Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness of cognitive-behavioral therapy on automatic Negative thoughts, irrational beliefs and worry in people with generalized anxiety disorder

Protocol summary

Study aim

General objectives: Determining the effectiveness of cognitive-behavioral therapy on self-negative thoughts, irrational beliefs and anxiety in people with generalized anxiety disorder areSub-objectives:

Design

The present study is a quasi-experimental study with a pre-test-post-test study with a control group. In this method, the experimental group receives cognitive-behavioral therapy and the control group does not receive any intervention. Both groups respond to pre-test and post-test at the same time. And our statistical population is 30 clients with generalized anxiety disorder

Settings and conduct

The statistical population of this study will include all patients with generalized anxiety disorder to clinics in Rasht who are eligible to participate in this study. Will be mentioned To select a subject, 30 clients are randomly selected and placed in two experimental groups (15 people) and a control group (15 people). All clients complete the ATQ Negative Self-Thinking Questionnaire, Jones's Irrational Beliefs, Pennsylvania State Concern, and Generalized Anxiety Disorder as a pre-test.

Participants/Inclusion and exclusion criteria

Entry requirements for participants who received a diagnosis of generalized anxiety disorder by a therapist (psychiatrist) in terms of DSM5 diagnostic criteria, are at least 20 years old and have a significant score on the questionnaires

Intervention groups

All clients complete the ATQ Negative Self-Esteem Questionnaire, Jones Irrational Beliefs, Pennsylvania State Concern, and Generalized Anxiety Disorder as a pre-test.

Main outcome variables

lGeneralized Anxiety Disorder, Negative Self Thoughts, Irrational Beliefs, Anxiety, Cognitive Behavioral Therapy

General information

Reason for update

Acronym

CBT

IRCT registration information

IRCT registration number: **IRCT20210609051523N1**
Registration date: **2021-06-29, 1400/04/08**
Registration timing: **prospective**

Last update: **2021-06-29, 1400/04/08**
Update count: **0**

Registration date

2021-06-29, 1400/04/08

Registrant information

Name

Samaneh Rabinejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 4242 7292

Email address

samaneh1441@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-11, 1400/04/20

Expected recruitment end date

2021-08-11, 1400/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effectiveness of cognitive-behavioral therapy on automatic Negative thoughts, irrational beliefs and worry in people with generalized anxiety disorder

Public title
Determining the Effectiveness of Cognitive Behavioral Therapy on automatic Negative Thoughts, Irrational Beliefs, and worry in People with Generalized Anxiety Disorder

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Participants should receive a diagnosis of generalized anxiety disorder by a therapist (psychiatrist) based on the DSM5 diagnostic criteria. Participants are eligible to participate in the study if they have not received any intervention Be at least 20 years old

Exclusion criteria:

Age
From **20 years** old to **35 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method is a simple randomization that 30 patients with generalized anxiety disorder in the centers are randomly selected according to the inclusion criteria. The randomization tool is a random table of numbers that the researcher on one of the numbers in the random table. Hands down the numbers and moves them to the right and down. Finally, he records the numbers and assigns them to two experimental groups (15 people) and a control group (15 people) whose numbers have already been determined.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Lahijan Azad University Ethics Committee

Street address
Sheikh Zahed St., Sheikh Zahed 7, Baharan 7

City
Lahijan

Province
Guilan

Postal code
۴۴۱۵۹۸۶۱۵۴

Approval date
2021-05-26, 1400/03/05

Ethics committee reference number
IR.IAU.LIAU.REC.1400.015

Health conditions studied

1

Description of health condition studied
Pervasive Anxiety Disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Generalized Anxiety Disorder Score in Generalized Anxiety Disorder Questionnaire (GADQ)

Timepoint
Before and after the intervention

Method of measurement
Generalized Anxiety Disorder Questionnaire (GADQ)

2

Description
Negative Self-Thoughts Score in the Negative Self-Thought Questionnaire (ATQ)

Timepoint
Before and after the intervention

Method of measurement
Negative Self Thought Questionnaire (ATQ)

3

Description
Irrational Beliefs Score on the Jones Irrational Beliefs Questionnaire

Timepoint
Before and after the intervention

Method of measurement
Jones Irrational Beliefs Questionnaire

4

Description
Concern score on the Pennsylvania Concern

Questionnaire

Timepoint
Before and after the intervention

Method of measurement
Pennsylvania State Concern Questionnaire

Secondary outcomes

1

Description
Reduce pervasive anxiety disorder

Timepoint
Before and after the intervention

Method of measurement
Generalized Anxiety Disorder Questionnaire (GAD_Q)

2

Description
Reduce negative self-thoughts

Timepoint
Before and after the intervention

Method of measurement
Negative Self-Esteem Questionnaire (ATQ)

3

Description
Reduce irrational beliefs

Timepoint
Before and after the intervention

Method of measurement
Jones Irrational Beliefs Questionnaire

4

Description
Reduce anxiety

Timepoint
Before and after the intervention

Method of measurement
Pennsylvania Concern Questionnaire

Intervention groups

1

Description
Intervention group:

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Royesh Mehr Family Counseling Center

Full name of responsible person
Alireza Nezamdoost

Street address
Golsar Intersection - Navab St. - Corner of Valiasr Alley - Parseh Building - 3rd Floor - No. 6

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Rasht

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4415986154

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info@salamati24.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Gholamreza Waqar Lahiji

Street address
Sheikh Zahed St., Sheikh Zahed 7, Baharan 7

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Lahijan

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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 Lahijan branch

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
Islamic Azad University

Full name of responsible person
Samaneh rabinejad

Position

Student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
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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
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
Yes - There is 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
After studying the documents, it is registered in the research system and in a separate article, we mention the scientific information of the participants and the effect of the intervention.
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
Only researchers have access to the data
Under which criteria data/document could be used
Only scientific data and documents with access to the source are accessible and personal data is unauthorized
From where data/document is obtainable
Refer to Lahijan Islamic Azad University for data
What processes are involved for a request to access data/document
Access the information as soon as possible with the following email address samaneh1441@gmail.com
Comments