Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effectiveness of cognitive behavioral therapy on dysfunctional thoughts and self-differentiation with symptoms of anxiety disorders in adolescents

Protocol summary

Study aim
Determining the effectiveness of cognitive behavioral therapy on dysfunctional thoughts and self-differentiation with symptoms of anxiety disorders in adolescents

Design
A controlled clinical trial with parallel groups, single-blind, randomized, on 30 adolescents. The rand function of Excel software was used for randomization.

Settings and conduct
Method: The study will be conducted as a quasi-experimental study with pre-test-post-test and control group, with convenient sampling and random allocation in accredited counseling centers in Ahvaz. Location: Licensed counseling centers and psychological clinics in Ahvaz.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Adolescents aged 12-18 years with a diagnosis of anxiety disorder (DSM-5), informed consent, and no active medication. Exclusion criteria: Severe psychiatric disorders, intellectual disability, or concurrent participation in other research.

Intervention groups
Intervention group: Received 12 structured cognitive-behavioral therapy (CBT) sessions (weekly, 60 minutes) focusing on identifying and modifying dysfunctional thoughts and improving self-differentiation. Control group: Received a non-specific intervention (such as general psychoeducation about anxiety, without active CBT techniques) or a waiting list (if no alternative intervention was available).

Main outcome variables
Dysfunctional thoughts, self-differentiation, anxiety symptoms.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250805066767N1**
Registration date: **2025-08-14, 1404/05/23**
Registration timing: **prospective**

Last update: **2025-08-14, 1404/05/23**
Update count: **0**
Registration date
2025-08-14, 1404/05/23

Registrant information
Name
Anis Taghikhani
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 61 3334 8420
Email address
anistaghikhani78@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-09-10, 1404/06/19
Expected recruitment end date
2026-03-10, 1404/12/19
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effectiveness of cognitive behavioral therapy on dysfunctional thoughts and self-differentiation with symptoms of anxiety disorders in adolescents

Public title
The effectiveness of cognitive behavioral therapy on dysfunctional thoughts and self-differentiation with symptoms of anxiety disorders in adolescents

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Age group 12 to 18 years Diagnosis of anxiety disorder Informed consent of the adolescent and parents.

Exclusion criteria:
Taking medications that affect anxiety Receiving parallel psychological treatment

Age
From **12 years** old to **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, block randomization was performed using SPSS software. Participants were divided into blocks of 4 based on anxiety symptom severity (with GAD-7 questionnaire) and gender, then randomly assigned to intervention (CBT) and control (waiting list) groups. Allocation concealment was ensured with sealed envelopes.

Blinding (investigator's opinion)
Single blinded

Blinding description
The participants and therapist are aware of the grouping, but because the assessors are unaware, this method of blinding is considered one-sided.

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, Ahvaz Branch

Street address
Islamic Azad University Ahvaz Branch، Farhangshahr، Golestan Highway

City
Ahvaz

Province
Khouzestan

Postal code
3733361349

Approval date
2025-04-05, 1404/01/16

Ethics committee reference number
IR.IAU.AHVAZ.REC.1404.008

Health conditions studied

1

Description of health condition studied
Anxiety disorders

ICD-10 code
F43.2

ICD-10 code description
Adjustment disorders

Primary outcomes

1

Description
Decreased anxiety symptom score

Timepoint
At the beginning of the study (before the intervention began) and two months later (when the intervention ended)

Method of measurement
Beck Anxiety Inventory

Secondary outcomes

1

Description
Reducing dysfunctional thoughts

Timepoint
At the beginning of the study (before the intervention began) and two months later (when the intervention ended)

Method of measurement
Spontaneous Thoughts Questionnaire

2

Description
Improving self-differentiation

Timepoint
At the beginning of the study (before the intervention began) and two months later (when the intervention ended)

Method of measurement
Self-Differentiation Questionnaire

Intervention groups

1

Description
Intervention group: (Cognitive-behavioral therapy - CBT): Protocol: 12 weekly 60-minute sessions based on the American Psychological Association (APA) treatment guidelines. Content: Training in identifying negative thoughts, cognitive restructuring, gradual exposure, breathing and relaxation exercises, problem-solving skills.
Category
N/A

2

Description
Control group: Received usual services: unstructured supportive counseling (45 minutes per week) including active listening and general advice
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Islamic Azad University, Ahvaz Unit
Full name of responsible person
Behnam Makvndi
Street address
Islamic Azad University Ahvaz Branch، Farhangshahr، Golestan Highway
City
Ahvaz
Province
Khouzestan
Postal code
3733361349
Phone
+98 61 3334 8420
Email
info@iauahvaz.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Pejman Taghipour Birgani
Street address
Islamic Azad University Ahvaz Branch، Farhangshahr، Golestan Highway
City
Ahvaz
Province
Khouzestan
Postal code
3733361349
Phone
+98 61 3334 8420
Email
info@iauahvaz.ac.ir
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
Behnam Makvndi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Islamic Azad University Ahvaz Branch، Farhangshahr، Golestan Highway
City
Ahvaz
Province
Khouzestan
Postal code
3733361349
Phone
+98 61 3334 8420
Email
info@iauahvaz.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University

Full name of responsible person
Behnam Makvndi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Islamic Azad University Ahvaz Branch، Farhangshahr، Golestan Highway
City
Ahvaz
Province
Khouzestan
Postal code
3733361349
Phone
+98 61 3334 8420
Email
info@iauahvaz.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Anis Taghikhani
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
No. 9, Complex, East 8th Street, Kianpars
City
Ahvaz
Province
Khouzestan
Postal code
3733361349
Phone
+98 61 3334 8420
Fax
Email
Anistaghikhani78@gmail.com

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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable