresses-emotions and worries, emphasizing the use of independent attention for triggering thoughts, allowing emotions and thoughts to peak and subside without effort to control them, repeated execution of new thinking styles. 8. Monitoring progress, presenting a summary of techniques presented in all therapy sessions, answering questions and problems in using these techniques, getting feedback from all sessions, conducting post-tests.
Category
Behavior

2

Description
Control group: The control group will undergo pre-tests and post-tests for variables such as belief in thoughts and anxiety, tolerance of emotional distress, and adherence to medication, and will not receive cognitive-behavioral therapy intervention.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Zare burn and psychiatric hospital
Full name of responsible person
Amirkeyvan Maroofi
Street address
Zare Psychiatry and Burns Hospital, km 3 of Sari Neka Road, Sari, Mazandaran
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Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3328 3886
Fax
Email
zarehospital@mazums.ac.ir
Web page address
https://zarehospital.mazums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Hossein Kermanian
Street address
Sari, km 7 of Darya Road (Farahabad), university complex of Islamic Azad University, Sari branch
City

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Postal code
4816119318
Phone
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Email
h_kermanian@sbu.ac.ir
Web page address
https://sari.iau.ir/fa
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
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
Ghodratollah Abbasi
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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

Title and more details about the data/document

The main results will be shared after the end of the study.

When the data will become available and for how long

6 months

To whom data/document is available

Upon request, the study results will be made available to other academic researchers

Under which criteria data/document could be used

The collected data is confidential and will not be shared with others

From where data/document is obtainable

To receive documents, send an email to the person responsible for updating

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

Within 15 days, the documents will be sent by email

Comments