Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effectiveness of Transdiagnostic treatment and Cognitive-behavioral therapy on Emotional regulation, Depressive symptoms, Anxiety and Social adjustment of adolescents with Generalized anxiety disorder

Protocol summary

Study aim

To compare the effectiveness of integrated meta-diagnostic and cognitive behavioral therapy (CBT) on emotional regulation, depressive symptoms, anxiety, and social adjustment of adolescents with generalized anxiety disorder.

Design

A clinical trial with a control group, parallel groups, one-way blind, randomized, on 45 patients. A table of random numbers will use for randomization.

Settings and conduct

Patients are treated approximately twice a week using transdiagnostic treatment or CBT. This study will be run at the Behin Clinic in Khoram Abad city.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Providing written informed consent for participation in the study by participants and their parents, No presence of any other mental disorders, No history of mental illness, Do not receive other current psychological treatment. Exclusion criteria: Having suicidal thoughts and beliefs, Declining to participate in therapy sessions

Intervention groups

- Integrated transdiagnostic intervention: Including twelve 60-70 minute sessions (two sessions per week) in the form of group counseling sessions. - CBT intervention: Including twelve 60-70 minute sessions (two sessions per week) in the form of group counseling sessions. - Control group intervention: After the intervention phase of this study, control group patients can be treated by psychologists in the Behin psychology clinic.

Main outcome variables

Emotional regulation: strategies used to reduce, increase or maintain emotional experiences; Depression: A type of mental disorder includes changes in five emotional, motivational, behavioral, cognitive, and physical domains; Anxiety: an unpleasant and vague feeling without a clear cause, often associated with autonomic nervous system symptoms; Social adjustment:is coordinating behavior to meet environmental needs, which often requires modifying impulses, emotions, or attitudes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220502054728N1**
Registration date: **2022-09-13, 1401/06/22**
Registration timing: **prospective**

Last update: **2022-09-13, 1401/06/22**
Update count: **0**

Registration date

2022-09-13, 1401/06/22

Registrant information

Name

mahmoodreza sharafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3341 3545

Email address

sharafipsychology@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2022-09-23, 1401/07/01
Expected recruitment end date
2022-10-11, 1401/07/19
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of Transdiagnostic treatment and Cognitive-behavioral therapy on Emotional regulation, Depressive symptoms, Anxiety and Social adjustment of adolescents with Generalized anxiety disorder

Public title
Comparison of the effectiveness of Transdiagnostic treatment and Cognitive-behavioral therapy on Generalized anxiety disorder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All adolescent referring to Khorram Abad counseling centers Fulfilling all diagnostic criteria of generalized anxiety disorder based on the SCID-5 Providing written informed consent for participation in the study by participants and their parents No presence of any other mental disorders No history of mental illness No dependence on alcohol or drugs Do not receive other current psychological treatment
Exclusion criteria:
Having suicidal thoughts and beliefs Diagnosis of other mental disorders Declining to participate in therapy sessions
Age
From **15 years** old to **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will run by using the Software Allocation Random. We will use the simple randomization method to assign subjects to three study groups. We will assign a unique number to every member of our study's sample (from 1 to 45). An independent researcher makes random allocation codes using computer-generated random numbers. Then, we will use the random allocation generator software to randomly assign each number to experimental groups and control groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
The study was single blind. The patients in three groups (cognitive-behavioral therapy and integrated meta-diagnostic therapy and control group) did not know about the type of intervention that was performed. Also, the data analyst and the person conducting the assessments will be blind to the specific participant's group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Islamic Azad University - Boroujerd Branch
Street address
Imam Khomeini University Complex, 3 km Yadgar Imam Road, Nawab Square, Borujerd
City
Boroujerd
Province
Lorestan
Postal code
6915136335
Approval date
2022-04-20, 1401/01/31
Ethics committee reference number
IR.IAU.B.REC.1401.007

Health conditions studied

1

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

Primary outcomes

1

Description
Emotion regulation: the score obtained by the Cognitive Regulation of Emotion Questionnaire (CERQ) (Garnefsky and Kraij, 2006).

Timepoint
One week before the intervention, one week after the last intervention session, three month after the last intervention session.
Method of measurement
Questionnaire

2

Description
Depression: the score obtained by the subjects of the sample group in the depression sub-scale of the depression, anxiety, and stress scale (DASS-21) (Lavibond and Lavibond, 1995).
Timepoint
One week before the intervention, one week after the last intervention session, three month after the last intervention session.
Method of measurement
Questionnaire

3

Description
Anxiety: the score obtained by the subjects of the sample group in the anxiety sub-scale of the depression, anxiety, and stress scale (DASS-21) (Lavi Band and Lavi Band, 1995).
Timepoint
One week before the intervention, one week after the last intervention session, three month after the last intervention session.
Method of measurement
Questionnaire

4

Description
Social adjustment: the score obtained by the subjects of the sample group in the social adjustment sub-scale of the student adjustment questionnaire (Sinha and Singh, 1993).
Timepoint
One week before the intervention, one week after the last intervention session, three month after the last intervention session.
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Transdiagnostic Treatment: Including twelve 60-70 minute sessions (two sessions per week) of transdiagnostic treatment, according to the standard protocol of transdiagnostic treatment for generalized anxiety disorder, in the form of group counseling sessions.
Timepoint
In each treatment session
Method of measurement
Behavior

2

Description
Cognitive-behavioral therapy: Including 60-70 minute sessions (two sessions per week) of cognitive-behavioral therapy, according to the standard protocol of cognitive-behavioral therapy for generalized anxiety disorder, in the form of group counseling sessions.
Timepoint
In each treatment session
Method of measurement
Behavior

Intervention groups

1

Description
Intervention group: transdiagnostic treatment: In the present study, twelve 60-70 minute sessions (two sessions per week) of transdiagnostic treatment, according to the standard protocol of transdiagnostic treatment for generalized anxiety disorder (Barlow and Durand, 2011), will be used in the form of group counseling sessions.
Category
Behavior

2

Description
Intervention group: cognitive-behavioral therapy: In the present study, twelve 60-70 minute sessions (two sessions per week) of cognitive-behavioral therapy, according to the standard protocol of transdiagnostic treatment for generalized anxiety disorder (Dagas and Robichaud, 2012; translation: Akbari, Cheiniforoshan and Abedi, 2015), will be used in the form of group counseling sessions.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Behin psychology clinic
Full name of responsible person
Mahmoodreza Sharafi
Street address
Unit 5, Nourizadeh building, Amiri alley, Alavi street, Khorramabad
City
khorramabad
Province
Lorestan
Postal code
6813918468

Phone
+98 66 3343 2180
Email
behinclinic@gmail.com
Web page address
https://behinclinic.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Mahmoodreza Sharafi
Street address
Imam Khomeini University Complex, 3 km Yadgar Imam Road, Nawab Square, Borujerd
City
Borujerd
Province
Lorestan
Postal code
6915136335
Phone
+98 66 3343 2180
Email
sharafipsychology@gmail
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
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
Mahmoud Reza Sharfi
Position
PhD Student
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Navab Square, 3 km of Yadegar Imam Road, Imam Khomeini University Complex, Boroujerd, Iran.
City
Boroujerd
Province
Lorestan
Postal code
6915136335
Phone
+98 66 3343 2180
Email
sharafipsychology@gmail

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Davood Jafari
Position
Assistant Proffesor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Navab Square, 3 km of Yadegar Imam Road, Imam Khomeini University Complex, Boroujerd, Iran.
City
Boroujerd
Province
Lorestan
Postal code
4765815615
Phone
+98 66 4251 8000
Email
davood_jafari5361@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Mahmoud Reza Sharfi
Position
PhD Student
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
Navab Square, 3 km of Yadegar Imam Road, Imam Khomeini University Complex, Boroujerd, Iran.
City
Boroujerd
Province
Lorestan
Postal code

6915136335

Phone

+98 66 3343 2180

Email

sharafipsychology@gmail

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

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